Preliminary Significant Analysis
For Rules Concerning
Ambulatory Surgical Facilities,
Chapter 246-330 WAC
February 2009

Briefly describe the proposed rule.

The 2007 legislature passed ESHB 1414, defining ambulatory surgical facilities (ASF) and requiring the Secretary of Health to create a licensing and survey program to operate in Washington State. Ambulatory surgical facilities are defined as entities that provide specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged by the facility within 24 hours and do not require inpatient hospitalization. These facilities must be licensed starting July 1, 2009. The Secretary of Health is authorized to adopt rules that are intended to establish minimum health and safety standards to protect the health and welfare of patients.

Medicare currently regulates ambulatory surgery centers some of which will also have to comply with these rules. Medicare estimates there are approximately 5,049 ambulatory surgical centers, which includes 220 in Washington State. These centers are authorized to perform surgical procedures and receive reimbursement from Medicare through a process known as "certification."

Of the 220 Washington State Medicare certified ambulatory surgery centers, the department estimates that 100 of these centers will also be required to obtain a license as an ASF. ASFs that are currently Medicare certified or accredited will need to submit an application and fee but will not be required to complete an on-site survey prior to receiving an initial license. Medicare certified and accredited ASFs will have at least one on-site survey by the department in order to receive a renewal license. It is anticipated that the number of ASFs that are neither certified or accredited, and thus required to submit an initial application along with completing an on-site survey, is a very low number.

ASFs are located in small communities as well as large cities all across the state. Based upon information from the Washington Ambulatory Surgical Center Association, individual ASFs perform 200 to 7500 surgical procedures per year. ASFs provide a range of surgical services, typically in the following areas: Ear, Nose and Throat (ENT), Gastroenterology, Gynecology, Orthopedics, Ophthalmology, Pain Management, Plastic Surgery, Podiatry and Urology.

These rules incorporate mandated 2007 legislation that places additional requirements beyond those for Medicare certification. Examples of these differences include requiring ASFs to review and revise policies to help direct the activities of their staff, potentially hire new staff to function as circulating nurses in operating rooms and to report adverse

events. Some ASFs may need to purchase additional emergency equipment to assure that equipment is available as required.

A license is not required for an ambulatory surgical facility that is maintained and operated by a hospital or a dental office, or for outpatient surgical services that do not require general anesthesia and are routinely and customarily performed in the office of a practitioner in an individual or group practice.

Is a Significant Analysis required for this rule?

Yes, the proposed rule requires a significant analysis. However, the Department has determined that no significant analysis is required for the following portions of the rule because these sections are directed at the department:

WAC #	Title	Reason why rule is not significant?
246-330-001	Purpose and applicability of chapter	No impact on ambulatory surgical facility
246-330-010	Definitions	Clarifies words used in rule
246-330-020	Department Responsibilities – Licensing	No impact on ambulatory surgical facility
246-330-025	Department Responsibilities – On-site Survey	No impact on ambulatory surgical facility
246-330-035	Exemptions, Interpretations, Alternative methods	No impact on ambulatory surgical facility
246-330-505	Department Responsibilities	No impact on ambulatory surgical facility
246-330-510	Design, construction review, and approval of plans	Current requirements of chapter 246-314 WAC

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The primary purpose of chapter 70.230 RCW is to promote safe and adequate care of individuals in ambulatory surgical facilities through the development, establishment and enforcement of minimum standards for maintenance and operation. To accomplish this purpose RCW 70.230.020 directs the department to establish in rule standards for the licensing and operation of ambulatory surgical facilities. The department will enforce the rules through surveys conducted every eighteen months and through surveys conducted by deemed organizations.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

Chapter 70.230 RCW requires the department to establish in rule standards for the licensing and operation of ambulatory surgical facilities. The 2007 legislature amended chapter 70.230 RCW and imposed new requirements on ambulatory surgical facilities. Policies and/or guidance documents are insufficient or lack the enforcement capacity of a rule amendment. The department must have authority established in rule to administer the program. If this rule is not adopted, facilities could not legally operate after July 1, 2009.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The department's assumption throughout this section is that unless otherwise specified, stated costs apply to all ambulatory surgical facilities regardless of their size.

There are 27 sections in this rule package. The following 11 sections were analyzed as a group because: (1) the requirement already exists for Medicare certified or accredited facilities and (2) all represent requirements to start a new facility that a consultant would assist in the developing as part of a business plan. The remaining sections are analyzed individually following this group analysis.

1. WAC 246-330-115 Governance
Description:
This section outlines the organizational guidance and oversight responsibilities of ambulatory surgical facility resources and staff to support safe patient care. A governing authority is responsible for determining, implementing, monitoring and revising policies and procedures (P&P) covering the operation of the facility.

2. WAC 246-330-120 Leadership
Description:
This section describes leaderships' role in assuring care is provided safely and consistently throughout the facility according to patient needs. Leaders delineate patient care responsibilities including but not limited to nursing personnel, implement procedures for double-checking certain drugs and implement policies to report suspected abuse to law enforcement.

3. WAC 246-330-125 Patient rights and organizational ethics.
Description:
The purpose of this section is to improve patient care and outcomes by respecting every patient and maintaining ethical relationships with the public. Ambulatory surgical facilities adopt policies that define each patient's right to: be treated with dignity and

respect; confidentiality; be protected from abuse and neglect; complain about their care and be involved in all aspects of their care.

4. WAC 246-330-140 Management of human resources.
Description:
This section ensures that ambulatory surgical facility provide competent staff within their planned scope of services. Facilities create and review job descriptions for all staff; supervise staff performance; verify staff credentials; provide infection control information to staff upon hire and implement an education plan that verifies training on human immunodeficiency virus (HIV).

5. WAC 246-330-145 Medical staff.
Description:
This section requires development of a medical staff structure to ensure a safe patient care environment. The medical staff is accountable to the governing authority; adopts an appointment and reappointment process; is professionally qualified and clinically competent for the positions they are appointed to; review medical staff privileges using peer review data; review and amend the scope of procedures performed in the facility and report practitioners according to RCW 70.230.120.

6. WAC 246-330-150 Management of information.
Description:
The purpose of this section is to improve patient outcomes and facility performance through obtaining, managing, and using information. A facility provide staff with access to patient information systems; maintain confidentiality of information; maintain a medical record for every patient assessed or treated and establish a systematic method for identifying each medical record.

7. WAC 246-330-176 Infection control program.
Description:
The purpose of this section is to identify and reduce the risk of acquiring and transmitting infections and communicable diseases between patients, employees, medical staff, volunteers, and visitors. A facility implements an infection control program; designates staff to manage the activities of the infection control program; ensures staff managing the infection control program have appropriate training; implements infection control policies consistent with the centers for disease control and prevention (CDC); implements a plan for reporting communicable diseases, investigating communicable disease occurrences in the facility and assessing data on infection rates, pathogen distributions and antimicrobial susceptibility profiles.

8. WAC 246-330-205 Patient Care Services.
Description:
This section guides the development of a plan for patient care. Facilities accomplish this by supervising staff, establishing, monitoring, and enforcing policies and procedures that define and outline the use of materials, resources, and promote the delivery of care. A facility provides personnel, space, equipment, training and supplies for the appropriate

care and treatment of patients; assures a registered nurse is available for consultation at all times patients are present; has a system to plan and document care in an interdisciplinary manner and completes and documents an initial assessment of each patient's physical condition.

9. WAC 246-330-210 Surgical Services.
Description:
The purpose of this section is to guide the development and management of surgical services. A facility implements policies that identify areas where surgical procedures may be performed; defines staff access to areas where such procedures are performed; defines staff qualifications and oversight; implements a system to identify the correct surgical site prior to beginning a procedure; provides emergency equipment and services to surgical areas; assures that a qualified nurse functions as a circulating nurse in every operating room during certain surgical procedures.

10. WAC 246-330-215 Anesthesia services.
Description:
The purpose of this section is to guide the management and care of patients receiving anesthesia. A facility must implement policies that identify the types of anesthesia and sedation that may be used, areas within the facility where each type of anesthesia or sedation may be used; define the staff qualifications for administering anesthesia and sedation; assure emergency equipment and services are immediately available in all areas where anesthesia and sedation are used.

11. WAC 246-330-220 Recovery Care.
Description:
The purpose of this section is to guide the management of patients recovering from anesthesia and sedation. An ambulatory surgical facility implements policies that define the qualifications of staff delivering recovery services; assures a physician or registered nurse capable of managing complications is immediately available for patients recovering from anesthesia; assures a register nurse is immediately available for patients recovering from anesthesia.

Grouped Section Analysis Summary:
The department estimated the costs in the table below based on experience with similar programs and discussion with ambulatory surgical facility industry. The range represents the additional costs for implementing and maintaining the requirements of each of the rule sections shown. These costs are an addition to what certified or accredited ASFs generally currently face.

In this analysis, the department makes the assumption that most new facilities will elect to hire a consultant to meet these initial requirements and will cost as shown in the table below. The initial costs have been combined as these represent the cost to start a new ambulatory surgical facility.

WAC Section	Initial Costs		Annual Costs		Notes
	Low	High	Low	High	
246-330-115 Governance	$4,000	$8,000	$0	$0	No additional state requirements, existing cost of being certified or accredited
246-330-120 Leadership			$250	$750	Annual review of specific state requirements
246-330-125 Patient Rights & Org. Ethics			$500	$1,500	State requires responding to unanticipated outcomes.
246-330-140 Management of Human Resources			$100	$200	State requires annually providing infection control information and training to staff
246-330-145 Medical Staff			$100	$200	State requires reporting practitioners
246-330-150 Management of Information			$200	$750	Reviewing state imposed system requirements and revising policies as needed
246-330-176 Infection Control			$10,000	$20,000	State requirements more specific, probably requiring a dedicated person part time
246-330-205 Patient Care Services			$250	$500	Annual review and possible revision of policies and procedures
246-330-210 Surgical Services			$250	$500	Annual review and possible revision of policies and procedures
246-330-215 Anesthesia Services			$250	$500	Annual review and possible revision of policies and procedures
246-330-220 Recovery Care			$40,000	$60,000	Immediate availability of a RN or physician, RN current in advanced cardiac life support

Summary of Costs:
The total costs for the 11 sections above range from approximately $52,000 to $85,000.

Benefits of Grouped Sections:
The accrued benefit of assuring people are provided safe and appropriate care while receiving and recovering from surgical services in a facility outweighs the costs that are demonstrated in the table above. Loss of life, limb or receiving a disability for one person while cared for in an ASF could exceed one million dollars.

Individual Section Analysis:
The following sections require an analysis because they contain new requirements:

1. WAC 246-330-100 Application for license — Annual update of ambulatory surgical facilities information - License renewal - Right to contest a license decision.

Description:
This section identifies the actions and responsibilities of an applicant or ambulatory surgical facility for a license. Applicants must submit an application packet and fee at least sixty days prior to the intended opening date of the new facility. Facilities must submit to the department annual update information prior to December 31. Facilities must submit a renewal application and fee at least thirty days before expiration of the license. An ASF has the right to contest a department decision to deny, modify, suspend or revoke a license.

Costs:
Ambulatory surgical facilities will incur costs to complete application packets and submit annual update information. The anticipated costs to meet this requirement are the time of the facility manager or administrator to collect the information requested on the form (e.g. facility name, address, number and type of procedures, ownership information), complete the form and return it to the department. The department estimates this will take 1 hour and no more than $50 per packet.

Benefits:
The benefit of this section is that by licensing ASFs, the department and regulated facilities are in compliance with the law.

2. WAC 246-330-105 Ambulatory Surgical Facility Responsibilities.
Description:
This section identifies the actions and responsibilities of a licensed ambulatory surgical facility. An ambulatory surgical facility must notify the department of an accreditation survey within two business days following the completion of a survey. An ASF must notify the department within thirty days of any accreditation decision or change in accreditation status.

Costs:
Ambulatory surgical facilities will incur minor costs in order to call or write and send a letter to the department. The anticipated costs to meet this requirement are the time of the facility manager or administrator to make a phone call, send a fax or and electronic message to inform the department that an accreditation survey was done. The same staff would need approximately 1 hour to compose a letter and send that to the department after learning of the accreditation decision. The department estimates this will take 1 hour and no more than $50 following the accreditation survey (usually done once every three years).

Benefits:
The benefit of this section is to minimize costs to the department of planning and traveling to conduct an 18 month survey directly following an accreditation survey. The department will also benefit in that any upcoming scheduled surveys can be canceled and staff reassigned thus saving resources. ASFs benefit by not paying higher fees that the department would have to recover for unnecessary travel, lost staff time and resources.

The department also benefits by receiving information on any change in an ASF's accreditation status and assuring each accredited ASF survey is recorded.

3. WAC 246-330-110 Requests for Exemptions, Interpretations, Alternative Methods.
Description:
This section outlines a process to request an exemption, interpretation, or approval to use an alternative method and the department's response. This enables an ASF that may have difficulty meeting a specific requirement to propose an alternative from meeting the exact rule. This section is not intended to prevent use of systems, materials, alternate design, or methods of construction as alternatives to those prescribed by this chapter.

Costs:
An ambulatory surgical facility will incur minor costs in order to write an exemption letter with supporting documentation. The anticipated costs are based on a consultant architect or engineer spending 2-4 hours researching and documenting the materials required in the section and submitting that to the department. At $100 per hour, the department estimates the cost to an ASF of $200-$400 per request. Experience with other licensing programs shows that costs occur most often when altering an existing building. The department's position is that although costs have been identified, the costs are not considered regulatory costs because facilities are given an avenue to save money through the exemption process.

Benefits:
The benefit of this section is to allow a facility to ask for exemptions to complying with specific rule requirements where they would have difficulty. The idea is to not preclude a business that would otherwise be able to provide the services safely and appropriately from doing so. This would primarily address construction standards but may also involve interpretations on how to meet an operational standard.

Secondarily, the exemption process is already in place for other facilities that the department licenses (hospitals, child birth centers). For example, a facility that is unable to meet the total requirements for a specific room in terms of dimension and size. The benefit is that an otherwise viable facility will be able to operate under that exemption request and not have to incur additional construction or operational costs.

4. WAC 246-330-130 Adverse Events.
Description:
The purpose of this section is to define adverse health events and the responsibilities of an ambulatory surgical facility when such events occur. ASFs must notify the department within forty-eight hours after confirming that an adverse event occurred. The ASF must also complete a root cause analysis following established methods and, if determined necessary, a corrective action plan. ASFs must submit a report to the department after conducting their own root cause analysis within forty-five days after confirming an adverse event has occurred.

Costs:
Although adverse events are rare, if an ASF has to complete the required tasks (i.e. 48 hour notification, root cause analysis, corrective action plan) the costs could range from $1,000 to $4,000 per event. For the purposes of this analysis, the department assumes an ASF will one adverse event per year.

Benefits:
The benefit of this section is compliance with the law (chapter 70.56 RCW) and the anticipated benefit to learning the cause of and corrections to eliminate specific errors from reoccurring. The result is an improved/revised facility process that contributes to safer patient care. Eliminating a practice that could have the potential of a patient death disability or extended recovery time also reduces the facility costs. Infections occur as a result of their stay in a facility. Loss of life, limb or receiving a disability for one person while in an ASF could exceed one million dollars.

5. WAC 246-330-155 Coordinated Quality Improvement Program.
Description:
The purpose of this section is to ensure the establishment and on-going maintenance of a coordinated quality improvement program. The intent is to improve the quality of health care services provided to patients and to identify and prevent medical malpractice. An ambulatory surgical facility must have a facility-wide approach to process design and performance measurement, assessment, and improving patient care services. ASFs must systematically collect, measure and assess data on processes and outcomes related to patient care and organization functions. The requirements for this program are described in the law, RCW 70.230.080.

Costs:
Those facilities that are Medicare certified or nationally accredited already have similar requirements for a "quality improvement program." However, some of the proposed requirements are specific to Washington State and will therefore increase costs. ASFs that do not have such a program in place will also incur initial development costs. The anticipated costs of these new requirements are reflected in the below table:

Annual Coordinated Quality Improvement Costs

	Establish Quality Improvement Program	Performance Assessment (at least twice a year)
Type of staff:	Quality Improvement Consultant	Governing Authority, Facility Managers, Physicians & RNs
Total Est. Cost:	$2,000 to $6,000	$1,000 to $3,000

Note: the annual performance assessment costs are for meeting the state requirements that exceed Medicare or accreditation requirements.

Benefits:
The benefits of this section is the ability of a facility to assess it's performance in numerous areas (through collecting information, measuring and assessing that data) and then use that information to determine if goals are being met as well as guide quality improvement efforts. This can be costly in that small facilities will need to band together with other organization in order to provide this function. It is almost impossible for the one doctor operation to evaluate their quality of care because they would just be reviewing themselves. The law allows them to create an organizational structure with other small entities to jointly review their performance.

6. WAC 246-330-199 Fees – License, Survey, Change of Ownership, Refund Process.
Description:
This section establishes the license, survey, and change of ownership fees, a late penalty fee and request for refund of an initial fee. This rule establishes fees for new and renewing licenses for ASFs. Fees are authorized by the Health Professions and Facility Fees Addendum DOH 2008 in the Conference Operating Budget as referenced in ESHB 2687. RCW 70.230.020 requires the department to establish a reasonable fees schedule. RCW 43.70.250 requires fees to cover the costs to administer the program. Additionally, all costs must be borne by the members of that licensed facility.

Costs:
Ambulatory surgical facilities will incur costs for their initial and renewal license as well as change of ownership. The proposed licenses fees are based upon the department's experience enforcing the Medicare ambulatory surgery center program. The Department estimated the total cost for conducting inspections and complaint investigations, licensing processes, maintaining the licensing systems, travel, supervision and the agency indirect costs when setting the fee amounts. The anticipated costs for the every three year license and change of ownership fees are reflected in the below table:

Comment [TT1]: Recommend adding information on how we came up with the specific fee amounts.

	Initial License Fee	Renewal License Fee	Change of Ownership Fee
0-999 procedures	$1,400	$1,300	$250
1000-5000 procedures	$1,800	$1,700	$250
Over 5000 procedures	$2,400	$2,300	$250

NOTE: a fee of $25 up to $500 is charged for each day the renewal fee is paid before 30 days of the license expiration date.

Benefits:
The benefits will be that the department will be able to assure ASFs comply with these licensing requirements by having adequate funding to support the effort (conduct inspection, complaint investigations, and issue licenses). The department went through a process with the ASF community to create a reasonable fee schedule based on facility size (numbers of surgical procedures performed). The fees enable the department to hire

staff and conduct business in order to enforce there regulations. The funds are saved in an account by the state treasurer and the department can only spend from that account to administer the cost of this licensing program.

7. WAC 246-330-200 Pharmaceutical Services.

Description:

This section assures patient pharmaceutical needs are met in a planned and organized manner. This section is consistent with the requirements for a health care entity license under RCW 18.46.450 and chapter 246-904 WAC. An ambulatory surgical facility must designate a pharmacist in charge to assure drugs are stored, compounded, delivered or dispensed appropriately; only administer, dispense or deliver legend drugs and controlled substances to patients receiving care in the facility and establish and use a process for selecting medications based on evaluating their relative therapeutic merits, safety and cost.

Costs:

Those facilities that are Medicare certified or nationally accredited already have similar requirements for "pharmaceutical services." However, ASFs that do not have such a program in place will incur costs for its initial development. The department assumes there is a one time initial cost for an ASF to establish policies and procedures from $1,000 to $2,000. Furthermore, for this analysis, the department assumes that an ASF will contract for a pharmacist in charge to assure compliance with the requirements of this section. We estimate the cost to range from $3,000 to $6,000 per year.

Benefits:

Currently an ambulatory surgical center (excluding a one doctor office) has to meet the pharmacy requirement for a healthcare entity. This section incorporates and replaces the requirements of the health care entity. Since this section contains the same standards of a healthcare entity, an ASF incurs no additional costs and will no longer have to get a health care entity pharmacy license.

For the small number of ASFs that currently maintain their drugs under a physician's license utilizing a DEA number they will have to contract with a pharmacist to meet the requirements in this section. The benefit to working with a pharmacist is that drugs will be maintained appropriately, managed and used as well as disposed of properly. This improves patient safety, assures patients receive care and that the drugs that are used are appropriate for the types of procedures being done.

8. WAC 246-330-225 Emergency services.

Description:

The purpose of this section is to guide the management and care of patients receiving emergency services. An ambulatory surgical facility must implement an emergency training program that includes on-site equipment, medication and trained personnel to manage medical emergencies; a transfer agreement with one or more local hospitals;

assure at least one registered nurse trained in emergency care is on duty at all times a patient is present; assure emergency equipment and services are immediately available.

Costs:
Those facilities that are Medicare certified or nationally accredited already have similar requirements for "emergency services." The department assumes there is a one time initial cost for an ASF to develop the Emergency Training Program from $500 to $1,000. Furthermore, the department assumes that the ongoing training requirement will cost $300 to $600 per year. Lastly, the department estimates that the requirement for ASFs to have emergency equipment will cost $500 to $1500 per year. For this analysis, the department assumes that ASFs already have this equipment because of the Medicare emergency equipment requirement and therefore we are not including these costs in the total probable cost estimate.

Benefits:
The costs for requiring this is no different because it is already a requirement of Medicare. The benefit assures competent staff are present to initiate and manage emergency care and help protect the patient until transported to a medical facility capable of meeting the care needs that lead to the emergency.

9. WAC 246-330-230 Management of environment for care.
Description:
The purpose of this section is to manage environmental hazards and risks, prevent accidents and injuries, and maintain safe conditions for patients, visitors, and staff. An ambulatory surgical facility 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.

Costs:
Ambulatory surgical facilities will incur costs to develop and implement this plan. The department assumes there is a one time initial cost for an ASF to develop the Environment of Care Management Plan from $1,000 to $3,000. Furthermore, the department assumes that the ongoing implementation costs will cost $250 to $750 per year.

Benefits:
Requiring facilities to develop and implement policies and procedures on safety related issues such as physical hazards and injury prevention promotes patient and staff safety. The following are examples of issues addressed through these policies and procedures: preventing the use of specialized equipment in power receptacles that could result in shock, injury, or damaging the equipment; preventing falls and injury due to water or other debris on the floor; maintaining the building's cooling system properly and free from bacteria and other contaminants; safe patient handling.

Requiring facilities to develop and implement a staff education training component related to emergency preparedness promotes staff safety. In the event of an emergency, staff should be properly trained and prepared to be able to provide the care that is necessary to meet the needs of community.

10. WAC 246-330-500 Applicability of WAC 246-330-500 through 246-330-510.

Description:
The purpose of the new construction regulations is to provide minimum standards for the construction, maintenance and operation of ambulatory surgical facilities and the establishment of a safe and adequate care and treatment environment. These rules apply when ASFs construct a new facility or when they renovate or alter an existing facility. These rules are consistent with accrediting organizations and federal agency rules and regulations without redundancy and contradictory requirements.

Costs:
If an ASF needs to submit a construction document for review and approval, the cost is based on the estimated value of the project and can range from $120 (for projects valued less than $1000) to $28,700 (for projects valued more than $60 million). For the purpose of this analysis, the department is unable to estimate the number of new construction projects and therefore these construction costs are not included in the total probable cost of the rule.

Benefits:
Compliance with the construction standards assures new buildings are constructed for the protection and safety of patients and staff.

Total Rule Costs and Benefits Summary:
The rules are designed to protect and improve the health and safety of people who receive care at ambulatory surgical facilities. This analysis shows ASFs could incur $9,200 to $20,700 for initial one time costs. It also shows ASFs incur ongoing annual costs from $58,117 to $99,919. The department believes that although there are significant costs for ASFs to comply with the requirements in this rule, the overall benefit of providing safe facilities, reducing patient health complications, reducing disability that could potentially save a person’s life outweighs the total probable costs.

Total Probable Cost of Rule

WAC Section	Initial Costs		Annual Costs		Notes
	Low	High	Low	High	
246-330-115 Governance	$4,000	$8,000	$0	$0	No additional state requirements, existing cost of being certified or accredited
246-330-120 Leadership			$250	$750	Annual review of specific state requirements
246-330-125 Patient Rights & Org. Ethics			$500	$1,500	State requires responding to unanticipated outcomes.
246-330-140 Management of Human Resources			$100	$200	State requires annually providing infection control information and training to staff
246-330-145 Medical Staff			$100	$200	State requires reporting practitioners
246-330-150 Management of Information			$200	$750	Reviewing state imposed system requirements and revising policies as needed
246-330-176 Infection Control			$10,000	$20,000	State requirements more specific, probably requiring a dedicated person part time
246-330-205 Patient Care Services			$250	$500	Annual review and possible revision of policies and procedures
246-330-210 Surgical Services			$250	$500	Annual review and possible revision of policies and procedures
246-330-215 Anesthesia Services			$250	$500	Annual review and possible revision of policies and procedures
246-330-220 Recovery Care			$40,000	$60,000	Immediate availability of a RN or physician, RN current in advanced cardiac life support
246-330-100 Application	$50	$50	$50	$50	Complete and submit application.
246-330-105 ASF Responsibilities	$50	$50	$50	$50	Notification of accreditation status. Applies to less than 20% of ASFs.
246-330-110 Exemptions	$0	$0	$0	$0	The costs of seeking exemptions are a benefit not a mandated cost.
246-330-130 Adverse Events	$0	$0	$1,000	$4,000	Assumes one adverse event per year.
246-330-155 CQIP	$2,000	$6,000	$1,000	$3,000	Costs due to specific State requirements.
246-330-199 Fees	$600	$600	$567	$567	Annualized 3 year license cost for a medium sized ASF.
246-330-200 Pharmaceuticals	$1,000	$2,000	$3,000	$6,000	Assumes a contract Pharmacist in charge
246-330-225 Emergency Srvs	$500	$1,000	$300	$600	Assumes no emergency equipment costs.
246-330-230 Environment Management	$1,000	$3,000	$250	$750	Develop, review and update facility plan, policy and procedures.
246-330-500 Construction	$0	$0	$0	$0	Only applies for ASFs planning new construction. No annual cost est.
Total:	$9,200	$20,700	$58,117	$99,917	

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

DOH staff worked closely with constituents and the public to minimize the burden of this rule. Many meetings were held with interested parties. Mutual interests were identified and considered throughout its deliberations. The rules are not intended to impose a burden upon the applicant, but to prescribe decision-making criteria that the department will use when evaluating applications. In the course of these and other efforts, the following are examples of alternative version(s) of the rule that were rejected:

Example #1: Circulating Nurse
The department drafted rules requiring a nurse circulator. Many attempts were made to modify the type of staff who could qualify to be a nurse circulator to provide flexibility to ASFs. This approach ended up not being acceptable under professional licensing requirements. The department ended up looking at where a circulating nurse was needed and concluded that, this oversight was related to the type of anesthesia or level of sedation. As a result the department proposed requiring a nurse circulator only when using general anesthesia and deep sedation.

Example #2: Adverse Events
Originally the department proposed to list all of the reportable adverse events in rule. The proposed rules were later altered to exclude certain events that would likely not occur in an ASF. It was determined that the least burdensome approach would be to require what's identified in the law by simply referencing the statute in the proposed rule.

Example # 3: Medical staff
The department originally proposed rule language that closely mirrored the hospital rules. Based on stakeholder input it was determined that this was too burdensome. The proposed rules reflect stakeholder input and are less burdensome.

Example # 4: Pharmacy section
Originally the rules were proposed requiring ASFs to be similar to a hospital pharmacy. Stakeholders felt this was overly burdensome. The department revised the section to be less burdensome and more consistent with the requirements that ASFs are already following under Medicare.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule is consistent with the intent and language of chapter 70.230 RCW. The rules only differ from any applicable federal regulation (CFR 42.416, ambulatory surgery centers) where the state law differs.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

Yes, the rule is coordinated to the maximum extent practicable with other applicable laws, including chapter 70.230 RCW, RCW 18.46.450, chapter 70.56 RCW, chapter 43.70 RCW, and CFR 42.416. The department reviewed all these laws to assure there were no conflicts and that the ASF rules are consistent where overlap exists.