STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

June 17, 2016

CERTIFIED MAIL # 7009 0960 0000 5564 6461

Lora Stamper, RN, MHA
Director of Clinical Operations
Seattle Reproductive Medicine
1505 Westlake Ave North, Suite 400
Seattle, Washington 98109

RE: Certificate of Need Application #16-10

Dear Ms. Stamper:

We have completed review of the Certificate of Need application submitted by Seattle Reproductive Medicine proposing to establish an ambulatory surgery center in King County. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Seattle Reproductive Medicine agrees to the following in its entirety.

Project Description:
This project approves the establishment of a three operating room ambulatory surgery center consisting of one general operating room and two procedure rooms. Services to be provided are limited to outpatient reproductive and fertility services and fertility related urology surgical services.

Conditions:
1. Seattle Reproductive Medicine Inc., agrees with the project description stated above. Seattle Reproductive Medicine Inc. further agrees that any change to the project as described in the project description is a new project and requires a new Certificate of Need.

2. Seattle Reproductive Medicine Inc., will provide charity care in compliance with the charity care policy reviewed. Seattle Reproductive Medicine Inc., will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average

amount of charity care provided by the hospitals currently operating in the King County Central Region. Currently, this amount is 1.64% of total revenue. Seattle Reproductive Medicine Inc. will maintain records documenting the amount of charity care it provides and demonstrating compliance with its charity care policies.

Approved Costs: The approved estimated capital expenditure for this project is $0.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response to the Certificate of Need Program, at one of the following addresses.

Mailing Address:	Physical Address:
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely,

Bart Eggen, Acting Director
Community Health Systems

Enclosure

EVALUATION DATED JUNE 17, 2016 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY SEATTLE REPRODUCTIVE MEDICINE, INC. PS TO ESTABLISH A NEW AMBULATORY SURGERY CENTER LOCATED IN SEATTLE, WASHINGTON

APPLICANT DESCRIPTION

Seattle Reproductive Medicine, Inc., PS (SRM) is a private physician owned Limited Liability Corporation that is owned by the following eight physicians.

Nancy A. Klein, MD	Gerard S. Letterie, DO
Paul C. Lin, MD	Janet L. Kennedy, MD
Angela C. Thyer, MD	Lynn B. Davis, MD, MS
Amy R. Criniti, MD	Paul S. Dudley, MD

In addition to these physicians, SRM operates with four additional physician employees on the medical staff. The four employed physicians are Nichole Barker, DO; Michele Cho, MD; Thomas Fisher, DO; and Brenda Houmard, MD, Phd

In 2003 the Seattle Reproductive Surgery Center (SRSC) was established as a separate Washington State Limited Liability Company owned and operated by SRM. [Application: pp 2-4 & 35, & SRM website]

As of the writing of this evaluation, SRM has five separate clinical locations. SRSC is operating at the address shown in bold. The five separate SRM locations are shown in the table below. [Source: Application, p4 & SRM website]

Seattle Reproductive Medicine Practice Locations

Address	City	Zip
1505 Westlake Avenue N, Suite 400	**Seattle**	**98109**
3055 112th Avenue NE, Suite 201	Bellevue	98004
3209 S 23rd Street, Suite 350	Tacoma	98405
12333 NE 130th Lane, Suite 220	Kirkland	98034
15920 E. Indiana Avenue, Suite 200	Spokane Valley	99216

PROJECT DESCRIPTION

This project focuses on SRM's facility known as Seattle Reproductive Surgery Center. SRSC currently operates the ambulatory surgery center (ASC)[1]without either a Certificate of Need or a Certificate of Need exemption[2]. The ASC has been licensed by Department of Health since September 2009 when licensing under RCW 70.230[3] became a requirement. [Source: DOH ILRS] The applicant states it is proposing to convert an existing ASC to a CN approved ASC in King County. The approval would allow it to continue to providing service. Also as part of this project the applicant proposes to allow other physicians the opportunity to perform surgeries and procedures at the ASC. [Source: Application, pp 8-9] Regardless of whether other physicians use the ASC or not, prior Certificate of Need review and approval

[1] For Certificate of Need purposes ambulatory surgery center (ASC) and ambulatory surgery facility (ASF) have the same meaning. For reader ease the term ASC will be used throughout this evaluation.
[2] In May of 2013, the department determined SRM's ASC did not qualify for an exemption from Certificate of Need review. [DOR 13-35]
[3] RCW 70.230 became effective July 1, 2009.

is required for the ASC to be in compliance with the Certificate of Need statute and regulations and continue operating.

If the project is approved, the location of the ASC would remain at the existing Westlake Avenue site. The facility would have a total of three operating rooms, one general and two procedure rooms. Services currently provided at the ASC are outpatient procedures related to reproductive endocrinology gynecology, and fertility related urology services including, but not necessarily limited to egg retrieval, operative hysteroscopy, cyst aspiration, dilation and curettage, vasovasotomy, testicular sperm aspiration, varicolectomies, and paracentesis. [Source: Application, p8]

The estimated capital expenditure associated with the project is zero dollars. The capital expenditure for construction of SRSC in 2004 was $3,033,000. [Source: Application Face Sheet]

The ASC is already operational. No new services or construction is required, if this project is approved, Completion of the project would occur immediately. Under this timeline, year 2017 would be the ASC's first full calendar year of operation as a CN approved ASC. [Source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

CRITERIA EVALUATION

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations, the department shall consider:

(i) The consistency of the proposed project with service or facility standards contained in this chapter;

(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2) (b) of this section; and

(ii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

"The department may consider any of the following in its use of criteria for making the required determinations:

(i) Nationally recognized standards from professional organizations;

(ii) Standards developed by professional organizations in Washington State;

(iii) Federal Medicare and Medicaid certification requirements;

(iv) State licensing requirements;
(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."

To obtain Certificate of Need approval, the applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need) including WAC 246-310-270 (ambulatory surgery); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment)[4].

APPLICATION CHRONOLOGY

Action	**Seattle Reproductive Medicine**
Letter of Intent Submitted	March 2, 2015
Application Submitted	September 1, 2015
Department's Pre-Review Activities • Department 1st Screening Letter Sent • SRSC's 1st Screening Responses Received • Department 2nd Screening Letter Sent • SRSC's 2nd Screening Responses Received	 September 22, 2015 November 1, 2015 December 8, 2015 January 22, 2016
Department Begins Review of the Application • public comments accepted throughout review • no public hearing requested or conducted	February 11, 2016
End of Public Comment[5]	March 17, 2016
Rebuttal Due	April 1, 2016
Department's Anticipated Decision Date	May 16, 2016
Department's Extended Anticipated Decision Date	June 15, 2016
Department's Actual Decision Date	June 17, 2016

AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person" as:

"…an interested person who:
(a) Is located or resides in the applicant's health service area;
(b) Testified at a public hearing or submitted written evidence; and
(c) Requested in writing to be informed of the department's decision."

For this project, only two entities Providence Health & Services and Swedish Health Services sought affected person status under WAC 246-310-010(2).

[4] Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (4), (5), (6); and WAC 246-310-240(2) and (3).
[5] No public comment submitted

Providence Health and Services

Providence Health and Services is a non-profit health system that operates 8 hospitals in Washington State. In King County, Providence provides hospice and home health services, as well as assisted living and nursing home services, among others. Providence is affiliated with Swedish Health Services, discussed below.

Swedish Health Services

Swedish Health Services is a non-profit health care provider that operates five hospital campuses – three of which are located in King County. Beginning in 2016, Swedish will be the primary hospital provider for inpatient services for adult Group Health HMO members. Swedish is affiliated with Providence Health and Services.

Both of these entities qualified as interested persons under WAC 246-310-010(34). The second requirement to be recognized as an affected person is to submit written comment or to testify at a public hearing. Since no public hearing was conducted, each requesting entity needed to submit written comments to qualify under WAC 246-310-010(2). Neither of the requesting entities submitted public comment throughout the course of review. As a result, neither of these entities met the criteria to be an "affected person."

SOURCE INFORMATION REVIEWED

- Seattle Reproductive Medicine Certificate of Need Application received on September 1, 2015
- Supplemental information received on November 13, 2015
- Supplemental information received on January 22, 2016
- Utilization survey responses from providers located in the planning area
- Claritas and Office of Financial Management population data for Central King planning area
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Department of Health Integrated Licensing & Regulatory System
- Licensing and compliance history data provided by the Department of Health's Medical Quality Assurance Commission
- SRM website at seattlefertility.com

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Seattle Reproductive Medicine Inc., PS proposing to establish a Certificate of Need approved ambulatory surgery center is consistent with the applicable review criteria, provided Seattle Reproductive Medicine Inc., PS agrees to the following in its entirety.

Project Description:

This project approves the establishment of a three operating room ambulatory surgery center consisting of one general operating room and two procedure rooms. Services to be provided are limited to outpatient reproductive and fertility services and fertility related urology surgical services.

Conditions:

1. Seattle Reproductive Medicine Inc., agrees with the project description stated above. Seattle Reproductive Medicine Inc. further agrees that any change to the project as described in the project description is a new project and requires a new Certificate of Need.

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Approved Costs: The approved estimated capital expenditure for this project is $0.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the 'Conclusion' section of this evaluation, the department determines that the applicant has met the need criteria in WAC 246-310-210 and WAC 246-310-270.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need

WAC 246-310-270(9) – Ambulatory Surgery Numeric Methodology

The Department of Health's Certificate of Need Program uses the numeric methodology outlined in WAC 246-310-270 for determining the numeric need for additional ASCs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient OR's in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 separate secondary health services planning areas. The proposed ASC would be located in the Central King planning area.

The methodology estimates OR need in a planning area using multi-steps as defined in WAC 246-310-270(9). This methodology relies on a variety of assumptions and initially determines existing capacity of dedicated outpatient and mixed-use operating rooms in the planning area, subtracts this capacity from the forecast number of surgeries to be expected in the planning area in the target year, and examines the difference to determine:

a) Whether a surplus or shortage of OR's is predicted to exist in the target year, and

b) If a shortage of OR's is predicted, the shortage of dedicated outpatient and mixed-use rooms are calculated.

c) Data used to make these projections specifically exclude endoscopy rooms and procedures.[6]

Applicant's Methodology

The numeric portion of the methodology requires a calculation of annual capacity of existing outpatient and inpatient ORs. To demonstrate numeric need for a new ASC in the planning area, the applicant provided the following methodology in its application. [Source: November 11, 2015 Supplemental Material p58]

Below is an outline of the applicant's assumptions used in their Methodology.

Table 1
SRM Numeric Methodology

Assumption	Data Used
Planning Area	Central King
Population Estimates and Forecasts	2014 OFM,s Population Forecast is 319,568 Project target year 2019 projected population is 352,164
Use Rate	Dividing 2014 estimated current surgical cases by estimated 2014 population results in the service area use rate of 104.76/1,000 population

[6] WAC 246-310-270(9)(a)(iv).

Assumption	Data Used
Percent of surgery ambulatory vs. inpatient	100.0% ambulatory (outpatient)
Average minutes per case	Outpatient 54.81 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; (per methodology in rule)
Existing providers	OR Capacity: 1 out patient

Using the assumptions outlined above, SRM calculated that there is not a shortage of ASCs in the Central King planning area, however since SRM is the only fertility clinic in the Central King planning area there is need for their existing fertility clinic. They are also projecting to increase their procedures by 4.3% per year.

Within its application, SRM also provided the following rationale for submitting this application. [Source: Application, pp8-17]

- SRM does not plan to expand current surgical services.
- Approval of this project would allow physicians not associated with SRM access to the facility.
- SRM is the only fertility ASC in the Central King planning area offering male urology surgical services.
- Over 36% of SRMs patients come from outside King County.

SRM offered the following information supporting the need for fertility services for the Central King planning area. SRM is the only reproductive endocrinology provider in the Central King planning area. SRM identified the other reproductive endocrinology providers in King County outside of the Central King planning area in Table 2.

Table 2
King County and Greater Seattle Health Services Area: Fertility ASCs

Facility	Operating Rooms
Poma Fertility Center	1
Overlake Reproductive Health	1
Pacific Northwest Fertility	1
Washington Center for Reproductive Medicine	1
Gyft Clinic	1
University Reproductive Care	1
Total	**6**

[Source: Application, p23]

SRM provided data from the Society for Assisted Reproductive Technology (SART) which indicates the following:

- The current utilization of Assisted Reproductive Technology (ART) in the Seattle market lags behind other large, metropolitan areas (4.2% versus 9%)
- The market as a whole continues to grow at 6%, but with large groups of individuals still untreated.

- The total potential market size of King County is estimated at approximately 61,000 women. Therefore the current market share for SRM (assuming only King County) is less than 4 %.
- There are only six other "fertility capable" operating rooms in the King County and Greater Seattle area. According to SART, in 2013 SRSC provided more services than these six facilities combined. SRSC provided 1,881 cycles versus 1,565 cycles for the other six clinics combined. Therefore, even with these other clinics operating ASCs in the King County area, it is unlikely that greater than 10% of the total eligible population is currently being served. [Source: Application, pp22-23]

Department's Methodology

The numeric portion of the methodology requires a calculation of the annual capacity of the existing providers inpatient and outpatient OR's in a planning area. SRM is located in central King County so the department applied the methodology to determine need in the planning area. According to the department's historical records, there are 30 providers including the applicant with OR capacity located in the planning area. The 30 providers are listed in table 3.[7] [Source: CN Historic Files]

Table 3
Central King Planning Area Providers

Hospitals	
Virginia Mason Medical Center	Harborview Medical Center
Group Health Central Hospital[8]	Swedish Medical Center-Cherry Hill
Seattle Cancer Care Alliance	Swedish Medical Center-First Hill
ASCs	
ASC/ Endoscopy Center	Plastic Surgery Associates of Seattle
Ageless	Seattle Surgery Center
Aesthetic Associates, Inc.	Seattle Spine Institute
Eye Associates Northwest Surgery Center	Seattle Skin Cancer Center
Eye Associates NW Nordstrom Ambulatory Surgery Center	**Seattle Reproductive Surgery Center**
Fremont Endoscopy Center	Seattle Plastic Surgery Center
Madison Tower Surgery Center	Seattle Orthopedic Center
North Seattle Surgery Center	Seattle Hand Surgery Group PC
Northwest Eye Surgeons	Seattle Endoscopy Center
Orthopedic International Ambulatory Surgery Center	Polyclinic-Plastic Surgery And Endoscopy Center
Pacific Northwest Center for Facial Plastic Surgery	Polyclinic-Plastic Surgery Center
PacMed Ambulatory Surgical Clinic	Westwood Eye Surgery and Laser Center

As shown above, there are six hospital facilities within the Central King planning area. As defined in WAC 246-310-010, mixed use operating rooms at Virginia Mason Medical Center, Harborview Medical Center, Swedish Medical Center Cherry Hill, Seattle Cancer Care Alliance, and Swedish Medical Center First Hill are included in the capacity calculations of available operating rooms for the

[7] Under WAC 246-310-270(9)(a)(iv), ORs and utilization at endoscopy ASCs are not counted in the numeric methodology.
[8] CN#1559 converted the hospital based ORs to a freestanding CN approved ASC.

planning area. Group Health Central outpatient operating rooms while CN approved are not included in the general ASC capacity calculation because the need for these particular ORs, by statute, is based on the need of Group Health enrollees and their use is limited to Group Health enrollees.

Of the 30 ASCs shown in Table 3, 24, with the exception of the applicant[9], are located within exempt ASCs which are within the clinical practice of either a solo practice or group practice. The use of these ASCs is restricted to members of the clinical practice or employed physicians[10]. For exempt ASCs, the utilization, but not ORs, is included in the numeric methodology for the planning area. To apply the numeric methodology, the department relied on its own survey results and data obtained from the Department of Health's Integrated Licensing & Regulatory System (ILRS) database. The assumptions used by the department to apply the methodology are shown in Table 4.

To determine the correct 2014 population for Central King planning area, the department reviewed Claritas population data. According to Claritas data, year 2014 Central King County population is 298,414 and year 2019 is projected to be 313,179. The department's population projection of 313,179 is used in the methodology attached to this evaluation.

Table 4
Department's Numeric Methodology

Assumption	Data Used
Planning Area	Central King
Population Estimates and Forecasts	Claritas population data for Central King County 298,414. Project target year is 2019 and the projected population is 313,179
Use Rate	Divide 2014 surgical cases by 2014 populations results in the service area use rate of 288.87/1,000 population
Percent of surgery ambulatory vs. inpatient	Based on DOH survey results, 32% ambulatory (outpatient) and 68% inpatient
Average minutes per case	Based on DOH survey results, Outpatient cases = 64.76 minutes; inpatient cases 135.85.41 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,850 inpatient or mixed-use surgery minutes
Existing providers	Based on 2014 listing of Central King planning area providers. 15 dedicated outpatient ORs and 102 mixed use ORs.

The department's application of the numeric methodology based on the assumptions described above indicates a need for 7 inpatient mixed-use ORs in year 2019; and a need for 14.15 dedicated outpatient ORs in year 2019. The department's methodology is Appendix A attached to this evaluation.

In summary, based solely on the numeric methodology contained in WAC 246-310-270, numeric need for outpatient OR capacity in the Central King planning area is demonstrated.

[9] As noted earlier, the applicant's ASC has neither a CN exemption or a CN.
[10] Employed physicians must work at least 75% of their time at the clinical practice and substantially perform the full range of patient care services that the physician routinely furnishes through that practice.

WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two ORs in an ASC. The ASC currently operates with three ORs. One general OR and two procedure rooms. The applicant does not propose any increase the number of ORs. [Source: November 13, 2015 Supplemental Material, p2]. The department concludes this criterion is met.

Based on the source information reviewed the department concludes that **this sub-criterion is met.**

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

SRM is currently providing ambulatory reproductive surgical services to residents of Washington State. To determine whether all residents of the service area would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, SRM provided a copy of its Admission Policy/Guidelines. The admissions policy provided the ASC's admitting procedures. The department also reviewed from the SRM website. Based on this review the department is satisfied patients requiring fertility surgical care that is appropriate to the ASC setting will have access to services. [Source: November 13, 2015 Supplemental Material and Seattle Reproductive Medicine website]

Typically to determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid certification or contracting with Medicaid as the measure to make that determination.

SRM although currently providing surgical services, it is not Medicaid certified. SRM stated the services and procedures performed at the SRM ASC are for infertility and are not medically necessary. SRM also provided a copy of a Kaiser Family Foundation's report released in 2009 on State Medicaid Coverage of Family Planning Services: Summary of State Survey Findings; there are no states that cover infertility treatment. [Source: November 13, 2015 Supplemental Material p12]

Washington Administrative Code 182-531-0150 identifies non-covered physician related and health care professional services. Section (1) states "*…the agency does not cover: ….(c) Care, testing, or treatment of infertility, frigidity, or impotency. This includes procedures for donor ovum, sperm, womb, and reversal of vasectomy or tubal ligation...*" Therefore, the department under these very specific circumstances would not expect the ASC to have a Medicaid contract since the procedures performed at the ASC are limited reproductive and fertility services and fertility related urology surgical services.

Typically, Medicare certification is a measure of an agency's willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. SRM does not provide services to the Medicare eligible populations. The department under these very specific circumstances

would not expect the ASC to be Medicare certified since the procedures performed at the ASC are limited reproductive and fertility services and fertility related urology surgical services.

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, or do not qualify for Medicaid. With the passage of the Affordable Care Act, the amount of charity care is expected to decrease, but not disappear.

Although SRM's services are for infertility and are not considered medically necessary, SRM offers several discount programs to ensure that their care is as accessible as possible within the planning area. Below are the financial programs and discounts currently offered by SRM.

- Financial Aid – each quarter, the physicians can provide $2,500 to patients who need financial support to cover their treatment costs. We have eight partner physicians, which is a total of $80,000 per year allocated for patients who need financial assistance.
- Military Discount
    - 25% off for all veterans and active duty military
    - 50% off for all veterans and/or active duty who are infertile due to injuries received while on active duty and require IVF.
- Discounts on subsequent cycles from 19-30% (oocyte freeze, IVF to donor IVF, DEPR fresh)
- Attain – This is a group of bundled IVF cycle plans, called flex plans that include multiple IVF cycles for a one-time, discounted fee.
- Medication Assistance Programs
    - Compassionate Care Program – This is a patient assistance program that offers a onetime supply of medications at no cost or a discounted rate to those who are eligible for the program. Eligibility is based off being uninsured or underinsured and meet an undisclosed income guideline.
    - Compassionate Corps Program – provides free fertility medication to those who are eligible. To be eligible for the Compassionate Corps Program, you must be a veteran or active duty military member who is infertile due to a service-related injury. [Source: Supplemental Material, pp12-13]

SRM demonstrated its intent to provide charity care to patients receiving treatment at the facility by submitting its charity care/discount policy that outlines the process one would use to access this service. Within the application, SRM also identified the dollar amounts of charity care that can be requested by its physicians and approved by management. [Source: January 22. 2016 Supplemental Material pp 1-6]

WAC 246-310-270(7) requires that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems (HPDS), divides Washington State into five regions: King County, Puget Sound, Southwest, Central, and Eastern. SRM's ASC is located in King County, within the King County Region. Currently, there are 22 hospitals operating, or approved to operate, in the region. There are three hospitals in the Central King planning are that could be affected by this project. The hospitals are Virginia Mason Medical Center, Swedish Cherry Hill and Swedish First Hill.

For this project, the department reviewed the most recent three years of charity care data for the 19 existing hospitals currently operating within the King County Region and focused on the hospitals located in the Central King planning area. The three years reviewed are 2012, 2013, and 2014.[11] Table 5 is a comparison of the average charity care for the King County [Source: 2012-2014 HPDS charity care summaries]

Table 5
Charity Care Percentage Comparisons

	% of Total Revenue	% of Adjusted Revenue
King County Region [12]	1.83	3.48
Average for Central King Planning Area Hospitals	1.64	3.29
SRM Projected	3.20	3.20[13]

As shown in table 5, the King County regional average is slightly higher than the average provided by the hospitals in the Central King planning area. SRM's projected charity care as a percentage of total revenue is more than 2.5 times of both the King County regional average and the Central King average. For this particular application review, the department is focusing its charity care evaluation on the percent of charity care of total revenue. Since SRM does not receive Medicare or Medicaid revenue including an adjusted revenue comparison would not be reasonable.

For Certificate of Need purposes, SRM is a new health care facility. To ensure that appropriate charity care percentages would be provided by SRM, if this project is approved, the department would attach a condition requiring SRM to use reasonable efforts to provide charity care at least at the King County central regional average, which is 1.64 percent of total revenues.

With the condition identified above, the department concludes **this sub-criterion is met**.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed the department determines that the applicant met the financial feasibility criteria in WAC 246-310-220.

(1) *The immediate and long-range capital and operating costs of the project can be met.*

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

[11] As of the writing of this evaluation, year 2015 charity care data is not available.
[12] Excludes Harborview
[13] SRM's charity care as a percentage of total revenue and adjusted revenue are the same. To calculated adjusted revenue, Medicaid and Medicare revenues are subtracted from total revenue. Since SRM does not have Medicaid or Medicare revenues adjusted revenue is the same as total revenue for charity care purposes.

To determine if the facility would meet its immediate and long range operating costs, the department reviewed the assumptions used as a basis for its financial projections. Additionally, the department reviewed SRM's financial statements for its first three full years of operation. Summarized below are the assumptions used by SRM as the basis for projecting utilization and the number of procedures it expects. [Source: January 22, 2016 Supplemental Material, p7]

- SRM identified 20 procedures that are currently performed at the ASC.
- SRM concluded that the mix of procedures projected to be performed at the ASC will remain the same for their 3 year projections.
- SRM calculated a growth rate for total procedures using the growth in procedures between calendar year 2011 and 2014.
- A growth rate of 4.3% was calculated by SRM.
- The growth rate of 4.3% was applied to the known number of procedures for calendar year 2014 (2874) and projected forward for 2015 through 2019.

Table 6 is a summary of the projected number of surgeries based on the assumptions above. [Source: November 13, 2015 Supplemental Material, p6]

Table 6
SRM's ASC Utilization Projections Year 2017- 2019

Surgical Procedure Description	**2017**	**2018**	**2019**
Abdominal Paracentesis	8	8	9
Abdominal Paracentesis w imaging guidance	6	6	6
Drainage of Peritoneum	2	2	2
Biopsy of Testis, Needle	34	36	37
Biopsy of Testis, Incisional	35	37	38
Vasovasotomy	66	69	72
Excision of Varicocele	27	28	30
Unlisted Procedure Male Genital System	9	9	10
Partial Hymenectomy	2	2	2
Endometrial Bx w/o Dilation w/wo Dilation & Curettage	56	58	60
Non Obstetric Dilation & Curettage	5	5	5
Hysteroscopy, Diagnostic	926	966	1,007
Hysteroscopy w/Bx/Polypectomy w/wo Dilation & Curettage	286	298	311
Hysteroscopy w/Lysis of Adhesions	56	58	60
Hysteroscopy w/ Resection of Septum	54	57	59
Hysteroscopy w/ Removal of Leiomyomata	49	51	53
Follicular Puncture (Sonographic Egg Retrieval)	1,387	1,446	1,508
Incomplete Abortion Dilation and Curettage	18	19	20
Missed Abortion Dilation and Curettage	234	244	254
Uterine Evacuation for Hydatiform Mole	2	2	2
Total	**3,261**	**3,401**	**3,547**

Summarized below are the financial assumptions used by SRM to prepare the pro forma financial projections.

- Revenue and expenses were projected to increase by 3%
- SRM's current depreciation schedule was used to calculate depreciation for each asset category.
- A one percent capital budget was assumed for addition non facility improvement assets.
- No additional capital projects were budgeted for facility assets.

Using the projections in Table 6 and the financial assumptions above; SRM projected its revenues and expenses for 2017 through 2019. Table 7 is a summary of that information. [Source: November 13, 2015 Supplemental Material p13 & Exhibit 6]

Table 7
Seattle Reproductive Medicine
Projected Revenue and Expenses Summary

	Year 2017	Year 2018	Year 2019
Net Revenue	$27,456,926	$28,305,102	$29,179,923
Total Expenses	$21,621,755	$22,127,963	$22,755,802
Net Profit or (Loss)	**$5,835,171**	**$6,177,138**	**$6,424,120**

The 'net revenue' line item in Table 7 is the result of gross revenue minus any deductions. The 'total expenses' line item includes staff salaries/wages and other expenses to include bad debt. As shown in Table 7, SRM is expected to operate at a profit for all years shown.

SRM has been operating from its current location since year 2004. SRSC provided a copy of the original lease and all amendments including the current lease (5th Amendment. The current lease (5th Amendment dated November 27, 2013 for a term of 120 months expires on February 25, 2025. The lease includes both the physician clinic as well as the surgery center. [Application: Exhibit 6]

In addition to the projected Profit and Loss Statements, SRM provided the projected balance Sheet for the year 2019. Table 8 shows a summary of the balance sheet. [Source: November 15, 2015 Supplemental Material, pp 61 & 62]

Table 8
Seattle Reproductive Medicine forecasted Balance Sheet-Year 2019

Assets		Liabilities	
Total Current Assets	$2,361,691	Total Current Liabilities	$221,166
Fixed Assets less Depreciation `	$912,826	Accrued Liabilities	$1,165,318
Other Assets	$524,232	Other Liabilities	$1,756,733
Intercompany	$200,578	Equity	$856,109
Total Assets	**$3,999,326**	**Total Liabilities & Equity**	**3,999,326**

The financial data submitted by SRM shows that it has been profitable and is projected to continue to be profitable.

Based on the source information reviewed the department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

(2) *The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.*

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

The applicant has documented that all financing costs from the original project in 2004 have been amortized and there is no capital expenditure for this current project.

To further demonstrate compliance with this sub-criterion, SRM provided its existing percentage of revenue by source shown in Table 9. [Source: Application, p31]

Table 9
SRM Existing Revenue Sources

Source of Revenue	Current
Self-Pay	42.4%
Premara Blue Cross	20.8%
Attain	8.2%
Regence Blue Shield	7.7%
Aetna	5.1%
Other Government	0.8%
Other Commercial	11.9%
Donor Account	3.1%
Total	100.00%

As shown in Table 9, most of the SRM's revenue sources are private pay and commercial insurance, which is expected based on the types of surgeries currently offered at the ASC. The applicant does not expect the sources to change if this project is approved.

Based on the above information, the department concludes that costs associated with this project will not have unreasonable impact on the costs and charges for healthcare services within the service area. **This sub-criterion is met**.

(3) *The project can be appropriately financed.*

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

The applicant has documented that all financing costs from the original project in 2004 have been amortized. There is no capital expenditure for this current project.

Based on the source information reviewed, the department concludes that no capital expenditure is required for this project. **This sub-criterion is met**.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed the department determines that the applicant has met the structure and process of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b)) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size.

SRM's ASC is currently providing fertility services to patients. As an operational ASC, the applicant has 116.08 FTE staff currently working in the facility. The applicant does not expect to increase the staffing since existing staff will be able to handle the proposed growth and no new services will be added. Table 10 shows the applicant's current and projected staff. [Source: Application, p 32]

Table 10
SRSC Current Staffing (FTEs)

FTEs	2015
Nursing	23.93
Endocrine	2.20
Ultrasound/Sonography	2.80
Call Center	6.00
Administration	6.60
Medical Assistant	14.40
Andrology	5.00
Patient Services	23.80
Donor Egg	7.60
Surgery	5.80
Embryology	13.00
Marketing	3.45
IT	1.50
Total	**116.08**

Given that the ASC is currently operational with low employee turnover and no new services are proposed to be provided, the department concludes that the ASC will be adequately staffed. The department concludes this **sub-criterion is met**.

(2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-

200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

SRM's ASC has been operating since year 2004, and has already established ancillary and support agreements with healthcare providers in the Central King planning area. SRM provided a copy of the existing transfer agreement between itself and Northwest Hospital that was established in 2004. The agreement identifies the roles and responsibilities of both entities. There is no indication that the current relationships would be negatively affected if this project was approved.

The department concludes **this sub-criterion is met**.

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant**.**

The ASC has been operating at its current location since September 2004. SRM also operates an exempt ASC in the Spokane Valley[14]. The Department of Health's Investigations and Inspections Office (IIO), which surveys ASCs within Washington State, has completed a compliance survey in 2012 for SRM's Seattle ASC. The survey revealed no substantial non-compliance issues for the ASC. [Source: IIO compliance data]

The Department of Health's Medical Quality Assurance Commission credentials medical staff in Washington State and is used to review the compliance history for all medical staff, which includes the six physician owners listed on page one of this evaluation. Additionally, one of the physician owners—Nancy Klein, MD—acts as the current medical director. These services are provided as part of the employment responsibilities, rather than under a medical director contract. A compliance history review of all the medical staff associated with the SRSC reveals no recorded sanctions for all. [Source: Compliance history provided by Medical Quality Assurance Commission]

After reviewing the compliance history of SRM's ASC and the compliance history of medical staff associated with the ASC, the department concludes that if approved, there is reasonable assurance that SRSC would operate in conformance with applicable state and federal licensing and certification requirements. **This sub-criterion is met.**

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2) (a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types

[14] DOR13-35 issued May 14, 2013. The date of first licensure for this ASC was May 5, 2014.

of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

SRM's ASC has operated 2004. Ancillary and support services and agreements are not expected to change if this project is approved. Additionally, the department considers the results of the numeric methodology and review criteria outlined in WAC 246-310-210. Application of the numeric methodology shows a need for additional OR capacity in the Central King planning area. Within the application, SRM demonstrated it met the standards to receive approval.

The department concludes **this sub-criterion is met**.

(5) *There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.*
This sub-criterion is evaluated in sub-section (3) above, and based on that evaluation; the department concludes **this sub-criterion is met**.

D. Cost Containment (WAC 246-310-240)
Based on the source information reviewed the department concludes the applicant has met the cost containment criteria in WAC 246-310-240.

(1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*
To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230 and WAC 246-310-270. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met the applicable criteria, the department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tie-breaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

For this project, SRM has met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Before submitting this application, SRM considered and rejected only the option of status quo or do nothing. The ASC is not currently utilized at full capacity, but in order to allow physicians not associated with the group practice access to the ASC a Certificate of Need is required. To best utilize the ASC and to ensure that the ASC continues to remain in operation in the future, this application was submitted.

The current ASC has been operating without a CN exemption or an approved CN since its inception. In May of 2013, the department determined SRM's ASC did not qualify for an exemption from Certificate of Need review. [Source: DOR 13-35] Therefore, if SRM wanted its ASC to continue in operation, the only option it had was to submit a Certificate of Need application. SRM is the only provider of fertility services in the Central King planning area and is the largest provider of these services in King County. SRSC is the only provider of fertility related urology surgery for men in King County. Based on this information, the department concludes this project is the best available alternative for the residents of Central King County. **This sub-criterion is met**.

Appendix A

Washington State Department of Health

ATTACHMENT A
ASC Need Methodology
Central King

CN APP NO.16-10.

Service Area Population: 2019 313,179 Claritas
Surgerie 309.3 96,868

a.i. 94,250 minutes/year/mixed-use OR

a.ii. 68,850 minutes/year/dedicated outpatient OR

a.iii. 15 dedicated outpatient OR's x 68,850 minutes = 1,032,750 minutes dedicated OR capacity 15,947 Outpatient surgeries

a.iv. 102 mixed-use OR's x 94,250 minutes = 9,613,500 minutes mixed-use OR capacity 70,766 Mixed-use surgeries

b.i. projected inpatient surgeries = 65,880 = 8,949,674 minutes inpatient surgeries
projected outpatient surgeries = 30,988 = 2,006,808 minutes outpatient surgeries

b.ii. Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's

30,988	-	15,947	=	15,041 outpatient surgeries

b.iii. average time of inpatient surgeries = 135.85 minutes
average time of outpatient surgeries = 64.76 minutes

b.iv. inpatient surgeries*average time = 8,949,674 minutes
remaining outpatient surgeries(b.ii.)*ave time = 974,058 minutes
9,923,732 minutes

c.i. if b.iv. < a.iv. , divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's
Not Applicable - Go to c.11. and ignore any value here.

9,613,500				
- 9,923,732				
-310,232	/	94,250	=	**-3.29**

c.ii. if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94,250 to determine shortage of inpatient OR's
USE THESE VALUES

8,949,674				
- 9,613,500				
(663,826)	/	94,250	=	**-7.04**

divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's

974,058	/	68,850	=	**14.15**

ATTACHMENT A
ASC Need Methodology
Central King

Facility	No. Special Procedure Rooms	No. Dedicated Inpatient ORs	No. Dedicated Outpatient ORs	No. Mixed Use ORs	Inpatient min/case	2014 Inpatient Cases in Mixed Use ORs	2014 Inpatient Mins. In Mixed Use ORs	Outpatient Min/Case	2014 Outpatient Cases	2014 Outpatient Mins.	Comments
Virginia Mazon Medical Center				24	97	17,788	1,733,731				
Harborview Medical Center				24	**179**	16,500	2,951,934				
Swedish Medical Center Cherry Hill				16	205	5,219	1,071,054				
Swedish Medical Center First Hill				38	119	23,275	2,772,161				
Seattle Cancer Care Alliance			**5**					**39**	**5,769**	**226,190**	
Group Health Cooperative ASC					HMO ORs not counted			77	5,822	449,566	
ASC Endoscopy Center					Endoscopy ORs and Minutes not counted						
Ageless	0	0	1		0	0	0	9	231	2,048	Data obtained from 2014 survey
Aesthetic Associates Inc.	0	0	1		0	0	0	94	283	26,558	Data obtained from 2014 survey
Eye Associates Northwest Surgery Center	0	0	2		0	0	0	50	2,061	103,050	ILRS 2014 data # cases x 50
Eye Associates Northwest Surgery Center	0	0	1		0	0	0	50	850	42,500	ILRS 2014 data # cases x 50
Fremont Endoscopy Center	0	0	endoscopy		Endoscopy ORs and Minutes not counted						
Madison Tower Surgery Center								144	482	69,623	
North Seattle Surgery Center			1					50	830	41,500	
Northwest Eye Surgeons			4					131	2,591	339,420	
Orthopedic International Ambulatory Surgery Center			2					134	86	11,508	
Pacific Northwest Center for Facial Plastic Surgery			1					151	322	48,680	
PacMed Ambulatory Surgical Clinic			1					219	83	18,180	
Plastic Surgery Associates of Seattle			1					164	170	27,937	
Seattle Surgery Center			7								
Seattle Spine Institute			1					50	28	1,400	
Seattle Skin Cancer Center			**1**					**50**	**932**	**46,600**	
Seattle Reproductive Surgery Center			1					26	1,694	43,855	
Seattle Plastic Surgery Center			1					135	200	27,000	
Seattle Orthopedic Center			**2**					**66**	**2,060**	**135,585**	
Seattle Hand Surgery Group PC			**1**					**45**	**1,840**	**83,000**	
Seattle Endoscopy Center			**2**					**61**	**186**	**11,290**	
Polyclinic Plastic Surgery and Endoscopy Center			**Endoscopy**								
Polyclinic Plastic Surgery Center			**4**					**55**	**1,253**	**69,062**	
Westwood Eye Surgery and Laser Center			1					50	1,758	87,900	
Totals	**0**	**0**	**41**	**102**	**600**	**62,782**	**8,528,880**	**1,850**	**29,531**	**1,912,452**	
					Ave min/case		**135.85**	Ave min/case		**64.76**	

Bolded ASCs have CoNs. ORs counted in supply **15**

Outpatient minutes calculated at default 50 minutes/case for those ASCs or hospitals not responding to survery.
Inpatient minutes calculated at default 100 minutes/case for those Hospitals not reporting minuters
ILRS: Integrated Licensing & Regulatory System
Population data source: Claritas

Total Surgeries Survery Year: 2014	92,313
Area population Survey Year: 2014	298,454
Use Rate Survey Year: 2014	309.304
Planning Area projected population for third year of operation: 2019	313,179
% Outpatient of total surgeries	31.99%
% Inpatient of total surgeries	68.01%