

PRELIMINARY REPORT:

Regulation of Ambulatory Surgical Facilities

LEGISLATIVE AUDITOR'S CONCLUSION:

DOH has not met its goal for how frequently it performs state licensing surveys of ambulatory surgical facilities. It is unclear how this affects patient safety. DOH should determine a survey frequency goal based on patient safety risks and ensure license fees are aligned with that goal.

December 2020

The Legislature directed JLARC to review DOH oversight of ambulatory surgical facilities

In 2019, the Legislature directed JLARC to review the Department of Health's (DOH) oversight of ambulatory surgical facilities (ASFs). ASFs are medical facilities whose primary purpose is to provide outpatient surgical services, such as general surgery, orthopaedics, plastic surgery, endoscopy, eye surgery, and others.

DOH administers a state licensing and a federal certification program for ambulatory surgery in Washington

- **State licensing program:** DOH establishes health and safety standards for ASFs and **surveys (inspects)** the facilities to determine whether they meet state regulations. As of 2019, 186 ASFs held licenses in Washington. Facilities pay a license fee every three years to cover the cost of oversight, including surveys, credentialing, and all other program activities.
- **Federal certification program:** Through an agreement with the federal Centers for Medicare and Medicaid Services (CMS), DOH surveys facilities that receive Medicare and Medicaid payments for eligible patients. DOH evaluates whether these facilities meet the federal standards for CMS certification. This program is funded by a federal grant to DOH.

State and federal surveys are similar in scope and process, and DOH is making efforts to reduce survey time

JLARC staff found the two survey programs to be similar in scope, process, and level of effort required, even though they evaluate different sets of regulations. Some facilities receive both a state licensing survey and a federal certification survey.

The length of time it takes DOH to conduct surveys is consistent with other states. DOH is taking steps to reduce survey time, including focusing surveys on past non-compliance issues, coordinating multiple visits to reduce travel time, and relocating staff closer to the facilities they survey. Although these efforts are underway, they are not yet fully implemented and their impact on survey length is not yet known.

DOH has not met its state licensing survey frequency goal nor demonstrated how its goal impacts patient safety

Although DOH is meeting the federal priorities for certification surveys, it is not meeting its own goals for the state licensing program.

DOH aims to perform state licensing surveys of ASFs every 18 months if they are state-licensed only, or every 36 months if the facilities are also CMS-certified or accredited by an approved accreditation organization. DOH has not met this goal since it began to perform ASF state licensing surveys. As a result, DOH is more than a year behind schedule in surveying 71 percent of ASFs.

DOH has latitude in setting its survey frequency goal as long as it does not survey more frequently than allowed by state law. The department has not demonstrated that its current survey frequency goal is optimal for protecting patient safety. It could meet a less frequent survey goal within current resources.

Anticipated program costs for state licensing surveys exceed license fee revenue

DOH is required to fully fund its state licensing survey program from its license fees. To perform more surveys, DOH increased ASF license fees in 2019. However, the inspection staffing level funded with the additional revenue is not sufficient to meet the department's survey frequency goal and reduce the survey backlog.

To increase its survey capacity, DOH intends to increase inspection staff above the level assumed when setting fees. The cost of additional staff puts DOH at risk of a revenue shortfall that could not be covered by its existing fund balance on an ongoing basis. Without making changes to offset these additional costs, the program could be out of compliance in the future with state law and its own policy for maintaining a reserve fund to cover three months of operating expenses.

Data quality improvements could help DOH prioritize its state licensing surveys

JLARC staff's review also identified missing and inaccurate records in DOH's licensing and survey database. Because the department relies on this data to prioritize ASFs for survey, it should take steps to ensure the data is accurate and complete.

Legislative Auditor recommendations

The Legislative Auditor makes four recommendations to improve the regulation of ambulatory surgical facilities.

1. DOH should identify how the frequency of licensing surveys is related to risks to patient safety and determine a survey frequency goal based on those risks.
2. DOH should follow its cost recovery policy and best practices by maintaining its reserve fund balance.
3. DOH should improve the procedures and data systems it uses to collect state licensing and survey data.
4. The Legislature should amend statute to permit DOH to collect ASF license fees annually.

You can find additional information in Recommendations.

REPORT DETAILS

1. DOH administers state and federal oversight of ASFs

The Department of Health (DOH) administers separately funded state and federal oversight programs for ambulatory surgical facilities in Washington

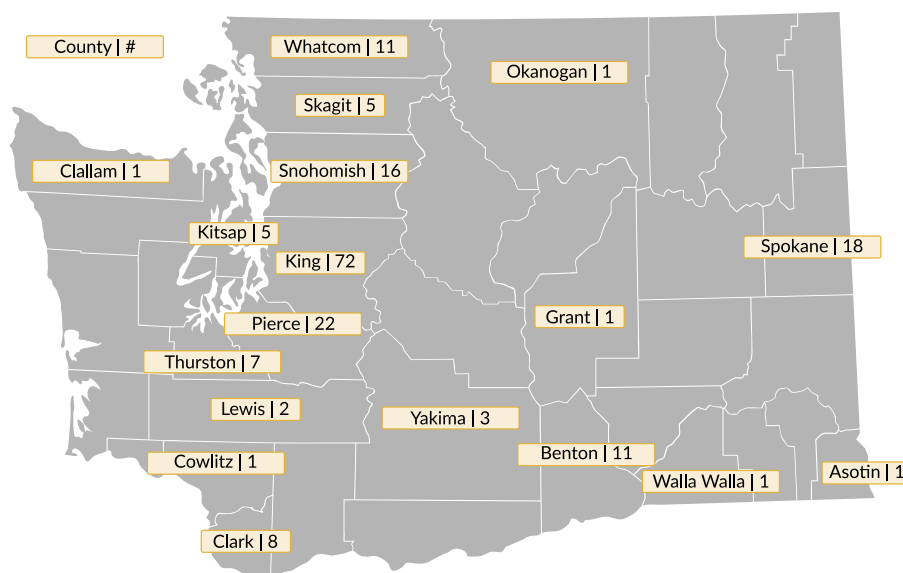
The Department of Health administers state and federal oversight programs for ambulatory surgical facilities (ASFs). These facilities provide outpatient surgical services such as general surgery, orthopaedics, plastic surgery, endoscopy, eye surgery, and others. Patients are admitted and discharged within 24 hours and do not require inpatient hospitalization.

State licensing program: DOH licenses and conducts routine surveys of 186 ambulatory surgical facilities

In 2009, the Legislature created state licensing requirements for ASFs, and required DOH to license and inspect them. Statute requires DOH to set license fees that will cover the full cost of this regulatory program. DOH establishes health and safety standards for ASFs and **surveys (inspects)** the facilities to determine whether they meet state regulations.

As of 2019, there are 186 licensed ambulatory surgical facilities (ASF) in Washington. To be licensed, all ASFs must undergo an initial state licensing survey and pay a license fee every three years. DOH conducts routine surveys of all ASFs after they are licensed.

Exhibit 1.1: There are 186 state-licensed ASFs in Washington



Source: JLARC analysis of DOH licensing data.

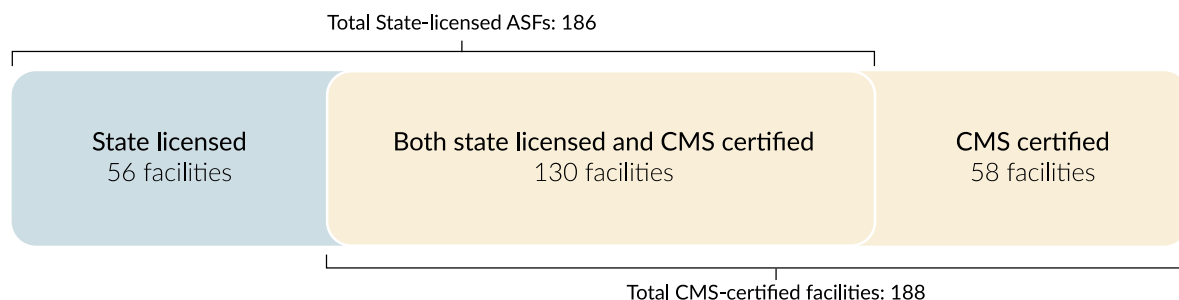
Federal certification program: DOH surveys ASFs that receive Medicare and Medicaid payments for eligible patients

Since 1985, DOH has had an agreement with the federal Centers for Medicare and Medicaid Services (CMS) to survey ASFs that participate in Medicare and Medicaid. CMS pays DOH to perform these surveys through a federal grant. The surveys include:

- An evaluation of whether the facilities meet federal standards.
- Written statements of deficiencies, if any deficiencies are found.
- Recommendations to CMS on whether or not a facility should be certified. CMS makes final certification decisions.

In 2019, there were 188 CMS-certified providers of ambulatory surgery in Washington. Of these, 130 meet the definition of an ambulatory surgical facility and are state licensed as ASFs. The other 58 include facilities such as office-based surgical practices or podiatry clinics regulated by state boards.

Exhibit 1.2: As of 2019, 130 facilities are both state licensed and CMS certified



Source: JLARC staff analysis of DOH licensing, CMS certification data.

The two programs have different funding sources

The state licensing program is funded through state license fees paid by each facility. The federal program is funded from a CMS grant to DOH, based on workload and cost estimates DOH submits to CMS in the preceding year.

DOH sets state licensing fees based on two criteria

State law requires DOH to fully fund its state oversight program from license fees. DOH establishes and updates fees in the Washington Administrative Code. Currently, ASF licensing fees range from \$12,900- \$27,200, depending on two criteria:

1. **Is the facility state-licensed only or is it also CMS-certified or accredited from a professional organization?** DOH assesses lower fees to ASFs that are also CMS-certified or accredited because these facilities are subject to less frequent state licensing surveys.
 - **State-licensed only:** DOH surveys these facilities to determine if they meet state regulatory standards.
 - **CMS-certified:** ASFs that are certified to meet federal Conditions for Coverage¹ are permitted to accept Medicare or Medicaid payments for eligible patients. In addition to state licensing surveys, these facilities are subject to periodic CMS-certification surveys to determine if they meet federal standards.
 - **Accredited:** ASFs may elect to become accredited by a private accrediting organization (AO)². In addition to state licensing surveys, these ASFs are also subject to periodic surveys by an AO to determine if they meet that organization's standards.

Of the 186 state-licensed ASFs, 170 are CMS-certified, accredited, or both.

2. **How many surgical procedures does the ASF perform each year?** DOH scales its licensing fees based on the volume of procedures performed at a facility. DOH assesses higher fees for facilities that perform more procedures because the agency assumes facilities with higher volumes are larger and will require more resources to survey. It is unclear whether surgical procedure volume and the cost of performing a survey are meaningfully related.

¹ASFs must meet federal standards for governance, safety, quality, and facility to participate in Medicare and Medicaid.

²The Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities, and the Accreditation Association for Ambulatory Health Care.

Exhibit 1.3: ASF licensing fees are based on certification/accreditation status and annual surgical procedure volume

Fee Type	Fees		
Initial and Renewal License	Performs 1,000 or fewer surgical procedures on an annual basis (70 ASFs)	Performs 1,001 – 5,000 surgical procedures on an annual basis (83 ASFs)	Performs more than 5,000 surgical procedures on an annual basis (33 ASFs)
State Licensed Only	\$17,550	\$22,000	\$27,200
Accredited and/or CMS Certified	\$12,900	\$16,000	\$19,650

Source: WAC 246-330-199, JLARC analysis of DOH licensing data.

Facilities do not pay fees for federal certification surveys

Unlike the state licensing program, facilities do not pay fees to DOH to cover the cost of federal certification surveys. The cost of the oversight program is funded by a federal CMS grant to DOH.

DOH establishes its own schedule for conducting licensing and certification surveys

DOH has flexibility in scheduling its state licensing and federal certification surveys. It must do so within the guidelines of state law and federal priorities.

For state licensing surveys, statute limits the frequency of routine surveys to no more than once every 18 months for state-licensed only ASFs, and no more than every 36 months for CMS-certified or accredited facilities. Routine surveys are performed after the facility receives an initial licensing survey.

While DOH does not formally document its process for prioritizing facility visits, it reports that its survey schedule is based on the following:

- The program's survey frequency goal. Currently, the goal is the maximum frequency allowed in statute. Section 3 provides more details on this goal.

- Whether facilities have received an initial licensing survey or a complaint has been filed against them.
- The amount of time elapsed since the last survey and whether an ASF is CMS certified or accredited. DOH aims to prioritize facilities that have gone the longest without a survey.
- Available inspector staff capacity.

For CMS surveys, the federal government establishes priorities for surveying facilities and assigns complaint investigations and validation surveys to DOH. As long as it meets the federal criteria below, DOH may select which facilities to survey, based on its judgment of risk at the facilities.

- Investigations of complaints to CMS that represent immediate patient risk.
- Validation surveys³ of a sample of facilities that maintain their CMS certification through an accrediting organization.
- Surveying 25 percent of facilities that maintain their certification through state oversight each year, and each facility at least once every 6 years.
- Complaint investigations that do not pose an immediate patient risk.
- Initial certification surveys. Facilities typically gain their CMS certifications through a survey by an accrediting organization rather than DOH.

DOH has performed fewer state licensing surveys on average than federal surveys

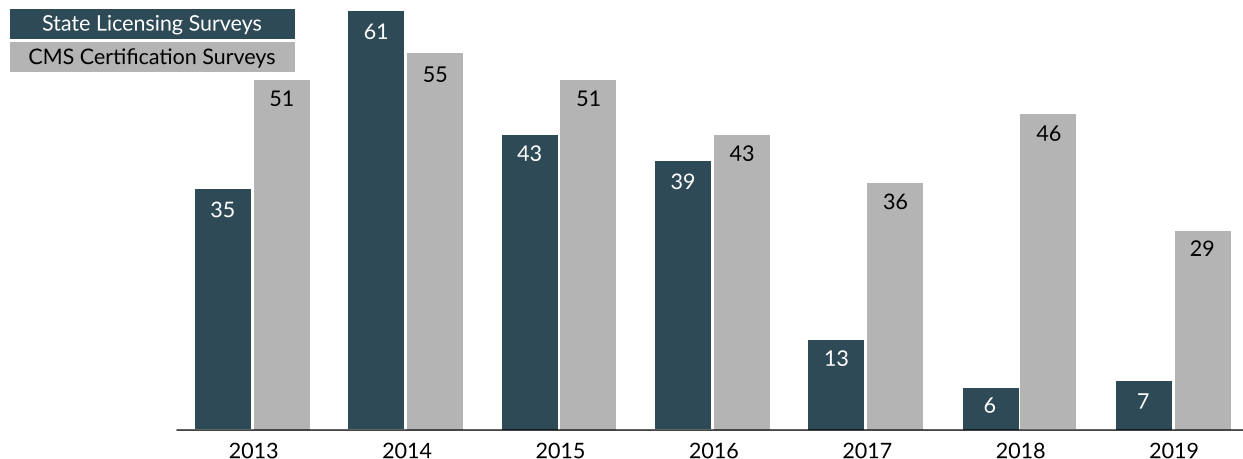
The primary cost driver for both survey programs is staffing, including inspectors, managers, and administrative staff. The state licensing program has had greater fluctuations in revenue and staffing than the federal program, resulting in fewer surveys performed in more recent years. In contrast, the CMS program has maintained steady funding and staffing levels and performed a more consistent number of surveys each year.

Between fiscal year 2013 and fiscal year 2019:

- DOH's state licensing program spent an average of \$398,000 annually, and 1.2 inspector FTEs surveyed an average of 29 ASFs per year.
- DOH's CMS-funded program spent an average of \$563,000 annually, and 2.4 inspector FTEs surveyed an average of 44 facilities per year.

³These surveys are performed after a facility receives an accreditation survey in order to validate the findings and ensure any deficiencies were identified.

Exhibit 1.4: The average number of state licensing surveys declined between FY17 and FY19



Source: JLARC staff analysis of DOH survey data.

State program includes cost of credentialing activities in addition to survey costs

It is difficult to directly compare the costs of the state licensing program and the CMS certification programs due to some differences in program structure. The state licensing program performs activities that are not directly associated with survey work. These include collecting license fees and paying the legal costs associated with enforcement activities. In contrast, DOH does not perform these types of activities for the federal program so they are not reflected in DOH's federally funded program costs.

Despite these differences, from fiscal year 2013 through fiscal year 2019, the program costs per survey for the two programs were similar, averaging \$13,700 for the state program and \$12,600 for the federal program.

This changed, beginning in fiscal year 2017, when the costs per state licensing survey increased as a result of several factors:

- The primary reason is the reduction in inspector staff to an average of 0.7 FTE, which resulted in fewer surveys performed. The program's fixed costs, including the costs of management, credentialing, and administrative staff, were distributed across a smaller number of surveys, causing the cost per survey to rise.
- Beginning in fiscal year 2018, all inspector salaries increased by 27 percent in response to a collective bargaining agreement.
- The program had several unanticipated cost increases, such as attorney general costs related to enforcement activities and public records requests.

DOH is meeting the federal priorities for certification surveys, but it is not meeting its own goals for the state licensing program

CMS sets priorities for surveying facilities that participate in Medicare and Medicaid. DOH has met the federal priorities. However, DOH is not meeting its own goals for the state licensing program. See Sections 3 through 5 for more details.

2. State and federal surveys are similar in scope and process

State and federal surveys cover regulations of similar scope and require a similar process and level of effort

State and federal surveys of ambulatory surgical facilities (ASFs) cover regulations of similar scope, are performed by the same types of DOH staff positions, and take approximately the same amount of time to complete.

State and federal surveys are similar in scope even though they assess different sets of regulations

JLARC staff worked with a consulting firm specializing in health policy and regulatory compliance to review state and federal regulations of ambulatory surgery. State licensing surveys and CMS-certification surveys inspect ASFs against different sets of regulations that cover similar topics.

- **State regulations are established in the Washington Administrative Code** and generally require ASFs to implement policies that satisfy the provisions of the regulations.
- **Federal regulations are called Conditions for Coverage**, and are established in the Code of Federal Regulations. They require facilities to follow specific practices, often according to recognized standards of care. One of the Conditions for Coverage requires that federally certified facilities also comply with state and local regulations, adding to the similarity between the two survey types.

Exhibit 2.1: How state licensing and federal certification surveys compare

ASF Survey Type	State Licensing	Federal CMS Certification
Applicable statutes	RCW 70.230	Social Security Act
Applicable regulations	WAC 246-330	CFR Title 42 part 416
Common regulatory areas included in both types of surveys	<ul style="list-style-type: none"> • Infection control • Patient care services • Quality improvement • Patient rights • Adverse events • Facility governance • Medical staff • Information management • Pharmaceutical services • Surgical services 	
Survey scope	<p>Initial licensing surveys cover all applicable ASF regulations. During routine surveys DOH inspectors may focus on areas of past deficiency or regulatory areas where standards may have changed since the last survey.</p> <p>Initial licensing surveys include a construction review, which assesses facility compliance with the building codes, including the federal life safety code related to fire and smoke protection. This review is not repeated during routine surveys.</p>	<p>DOH inspectors must review compliance with all federal Conditions for Coverage during CMS surveys.</p> <p>Each survey includes an inspection of compliance with the life safety code, performed by the State Fire Marshal.</p>
Survey notification	Except for the initial survey before a license is issued, all routine surveys are unannounced . This is standard practice and is not required by state law or regulation.	CMS requires all surveys to be unannounced .
Survey staff	DOH's Nursing Consultant Institutional positions.*	DOH's Nursing Consultant Institutional positions.*

Source: JLARC staff and independent contractor analysis of DOH and CMS regulations.

*DOH staff that perform state and federal surveys must have the same professional qualifications and training.

Licensing and certification surveys follow the same structured process

State licensing and federal CMS certification surveys follow the same survey process based on steps developed by CMS:

- **Off-site survey preparation.** This includes reviewing materials specific to each facility such as previous survey reports.
- **Entrance activities.** Surveyors meet with the ASF staff on-site to explain the survey process.
- **Information gathering/investigation.** Surveyors observe facility practices and patient care, starting from patient check in through surgeries or other medical procedures and ending with patient discharge. Surveyors also tour the facilities, interview staff, and review infection control programs, quality assurance and performance improvement programs, facility policies and human resources records.
- **Preliminary decision-making and analysis of findings.** Surveyors review and analyze all information collected from observations, interviews, and record reviews and determine findings.
- **Exit conference.** At the end of the on-site portion of the survey, the inspector meets with ASF staff to discuss any preliminary findings and next steps.
- **Post-survey activities.** Inspectors communicate official survey findings to the ASF in a statement of deficiencies (SOD). After the facility receives the SOD, the ASF writes a plan of correction that DOH or CMS must approve. SODs for state licensing and CMS certification surveys are similar in content and appearance.

State licensing surveys take less time to conduct than CMS surveys

CMS requires DOH staff to track the length of time it takes to conduct CMS certification surveys. DOH also records this data for state licensing surveys. Based on data recorded between fiscal years 2011 and 2019, state licensing surveys have taken, on average, less time than CMS certification surveys.

One factor that contributes to this difference in survey length is the relative prevalence of revisits for CMS surveys. Usually DOH can complete a survey by making only one on-site visit. However, in some cases, a survey may require subsequent revisits to an ASF before the survey is

complete. For federal surveys, CMS orders any such revisits to take place based on the deficiencies found. When revisits are included with the first visit times, the average survey length increases.

Exhibit 2.2 shows average survey lengths for first visits and for first visits combined with survey revisits. During the time period analyzed, 40 percent of CMS survey visits were revisits, compared with 3 percent for state licensing surveys.

Another contributing factor may be the difference in the scope of each survey. State licensing surveys review compliance with state regulations only, and DOH may limit the scope to high-risk regulatory areas or areas of past noncompliance. By contrast, CMS surveys must review compliance with all the federal Conditions for Coverage as well as state regulations.

JLARC staff also compared the length of CMS surveys in Washington to other states. While the results were comparable, the surveys themselves may not be. Federal regulations require certification surveys to cover state and local regulations, and these can vary in complexity from state to state.

Exhibit 2.2: State surveys are shorter in length than CMS surveys. CMS surveys in Washington are similar in length to other states.

	State Licensing in WA	CMS Certification in WA (includes compliance with federal and state regulations)	CMS Certification in Peer States (includes compliance with federal and state regulations)
	Average survey length		
First visit only	48.6 hours	57.6 hours	61.2 hours
First visit and any revisits	48.9 hours	65.8 hours	67.4 hours

Source: JLARC staff analysis of DOH and CMS 670 report data for Washington and 15 peer states for fiscal years 2011-2019.

DOH is making efforts to reduce the length of ASF surveys

DOH has documented and communicated several steps it is taking to reduce its average survey time. Although these efforts are underway, they are not yet fully implemented and their impact on survey length is not yet known.

- DOH is **piloting** what it terms "**focused surveys**" where the scope is limited to areas of past noncompliance, high-risk regulatory areas such as infection control, and to regulatory areas that may have changed since the facility's last state licensing survey. By focusing on a narrower set of regulations, DOH intends to reduce total survey time. Violations of regulatory areas that are outside the focused scope may still be cited.
- DOH aims to **schedule surveys of multiple facilities when significant travel is required**. This allows the department to share travel time and costs across multiple surveys. DOH also prepares contingencies in the event an ASF is closed or not performing surgical procedures on the planned survey day.
- Historically, ASF survey staff have been located in Tumwater. DOH is relocating its survey staff to its satellite office in Kent, which is closer to the majority of ASFs, and which could minimize survey staff travel time.

3. DOH has not met its state licensing survey goal

Based on DOH's survey frequency goal, 71 percent of ASFs are more than a year past due for a licensing survey. DOH has not demonstrated a relationship between survey frequency and patient safety.

DOH has chosen a state licensing survey frequency goal that is the shortest interval allowed by law. The agency has never met its goal.

From 2009 through 2015, statute set a **minimum required frequency for routine licensing surveys**: all state-licensed ASFs had to be surveyed once every 18 months. If an ASF was also CMS-certified or accredited, those respective surveys could replace one state licensing survey every three years.

In 2016, the Legislature amended statute to set a **maximum allowable frequency for routine licensing surveys**: state-licensed only ASFs can be surveyed no more than once every 18 months and CMS-certified or accredited facilities can be surveyed no more than once every 36 months. DOH has not updated agency rules to reflect this statutory change.

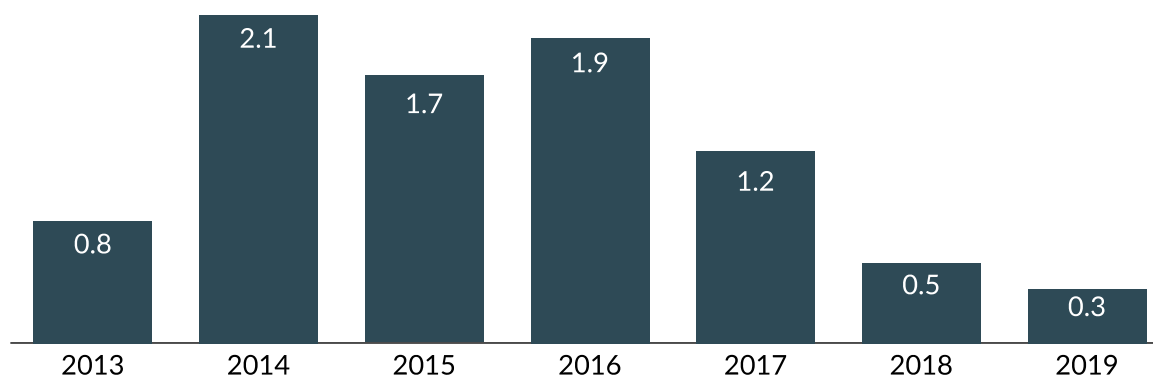
Though it is no longer required, DOH's survey frequency goal is the shortest interval allowed by law: once every 18 months for state-licensed only facilities and once every 36 months for CMS-certified or accredited facilities.

To meet this goal, DOH would need to conduct 77 licensing surveys per year for the 186 state-licensed ASFs in Washington, which would include 67 routine surveys, as well as 8 initial licensing surveys and 2 complaint investigations.

The number of DOH state licensing inspectors has declined over time

JLARC staff analysis of DOH payroll data shows the department has not maintained a level of inspector staffing that would allow it to meet its survey frequency goal. DOH estimates it would need 2.1 Nursing Consultant Institutional (NCI) FTEs to meet its goal, but the program has only reached this staffing level once, in fiscal year 2014. From fiscal years 2017 through 2019, the department's inspection staff declined from 1.2 FTE to 0.3 FTE.

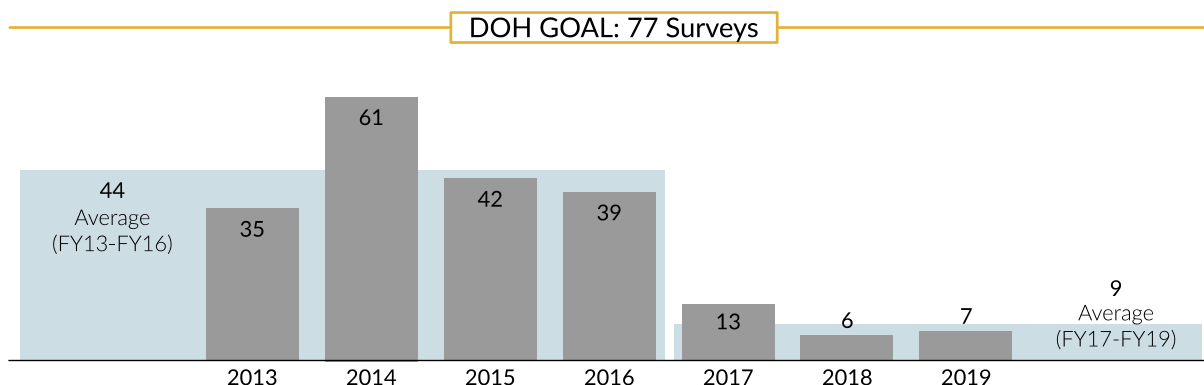
Exhibit 3.1: The number of ASF inspectors decreased after fiscal year 2016



Source: JLARC staff analysis of DOH payroll data.

From fiscal year 2013 through fiscal year 2016, DOH performed an average of 44 licensing surveys per year. The number of surveys declined in fiscal years 2017 through 2019 to an average of 9 surveys per year. This decline coincides with the decline in staffing.

Exhibit 3.2: DOH went from an average of 44 surveys per year to an average of 9 surveys

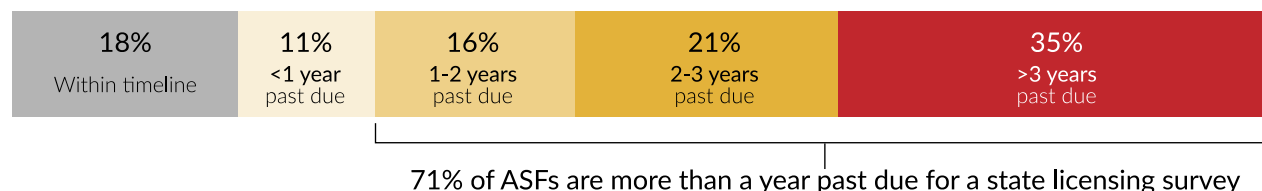


Source: JLARC analysis of DOH survey data.

71 percent of ASFs are more than a year past due for a routine state licensing survey

DOH has a backlog of surveys because it has consistently performed fewer routine surveys than its frequency goal.

Exhibit 3.3: As of March 2020, 18% of facilities have been surveyed on time and the rest are past due



Note: Percentages may not sum to totals due to rounding.

Source: JLARC staff analysis of DOH survey backlog estimate.

These backlog estimates reflect the amount of time that DOH is past due in performing a state licensing survey. However, many of these facilities are also subject to CMS certification or accreditation surveys and may have received those surveys in the interim. DOH has historically met CMS performance targets for certification surveys.

DOH bases its survey goal on previous statutory requirements and its survey schedule for acute care hospitals

DOH has flexibility in setting its survey frequency goal within the maximum frequency limits allowed by state law. However, in the agency's legislative reports and communications with JLARC staff, DOH asserts that surveying facilities as frequently as allowed is in the interest of patient safety.

DOH's survey frequency varies by type of medical facility

DOH reports its current frequency goal is based on the original ASF survey frequency established by the Legislature and the survey frequency for acute care hospitals. These facilities are inspected once every 18 or 36 months, depending on their certification and accreditation status. DOH's survey schedules for other types of medical facilities range from unscheduled visits to one survey every 36 months.

Exhibit 3.4: Survey frequencies of other DOH-licensed medical facilities range from unspecified to every 36 months

Facility Type	DOH Survey Frequency
Ambulatory Surgical Facilities	18 months (36 mos. if CMS-certified or accredited)
Acute Care Hospitals	18 months (36 mos. if CMS-certified or accredited)
Psychiatric Hospitals	12 months
Residential Treatment Facilities	Unspecified. DOH may perform unannounced survey at any time
Birth Centers, In-home Services Agencies	24 months

Source: JLARC staff analysis of Washington Administrative Code.

Other organizations and states survey ASFs on different schedules

Surveys performed by different organizations and other states may not be directly comparable to DOH's surveys. For example, an entity that surveys facilities annually may conduct a narrow review and require fewer resources than more extensive surveys that occur less frequently. However, the survey schedules used by other entities can provide some context for DOH's survey frequency goals.

- The three **accrediting organizations** that accredit ASFs in Washington require accreditation surveys every three years.
- CMS requires DOH to perform certification surveys of 25 percent of facilities that maintain their certification through state oversight each year. Over time, this equates to an average frequency of one survey every four years.
- Surveys of 21 other states conducted by DOH and JLARC staff's consultant found that survey frequency ranged from every year to once every four years.

DOH's survey frequency goal is not based on a demonstrated link between surveys and patient safety

DOH reports that its survey frequency goal is consistent with its general experience conducting surveys and feedback from other states.

- During the 2015-2017 biennium, DOH asserts that 68 percent of CMS certification surveys found condition-level violations⁴. The department expressed concern that similar patterns of noncompliance may occur in ASFs not subject to CMS certification surveys and that this creates the potential for patient harm.
- DOH cites outreach to other state ASF regulatory programs in concluding that frequent surveys encourage compliance.

So far, DOH has not cited any research that supports its frequency goal or identifies an optimal interval between surveys. Additionally, DOH's own experience with surveying facilities more than once is limited to 20 facilities. On average, the interval between these surveys was 4.7 years and ranged from under 2 years to 7 years. This sample size does not provide strong support for or against the department's goal for more frequent surveys.

While survey frequency has fluctuated, the number of reported adverse events at ASFs has trended downward

ASFs must report adverse events⁵ to DOH within 48 hours of their occurrence. Adverse events are organized into 7 categories, including negative situations related to surgical or invasive procedures, products or devices, patient protection, and the environment.

⁴More severe issues, indicating a facility is out of compliance with one of the federal conditions for coverage.

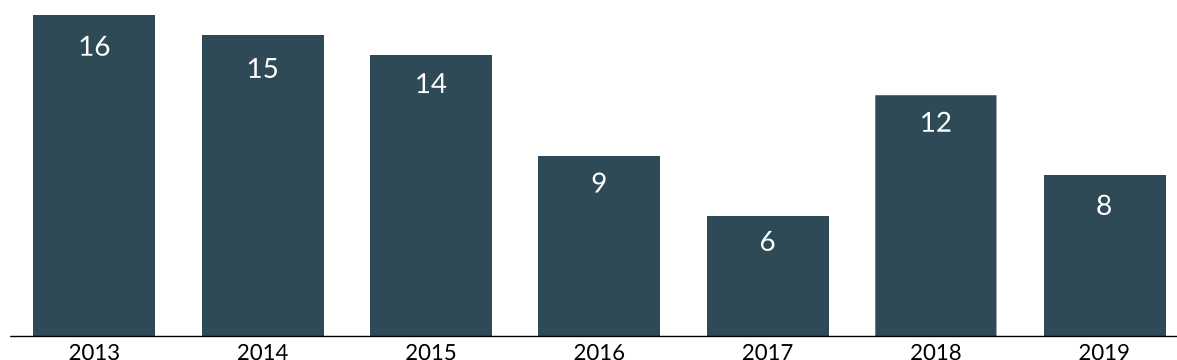
⁵29 serious reportable events which medical facilities are required to report to DOH.

Although DOH performed fewer surveys in recent years, the number of reported adverse events did not increase. JLARC staff do not assert a causal relationship between the department's survey frequency and the frequency with which adverse events occur or are reported.

From fiscal year 2013 through fiscal year 2019, the ASFs reported an average of 11 adverse events per year. The most commonly reported adverse events during this period were:

- Wrong surgery/invasive procedure site (31 events, 4.4 per year).
- Unintended retention of foreign object (12 events, 1.7 per year).
- Wrong surgical/invasive procedure (12 events, 1.7 per year).

Exhibit 3.5: Adverse events reported at ASFs have trended downward during fiscal years 2013-2019



Source: JLARC analysis of DOH

4. Anticipated program costs exceed estimated revenue

DOH is increasing its survey staff to reduce the survey backlog. The cost of additional staff puts DOH at risk of a revenue shortfall and a negative reserve fund balance.

DOH is required by law to ensure license fees fully cover program costs

RCW 43.70.250 requires DOH to fully fund its state licensing program from license fees. ASFs pay a license fee once every three years, and licenses are issued for three-year terms. If DOH decides to revise fees, ASFs do not have to pay the new rates until they are due for a license renewal.

DOH raised ASF license fees in 2019 to increase survey capacity

DOH raised its license fees in 2019 in order to hire more inspectors and complete more surveys. The fee increase ranged from 170% to 263%, depending on whether the ASF was state licensed only or CMS certified or accredited.

Exhibit 4.1: The 2019 fee increase ranged from 170% to 263%

	Previous Fees Set in 2012			New Fees as of April 2019			% Change		
	1,000 or fewer	1,001-5,000	5,001 and more	1,000 or fewer	1,001-5,000	5,001 and more	1,000 or fewer	1,001-5,000	5,001 and more
Number of surgical procedures									
State Licensed Only	\$6,507	\$8,142	\$10,068	\$17,550	\$22,000	\$27,200	170%	170%	170%
Accredited	\$3,630	\$4,447	\$5,410	\$12,900	\$16,000	\$19,650	255%	260%	263%
CMS Certified	\$4,781	\$5,925	\$7,273	\$12,900	\$16,000	\$19,650	170%	170%	170%

Source: JLARC staff analysis of WAC 246-330-199.

DOH fee assumptions are not based on the program's past survey performance

DOH followed some best practices when determining its fee increases, including making sure that all program costs were factored into its budget. However, DOH did not base its staffing assumptions on the program's past performance. The assumptions are based on the program's goals for how long it **should** take to complete a survey rather than the **actual** time it takes to do so.

Exhibit 4.2 shows DOH estimated that it would need 2.1 inspection FTEs to meet its survey frequency goal of 77 surveys per year. The new fees assume that surveys take 40 hours to complete, but state licensing surveys have averaged 48.9 hours in recent years.

Exhibit 4.2: Fee assumptions in 2019 do not reflect the actual time it has taken to complete surveys

	Annual Averages from FYs 2013-19	2019 Fee Assumptions
Number of inspection staff	1.2 FTE	2.1 FTE
Number of surveys completed per FTE	24 per year	36 per year
Total number of surveys completed	29 per year	75-80 per year
Hours to complete a survey	48.9 hours	40 hours

Source: JLARC staff analysis of DOH fee setting work papers, payroll reports, and ILRS survey data.

DOH plans to increase staffing again in 2020 to meet its survey goal

In 2020, DOH acknowledged that it would not meet its survey frequency goal with 2.1 inspection FTEs. The department reports that it will add 0.9 inspection FTE to its program, for a total of 3 FTE. Based on the actual time it took to complete surveys in fiscal years 2013 through 2019, DOH should be able to meet its survey goal of 77 per year once these additional staff are trained. It could meet a less frequent survey goal within current resources.

The cost of additional staff puts DOH at risk of a revenue shortfall and a negative reserve fund balance

If DOH adds another 0.9 FTE to its inspection staff in 2020, its estimated program costs will exceed its estimated revenue. This conflicts with the statutory requirement to set fees at a level that covers program costs.

- Estimated program costs: \$1.052 million per year.
- Estimated average license fee revenue: \$1.041 million per year (for fiscal year 2021 through fiscal year 2023).
- Estimated shortfall: \$11,000 per year.

DOH has indicated that it plans to cover the shortfall with its reserve fund balance. However, its beginning fund balance of \$16,000 in fiscal year 2021 is insufficient to cover these costs on an ongoing basis.

DOH may violate its own reserve fund policy and best practices for stabilizing revenues

Unless DOH reduces survey frequency, shortens the length of its surveys, or increases license fees, it risks a revenue shortfall and a negative reserve fund balance.

DOH has a policy to maintain a reserve fund balance for its programs in order to absorb unanticipated expenditures or revenue changes. For the ASF program, the department has determined an appropriate fund balance is 12.5% of biennial operating expenses (3 months).

With recent rate increases and DOH's projected addition of 0.9 FTE, the program's estimated reserve fund balance in fiscal year 2023 will be \$4,000. This is only 1% of the department's target reserve balance.

There are additional risks to the agency's fund balance during the COVID-19 pandemic. In response to this safety and health emergency, ASFs may be performing fewer surgeries or closing facilities. This could lower DOH's license fee revenue. This uncertainty, along with other risks that have previously occurred, such as cost-of-living increases or unanticipated program costs, highlights the importance of maintaining a sufficient reserve fund balance.

Best practices for setting reserve fund balances suggest that there be adequate funds to stabilize revenue fluctuations and cover unanticipated expenditures. Best practices also support stabilizing revenue sources by collecting fees annually. Because ASF license fees are paid on a three-year cycle, the revenue for the 2019 fee increase will not be fully realized until 2021. Collecting fees each year rather than on a three-year cycle may help stabilize the impacts of revenue shortfalls within each year.

5. Data improvements could help to prioritize surveys

Improving data quality could help DOH prioritize the facilities most overdue for state licensing surveys

Inaccurate and incomplete data in its state licensing and survey database may inhibit DOH's ability to prioritize licensing surveys of ASFs.

DOH uses state and federal data systems to maintain licensing and survey data

The state's ILRS database tracks state licensing and survey data

The Integrated Licensing and Regulatory System (ILRS) is DOH's main database for recording state ASF licensing information. The department's inspection staff enter data into ILRS. Until 2016, ILRS included data on each state licensing survey as well as federal CMS and accreditation surveys. After 2016, the department stopped entering certification and accreditation survey information into ILRS.

The federal ASPEN database tracks CMS certification, accreditation, and survey data

DOH uses the federal Automated Survey Processing Environment (ASPEN) database to record information on its surveys of CMS-certified and accredited ASFs. The department also uses the system to draft Statement of Deficiency reports for both its CMS-funded and state licensing surveys.

DOH uses multiple data sources to develop a prioritized schedule for surveying ASFs

DOH schedules state licensing surveys based on a priority list of licensed ASFs. It ranks facilities based on the amount of time elapsed since their last survey. To determine this, DOH manually creates a priority list using data from ILRS, ASPEN, accreditation organization websites, and individual ASFs. DOH gives highest priority to ASFs that have gone the longest since their last survey. The accuracy of its prioritized list depends largely on the quality of the data entered into its systems.

Data inaccuracies in ILRS could limit DOH's ability to ensure ASFs are surveyed in the highest priority order

JLARC staff reviewed ILRS data and identified missing and inaccurate records. Staff identified 31 instances of facilities with active licenses that do not appear in ILRS survey records. Some of these are due to errors that could result in a facility's incorrect placement on DOH's prioritized list for survey visits. These 31 instances include:

- 19 facilities where a change in ownership resulted in missing historical data on credential status. DOH assigns a new credential number when an ASF changes ownership and ILRS does not link that new number to the ASF's previous credential history. While DOH indicated that change of ownership status can be manually reviewed in notes appended to the facility's ILRS record, this creates a potential risk that a facility will be incorrectly ranked on DOH's priority list for surveys.
- 3 ASFs that did not appear in ILRS because their survey records were not complete, although DOH had performed the on-site portion of the survey. One of these facilities had been licensed since 2009 and did not receive its first state licensing survey until 2019.
- 4 ASFs that did not appear in the ILRS survey data due to other data entry errors.
- 4 ASFs that did not appear in the survey record, but DOH reports that surveys were completed. DOH staff could not locate the associated Statements of Deficiencies for these facilities in either ILRS or ASPEN.
- 1 facility licensed since 2009 has never had a routine state licensing survey.

In addition to the above issues with ILRS records, during this review DOH identified at least 19 instances of CMS surveys incorrectly labeled as state licensing surveys. DOH states this issue appears to be isolated to a former survey staff member, but the department has not confirmed whether it has identified all instances of CMS surveys incorrectly labeled in ILRS as state licensing surveys.

New data system will replace ILRS in several years

DOH has stated that ILRS will be replaced by a new system, the Healthcare Enforcement and Licensing Modernization Solution (HELMs). Implementation of the new system is still several years out, but DOH hopes the new system will have functionality that allows it to track credential numbers across changes in ownership and minimize other data errors. This update also provides DOH an opportunity to develop business practices that minimize data entry issues and other inaccuracies.

Appendix A: Applicable statutes and rules

RCW 43.70.250, RCW 70.230.050, RCW 70.230.100, WAC 246-330-199

License fees for professions, occupations, and businesses.

RCW 43.70.250

(1) It shall be the policy of the state of Washington that the cost of each professional, occupational, or business licensing program be fully borne by the members of that profession, occupation, or business.

(2) The secretary shall from time to time establish the amount of all application fees, license fees, registration fees, examination fees, permit fees, renewal fees, and any other fee associated with licensing or regulation of professions, occupations, or businesses administered by the department. Any and all fees or assessments, or both, levied on the state to cover the costs of the operations and activities of the interstate health professions licensure compacts with participating authorities listed under chapter 18.130 RCW shall be borne by the persons who hold licenses issued pursuant to the authority and procedures established under the compacts. In fixing said fees, the secretary shall set the fees for each program at a sufficient level to defray the costs of administering that program and the cost of regulating licensed volunteer medical workers in accordance with RCW 18.130.360, except as provided in RCW 18.79.202. In no case may the secretary increase a licensing fee for an ambulatory surgical facility licensed under chapter 70.230 RCW during the 2019-2021 fiscal biennium, nor may he or she commence the adoption of rules to increase a licensing fee during the 2019-2021 fiscal biennium.

(3) All such fees shall be fixed by rule adopted by the secretary in accordance with the provisions of the administrative procedure act, chapter 34.05 RCW.

[2019 c 415 § 966; 2017 c 195 § 26; 2016 c 146 § 1; 2013 c 77 § 2; 2006 c 72 § 4; 2005 c 268 § 3; 1996 c 191 § 1; 1989 1st ex.s. c 9 § 319.]

NOTES:

Effective date—2019 c 415: See note following RCW 28B.20.476.

Effective date—2013 c 77: See note following RCW 43.70.110.

Finding—2005 c 268: See note following RCW 18.79.202.

Licenses—Applicants—Renewal.

RCW 70.230.050

(1) An applicant for a license to operate an ambulatory surgical facility must demonstrate the ability to comply with the standards established for operating and maintaining an ambulatory surgical facility in statute and rule, including:

(a) Submitting a written application to the department providing all necessary information on a form provided by the department, including a list of surgical specialties offered;

(b) Submitting building plans for review and approval by the department for new construction, alterations other than minor alterations, and additions to existing facilities, prior to obtaining a license and occupying the building;

(c) Demonstrating the ability to comply with this chapter and any rules adopted under this chapter;

(d) Cooperating with the department during on-site surveys prior to obtaining an initial license or renewing an existing license;

(e) Providing such proof as the department may require concerning the ownership and management of the ambulatory surgical facility, including information about the organization and governance of the facility and the identity of the applicant, officers, directors, partners, managing employees, or owners of ten percent or more of the applicant's assets;

(f) Submitting proof of operation of a coordinated quality improvement program in accordance with RCW 70.230.080;

(g) Submitting a copy of the facility safety and emergency training program established under RCW 70.230.060;

(h) Paying any fees established by the secretary under RCW 43.70.110 and 43.70.250; and

(i) Providing any other information that the department may reasonably require.

(2) A license is valid for three years, after which an ambulatory surgical facility must submit an application for renewal of license upon forms provided by the department and the renewal fee as established in RCW 43.70.110 and 43.70.250. The applicant must demonstrate the ability to comply with the standards established for operating and maintaining an ambulatory surgical facility in statutes, standards, and rules. The applicant must submit the license renewal document no later than thirty days prior to the date of expiration of the license.

(3) The applicant may demonstrate compliance with any of the requirements of subsection (1) of this section by providing satisfactory documentation to the secretary that it has met the standards of an accreditation organization or federal agency that the secretary has determined to have substantially equivalent standards as the statutes and rules of this state.

[2016 c 146 § 3; 2007 c 273 § 5.]

Ambulatory surgical facilities—Surveys.

RCW 70.230.100

(1) The department shall make or cause to be made a survey of all ambulatory surgical facilities according to the following frequency:

(a) Except as provided in (b) of this subsection, an ambulatory surgical facility must be surveyed by the department no more than once every eighteen months.

(b) An ambulatory surgical facility must be surveyed by the department no more than once every thirty-six months if the ambulatory surgical facility:

(i) Has had, within eighteen months of a department survey, a survey in connection with its certification by the centers for medicare and medicaid services or accreditation by an accreditation organization approved by the department under RCW 70.230.020(5);

(ii) Has maintained certification by the centers for medicare and medicaid services or accreditation by an accreditation organization approved by the department under RCW 70.230.020(5) since the survey in connection with its certification or accreditation pursuant to (b)(i) of this subsection; and

(iii) As soon as practicable after a survey in connection with its certification or accreditation pursuant to (b)(i) of this subsection, provides the department with documentary evidence that the ambulatory surgical facility is certified or accredited and that the survey has occurred, including the date that the survey occurred.

(2) Every survey of an ambulatory surgical facility may include an inspection of every part of the surgical facility. The department may make an examination of all phases of the ambulatory surgical facility operation necessary to determine compliance with all applicable statutes, rules, and regulations. In the event that the department is unable to make a survey or cause a survey to be made during the three years of the term of the license, the license of the ambulatory surgical facility shall remain in effect until the state conducts a survey or a substitute survey is performed if the ambulatory surgical facility is in compliance with all other licensing requirements.

(3) Ambulatory surgical facilities shall make the written reports of surveys conducted pursuant to medicare certification procedures or by an approved accrediting organization available to department surveyors during any department surveys or upon request.

[2016 c 146 § 4; 2007 c 273 § 11.]

Fees—License, change of ownership, refund process.

WAC 246-330-199

This section establishes the initial and renewal license fees, change of ownership fee, late fee, and request for refund of an initial license fee for an ambulatory surgical facility (ASF).

(1) Initial and renewal license fees. An initial license or a renewal license and fee are valid for three years from date of issuance. An applicant for an initial or renewal license must submit one of the following fees to the department:

Ambulatory surgical facility initial and renewal fees

Fee Type	Fees		
Initial and Renewal License	Performs 1,000 or Fewer Surgical Procedures on an Annual Basis	Performs 1,001 - 5,000 Surgical Procedures on an Annual Basis	Performs More than 5,000 Surgical Procedures on an Annual Basis
Accredited or Medicare Certified	\$12,900	\$16,000	\$19,650
State Licensed Only	\$17,550	\$22,000	\$27,200

(a) Accredited means an ASF is accredited by one of the organizations identified in WAC 246-330-025 (1)(b).

(b) Medicare certified means an ASF is certified by the Centers for Medicare and Medicaid Services (CMS).

(c) State licensed only means an ASF that is not accredited and is not medicare certified.

(2) Late fee. A licensee must send the department a late fee in the amount of fifty dollars per day, not to exceed one thousand dollars, whenever the renewal fee is not paid by thirty days before the license expiration (date as indicated by the postmark).

(3) Change of ownership. The change of ownership fee is good for that transaction and does not change the original license ending date. The person purchasing or taking over ownership of a licensed ASF must:

(a) Send the department a change of ownership fee in the amount of five hundred dollars thirty days before the change of ownership becomes final (date as indicated by the postmark); and

(b) Receive from the department a new license valid for the remainder of the current license period.

(4) An applicant may request a refund for initial licensure as follows:

(a) Two-thirds of the initial fee paid after the department has received an application but has not conducted an on-site survey or provided technical assistance and has not issued a license; or

(b) One-third of the initial fee paid after the department has received an application and has conducted either an on-site survey or provided technical assistance but not issued a license.

[Statutory Authority: RCW 43.70.250, 43.70.280, 70.230.100 and 70.230.050. WSR 19-02-044, § 246-330-199, filed 12/26/18, effective 4/15/19. Statutory Authority: Chapter 43.70 RCW, 2011 c 76, and 2011 1st sp.s. c 50. WSR 12-10-010, § 246-330-199, filed 4/19/12, effective 6/1/12. Statutory Authority: Chapter 70.230 RCW. WSR 09-09-032, § 246-330-199, filed 4/7/09, effective 5/8/09.]

RECOMMENDATIONS & RESPONSES

Legislative Auditor Recommendation

The Legislative Auditor makes four recommendations regarding the Department of Health's oversight of ASFs in Washington

Recommendation #1: The Department of Health should identify how the frequency of licensing surveys is related to risks to patient safety and determine a survey frequency goal based on those risks.

In performing this review, DOH should:

- Refer to any research literature concerning the relationship between survey frequency and health and patient safety outcomes of medical facilities.
- Continue to explore efficiencies that could reduce the level of effort required to perform each survey to improve its ability to meet frequency goals.
- Determine if any licensing fee adjustments are necessary related to proposed changes in survey frequency.
- Report its findings to the Legislature.

Legislation
Required: No

Fiscal Impact: Impacts on costs and licensing fees will depend on whether changes in frequency and efficiencies are proposed by DOH

Implementation
Date: December 31, 2021

Agency Response: To be included with Proposed Final Report

Recommendation #2: The Department of Health should follow its cost recovery policy and best practices by maintaining its reserve fund balance.

When it determines the appropriate survey frequency and program level of effort, DOH should ensure license fees and staffing are at a level that allows the department to meet its goal while maintaining its target reserve fund balance.

Maintaining such a reserve would enable DOH to continue operations while absorbing unexpected cost increases or revenue reductions.

Legislation
Required: No

Fiscal Impact: Impacts on costs and licensing fees will depend on whether changes in frequency and efficiencies are proposed by DOH

Implementation
Date: July 1, 2022

Agency Response: To be included with Proposed Final Report

Recommendation #3: The Department of Health should improve the procedures and data systems it uses to collect state licensing and survey data.

DOH should identify the data elements that are most important for effectively prioritizing and scheduling ASF surveys. DOH should document and implement procedures for this data collection to ensure accuracy and reliability.

Legislation Required: No

Fiscal Impact: None

Implementation Date: December 31, 2021

Agency Response: To be included with Proposed Final Report

Recommendation #4: The Legislature should amend statute to permit DOH to collect ASF license fees annually. Annual fee collections could help to stabilize the program's revenues and potentially reach its reserve fund balance goals.

Annual fee collection would provide revenue stability to the program. It would also accelerate the impact of changes to licensing fees, allowing DOH to respond more quickly to program and cost changes. ASFs may prefer smaller annual licensing payments to larger, more infrequent payments.

Legislation Required: Yes

Fiscal Impact: None

Implementation Date: N/A

Agency Response: To be included with Proposed Final Report

RECOMMENDATIONS & RESPONSES

Agency Response

Agency response(s) will be included in the proposed final report, planned for January 2021.

Current Recommendation Status

JLARC staff follow up with agencies on Legislative Auditor recommendations for 4 years. Responses from agencies on the latest status of implementing recommendations for this report will be available in 2022.

MORE ABOUT THIS REVIEW

Audit Authority

The Joint Legislative Audit and Review Committee (JLARC) works to make state government operations more efficient and effective. The Committee is comprised of an equal number of House members and Senators, Democrats and Republicans.

JLARC's non-partisan staff auditors, under the direction of the Legislative Auditor, conduct performance audits, program evaluations, sunset reviews, and other analyses assigned by the Legislature and the Committee.

The statutory authority for JLARC, established in [Chapter 44.28 RCW](#), requires the Legislative Auditor to ensure that JLARC studies are conducted in accordance with Generally Accepted Government Auditing Standards, as applicable to the scope of the audit. This study was conducted in accordance with those applicable standards. Those standards require auditors to plan and perform audits to obtain sufficient, appropriate evidence to provide a reasonable basis for findings and conclusions based on the audit objectives. The evidence obtained for this JLARC report provides a reasonable basis for the enclosed findings and conclusions, and any exceptions to the application of audit standards have been explicitly disclosed in the body of this report.

Study Questions



PROPOSED STUDY QUESTIONS Regulation of Ambulatory Surgical Facilities

State of Washington Joint Legislative Audit and Review Committee

Revised December 2019

JLARC was directed to review the Department of Health's regulatory program for ambulatory surgical facilities

The Department of Health (DOH) licenses and inspects more than 180 ambulatory surgical facilities (ASFs) in Washington. ASFs provide outpatient surgical services in various specialties such as orthopedics, eye surgery, and plastic surgery. ASFs must be state licensed, and many are also certified to participate in Medicare and Medicaid.

The 2019-21 operating budget directed JLARC to review DOH's regulatory program for ASFs.

DOH inspects ASFs to ensure they meet health and safety standards

DOH performs state licensing inspections of ASFs to ensure they meet minimum state health and safety standards. These inspections, known as surveys, may occur no more than once every 18 months if an ASF is state licensed only.

To participate in the Medicare and Medicaid programs, ASFs must certify that they meet federal health and safety standards. This also requires periodic surveys, which DOH is contracted to perform for the Centers for Medicare & Medicaid Services (CMS). For CMS-certified facilities, DOH performs less frequent state licensing surveys.

State license fees and federal funds pay for DOH oversight

State law requires that ASFs fully cover the cost of state oversight. DOH must set license fees at an appropriate level to fund the costs of administering the state-licensing program. The federal government provides funding for DOH to inspect CMS-certified facilities.

In 2016 and 2017, DOH reported to the Legislature that license fees were insufficient to cover the full costs of the regulatory program. DOH reports this resulted in an inspection backlog. DOH last increased license fees for ASFs in April 2019.

This study will address the following questions

1. Do state license fees and federal funds cover the respective costs of regulating ASFs?
2. Is staffing for DOH's regulatory program aligned with statutory requirements?
3. How does DOH's survey program for state licensing compare to its program for CMS certification?
4. How do licensing and inspection requirements for Washington ASFs compare to requirements in other states?
5. Do conclusions from these questions provide opportunities to improve efficiency?

Study Timeframe

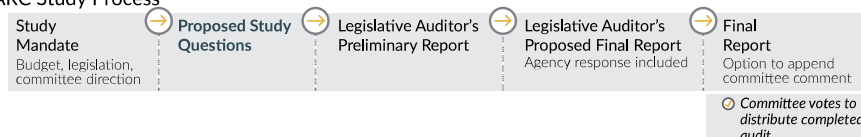
Preliminary Report: December 2020

Proposed Final Report: January 2021

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JLARC Study Process



JOINT LEGISLATIVE AUDIT & REVIEW COMMITTEE

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Methodology

The methodology JLARC staff use when conducting analyses is tailored to the scope of each study, but generally includes the following:

- **Interviews** with stakeholders, agency representatives, and other relevant organizations or individuals.
- **Site visits** to entities that are under review.
- **Document reviews**, including applicable laws and regulations, agency policies and procedures pertaining to study objectives, and published reports, audits or studies on relevant topics.
- **Data analysis**, which may include data collected by agencies and/or data compiled by JLARC staff. Data collection sometimes involves surveys or focus groups.
- **Consultation with experts** when warranted. JLARC staff consult with technical experts when necessary to plan our work, to obtain specialized analysis from experts in the field, and to verify results.

The methods used in this study were conducted in accordance with Generally Accepted Government Auditing Standards.

More details about specific methods related to individual study objectives are described in the body of the report under the report details tab or in technical appendices.

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