

**RECONSIDERATION EVALUATION OF THE CERTIFICATE OF NEED APPLICATION
SUBMITTED ON BEHALF OF THE DOCTORS CLINIC PROPOSING TO ESTABLISH AN
AMBULATORY SURGERY CENTER IN KITSAP COUNTY**

PROJECT DESCRIPTION

On January 2, 1992, The Doctors Clinic was established as a professional corporation licensed in the state of Washington. On January 28, 2005, The Doctors Clinic obtained a Determination of Non-Reviewability related to the establishment of an exempt ambulatory surgery center (ASC) to be located at 2200 Northwest Myhre Road in the city of Silverdale, within Kitsap County. The exempt ASC would have three operating rooms and at least one procedure room. The ownership of The Doctors Clinic was comprised of 14 physicians, and each would have surgical privileges at the exempt ASC. As an exempt ASC, physician access is limited to those physicians that are part of The Doctors Clinic corporation or employed by the corporation.¹ Services to be provided include ENT, general GI, orthopedic; and gynecology procedures. Department files indicate that The Doctors Clinic received its Medicare certification and became operational in May 2005. [source: January 28, 2005, Determination of Non-Reviewability; October 24, 2005, supplemental documents; DOH, ILRS database]

On July 12, 2007, The Doctors Clinic (TDC) submitted its Certificate of Need application to establish an ASC in Silverdale. Within the application, TDC acknowledged that it had been operational since May 2005 as an exempt ASC, and the impetus for submission of the application is to allow physicians, not part of the TDC corporation, access to the ASC. [source: Application cover sheet and p4] Between the date the exempt ASC became operational—May 2005—and submission of the application—July 2007—an additional 41 physicians have joined the corporation. Each physician has equal ownership in the TDC corporation and surgical privileges at the exempt ASC. [source: September 14, 2007, supplemental information, p5] With the additional physicians, services at the exempt ASC have expanded to include ENT, gynecology, general surgery, dental, podiatry, pain management, plastics, urology, ophthalmology, GI, and vascular. [source: Application, p5]

For this project, TDC does not propose to change the location of the ASC at 2200 Northwest Myhre Road in the city of Silverdale, the current number of ORs (3), or the number of procedure rooms (4). Given that the facility became operational in year 2005, there are no additional capital costs beyond those already expended for the establishment of the exempt facility in May 2005. [source: Application pp4, 6, 7]

If this project is approved, TDC anticipates commencement and completion of the project within six months of approval. Under this timeline, the ASC would become operational in mid year 2008, and year 2009 would be the facility's first full calendar year of operation; year 2011 would be the third full year of operation. [source: September 14, 2007, supplemental information p10]

¹ Additional limitations are required in order to maintain exempt ASC status; however, those limitations are not relevant to this evaluation.

BACKGROUND INFORMATION ON THE PROJECT

On March 28, 2008, the Program denied TDC's application primarily based on its failure to meet the criteria related to need. On April 25, 2008, TDC submitted its "Request for Reconsideration" related to the department's denial, which included information related to the criteria denied. Within its reconsideration request, TDC also requested the Program "stay" the reconsideration process until completion of the remand review of the Certificate of Need decision related to the Surgery Center of Silverdale adjudicative appeal [Docket #07-01-C-2004CN]. The Program agreed with TDC's request without an acknowledgement that the issues in the two projects (TDC and Surgery Center of Silverdale) were the same.

On August 12, 2008, the Surgery Center of Silverdale adjudicative appeal was dismissed without the Program's completion of the remand evaluation. On September 9, 2008, the Program granted TDC's reconsideration request. A reconsideration hearing was conducted on October 10, 2008. This document is the evaluation of the reconsideration information.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the 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).

APPLICATION CHRONOLOGY

A chronological summary of the initial review and this reconsideration review is summarized below.

Initial Review

January 18, 2007	Letter of Intent Submitted
July 12, 2007	Application Submitted
July 13, 2007, through December 2, 2007	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses• 2nd screening activities and responses
December 3, 2007	Department Begins Review of Application
January 28, 2008	Public Hearing Conducted/End of Public Comment
February 12, 2008	Rebuttal Documents Received at Department
March 28, 2008	Department's Anticipated Decision Date
March 28, 2008	Department's Actual Decision Date

Reconsideration Review

April 25 2008	Applicant Submits Request for Reconsideration and Stay of Request Until Completion of Appeal of Related Project
April 28, 2008	Department Grants Applicant's Request for Stay of Reconsideration
September 11, 2008	Department Grants Reconsideration
October 11, 2008	Reconsideration Public Hearing Conducted in Bremerton
December 12, 2008	Department's Anticipated Reconsideration Decision Date
December 12, 2008	Department's Actual Reconsideration Decision Date

CRITERIA EVALUATION

The review for a reconsideration project is limited to only those criteria that were denied in the initial evaluation. To obtain approval for this project, The Doctors Clinic must demonstrate compliance with the relevant criteria found in WAC 246-310-210 (need), WAC 246-310-270 (ambulatory surgery); WAC 246-310-230 (structure and process of care); and WAC 246-310-240 (cost containment).²

AFFECTED PERSONS

Throughout the initial review of this project, two CN approved ASCs located in Kitsap County sought and received affected person status under WAC 246-310-010.

- 1) Olympic Ambulatory Surgery Center located at 2613 Wheaton Way in Bremerton owned by Surgical Care Affiliates of Birmingham (Alabama).
- 2) Surgery Center of Silverdale located at 9800 Levin Road, #102 in Silverdale co-owned by Harrison Medical Center in Bremerton and individual local physicians.

On August 15, 2008, Surgical Care Affiliates of Birmingham closed Olympic Ambulatory Surgery Center thereby relinquishing its affected person status for this project.³

While Surgery Center of Silverdale continues to be operational, it did not participate in the reconsideration review of TDC, and thereby, also relinquished its affected person status for this project.⁴

As a result, for this reconsideration project, there were no entities that sought and received affected or interested person status as defined in WAC 246-310-010.

SOURCE INFORMATION REVIEWED

Initial Review

- The Doctors Clinic Certificate of Need Application received July 12, 2007
- The Doctors Clinic supplemental information dated September 14, 2007, and November 21, 2007
- Public comment received throughout the review of the application
- Public hearing documents received at the January 28, 2008, public hearing
- The Doctors Clinic rebuttal comments received February 12, 2008
- Olympic Ambulatory Surgery Center's rebuttal comments received February 12, 2008
- Kitsap County ASC and/or operating room utilization survey responses

² Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this reconsideration review: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-240(2).

³ Surgical Care Affiliates of Birmingham also closed a second ASC in Spokane County.

⁴ In order to maintain its affected person status under this reconsideration process, Surgery Center of Silverdale must 1) be located or reside in the applicant's health service area; 2) provide written or oral comments at the reconsideration hearing; and 3) provide a written request to receive a copy of the reconsideration evaluation. Surgery Center of Silverdale did not provide written or oral comments at the reconsideration hearing or submit a request to receive a copy of the reconsideration evaluation.

SOURCE INFORMATION REVIEWED (continued)

- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2004, 2003, and 2006 summaries)
- Population data obtained from the Office Financial Management based on year 2000 census published November 2007
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Certificate of Need Historical files

Reconsideration Review

- The Doctors Clinic Reconsideration Request received April 25, 2008
- The Doctors Clinic Supplemental Reconsideration Request received August 7, 2008
- Harrison Medical Center's document received at the October 10, 2008, public hearing

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of The Doctors Clinic proposing to establish an ambulatory surgery center in Silverdale, within Kitsap County is consistent with applicable criteria of the Certificate of Need Program, provided The Doctors Clinic agrees to the following term and condition.

Term

Before commencement of the project, The Doctors Clinic must provide to the department for review and approval a copy of the revised Admissions Policy. The revised policy must include language ensuring all patients, including low-income, racial and ethnic minorities, handicapped and other underserved groups would have access to surgical services.

If The Doctors Clinic agrees to the term outlined above, a Certificate of Need would be issued with the condition below.

Condition

The Doctors Clinic will provide charity care in compliance with the charity care policies provided in this Certificate of Need application, or any subsequent policies reviewed and approved by the Department of Health. The Doctors Clinic will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Puget Sound Region. Currently, this amount is 1.90% of gross revenues and 4.07% of adjusted revenue. The Doctors Clinic will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.

There is no capital expenditure associated with the establishment of The Doctors Clinic Ambulatory Surgery Center.

RECONSIDERATION EVALUATION

A. Need (WAC 246-310-210;) and Ambulatory Surgery Standards and Methodology (WAC 246-310-270)

Based on the source information reviewed, the department determines that The Doctors Clinic application has met the applicable need criteria in WAC 246-310-210 and the ambulatory surgery standards and methodology in 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.

The Program uses the numeric methodology found in WAC 246-310-270 for determining the need for additional ASCs in Washington State. The numeric methodology provides a basis of comparison of existing 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 Doctors Clinic ASC would be located in the Kitsap County 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.

Initial Evaluation Summary

In the initial application, TDC failed to provide a meaningful need calculation as required by WAC 246-310-270(9). Rather, TDC relied on the department's findings from a prior CN project in the planning area using 2004 utilization and OR capacity. The department used 2006 data and applied the step-by-step methodology outlined in WAC 246-310-270(9), and calculated a surplus of 1.48 mixed-use operating rooms (ORs) for the Kitsap planning area in year 2011. As a result, the TDC project failed to meet the applicable criteria under WAC 246-310-210 and WAC 246-310-270. [source: Initial Evaluation, p7 and Appendix A]

Reconsideration Evaluation

In the initial evaluation, the Program counted 10 dedicated outpatient and 10 mixed use operating rooms as OR capacity for the planning area. On August 15, 2008—approximately 5 months after the Program released its initial evaluation of this project—Surgical Care Affiliates of Birmingham closed Olympic Ambulatory Surgery Center in Bremerton. Closure of Olympic Ambulatory Surgery Center and its 4 ORs reduces the dedicated outpatient capacity in the Kitsap planning area from 10 to 6. Below is a re-calculation of the numeric methodology using the existing capacity of ORs in the planning area.

Department's Reconsideration Methodology

Given that the ASC would be located in Kitsap County, the Program will apply the methodology to that health service planning area. There are seven providers in the Kitsap County planning area, including the applicant. The seven providers are listed below. [source: CN historical files-FSL database]

Kitsap Planning Area Providers	
1 Hospital / City	7 ASCs / City
Harrison Medical Center / Bremerton & Silverdale campuses	Digestive Disease & Endoscopy Center, PLLC / Bremerton North Kitsap ASC/Poulsbo Olympic Plastic Surgery Suite / Bremerton Pacific Cataract & Laser Institute / Silverdale Surgery Center of Silverdale/Silverdale The Doctors Clinic / Silverdale (applicant)

As shown above, the seven facilities include one hospital and six ASCs. Harrison Medical Center is the only hospital operating in the planning area. All appropriate OR capacity will be used in the numeric methodology calculations under WAC 246-310-270.

Of the six ASCs shown above, four—including the applicant, TDC—are located within a solo or group practice (considered an exempt ASC) and therefore, the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. Therefore, these four facilities do not meet the ASC definition found in WAC 246-310-010 and the ORs are not included in the capacity calculations of available ORs for the Kitsap planning area.

The two remaining ASCs—North Kitsap ASC in Poulsbo and Surgery Center of Silverdale in Silverdale—are ASCs as defined in WAC 246-310-010 and the OR capacity of the two ASCs will be included in the capacity calculations of available ORs for the Kitsap planning area.⁵

To assist in its application of the numeric methodology for this project during the initial review, on December 11, 2007, the Program requested utilization information from each of the facilities identified above. For the initial evaluation, responses were received from all except Harrison Medical Center and Olympic Plastic Surgery Suite. For Harrison Medical Center's utilization, the Program used quarterly data reported by the hospital to the Department of Health's Office of Hospital and Patient Data Systems. Data for Olympic Plastic Surgery Suite was not available.

For this reconsideration evaluation, Harrison Medical Center provided utilization data for years 2004, 2005, and 2006 at the October 10, 2008, reconsideration public hearing. The Program was able to include Harrison Medical Center's utilization and capacity data in the reconsideration methodology. The Program also relied on the following assumptions to apply its reconsideration methodology.

⁵ North Kitsap ASC was issued CN #1124 on June 29, 1995; and Surgery Center of Silverdale was issued CN #1334 on July 14, 2006.

Assumption	Data Used
Planning Area	Kitsap County
Population Estimates and Forecasts	Office of Financial Management's Kitsap County-medium series, published November 2007. Target year 2011
Use Rate	Divide estimated current surgical cases by estimated 2006 populations results in the service area use rate of 97.12 per 1,000 population
Percent of surgery ambulatory vs. inpatient	Based on DOH survey results, 75.9% ambulatory setting; 24.1% inpatient setting
Average minutes per case	Based on DOH survey results, Outpatient cases = 46.87 minutes; inpatient cases 101.74 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes
Existing providers	Based on 2008 listing of Kitsap County providers

The Program's application of the numeric methodology using available survey responses and existing OR capacity indicates a need for 6.67 outpatient ORs for the Kitsap planning area in year 2011. The Program's reconsideration methodology is Appendix A attached to this evaluation.

In the initial review of this project, the Program obtained comments related to any impact the TDC project would have on the existing providers. All five ASC providers that responded indicated either "no impact" or "minimal impact" on their existing ASCs if the TDC project is approved.⁶ In the initial and reconsideration reviews of this project, Harrison Medical Center remained stated it would remain neutral by not supporting or opposing the project.

In conclusion, in this reconsideration numeric need for additional OR capacity in the Kitsap planning area is demonstrated. TDC submitted an application proposing to meet a portion of the demonstrated need with its 3 ORs. None of the existing providers indicate approval of the TDC project would result in a negative impact to their ASC. 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.

To determine whether all residents of the service area would continue to have access to an applicant's services, the department requires 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 determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the

⁶ In the initial review, OASC was the only provider that stated approval of the TDC project would result in a significant impact on its ASC. Given that OASC is now closed, approval of TDC would no longer impact OASC.

measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

Initial Evaluation Summary

In its March 28, 2008, initial evaluation, the department concluded that TDC would provide services to the low income and elderly patients based on its current and continued contractual relationships with Centers for Medicare and Medicaid Services (CMS). [source: Initial evaluation, p8]

Based on TDC's charity care policy and pro forma financial statements, the department concluded that TDC would provide charity care services to residents of the service area. Additionally, the evaluation also recommended a condition attached to any approval of this project to ensure that TDC's percentage of charity care would be at least equal to the average percentages provided in the Kitsap planning area. [source: Initial evaluation, p9]

The department concluded that TDC failed this sub-criterion because the admission policy submitted by TDC did not include language to demonstrate that patients are admitted to the ASC without regard to age, race, color, religion, sex, national origin, handicap, or sexual preference and would be treated with respect and dignity. [source: Initial evaluation, p8]

Reconsideration Evaluation

For this reconsideration review, TDC did not submit any additional documentation related to this sub-criterion. TDC will continue to maintain its contractual relationship with CMS regarding Medicare and Medicaid services.

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 (less King County), Southwest, Central, and Eastern. TDC's ASC would be located in Kitsap County within the Puget Sound region. For charity care reporting purposes, the affected hospital includes Harrison Medical Center located in Bremerton within Kitsap County. For this project, the department reviewed charity care data for Harrison Medical Center and the 18 existing hospitals currently operating within the Puget Sound Region.

According to 2004-2006⁷ charity care data obtained from HPDS, the three-year average for the Puget Sound Region is 1.90% for gross revenue and 4.07% for adjusted revenue. The three-year charity care data reported by Harrison Medical Center is 1.55% of gross revenue and 3.86% of adjusted revenue. [source: HPDS 2004-2006 charity care summaries]

⁷ Year 2007 charity care data is not available as of the writing of this evaluation.

TDC's pro formas indicate that the ASC will provide charity care at approximately 1.20% of gross revenue, and 2.00% of adjusted revenue. [source: November 21, 2007, supplemental information, p5] These averages are below the average charity care provided in the Puget Sound Region and Harrison Medical Center for its gross and adjusted revenues. Given that the amount of charity care proposed to be provided at TDC is below to the three-year historical gross and adjusted revenue averages for the region and the local hospital, the department concludes that a condition related to the percentage of charity care to be provided at the ASC would be necessary for this reconsideration approval.

TDC did not provide a revised admission policy. If this project is approved under reconsideration, the department would require TDC to provide a revised admission policy that includes language to ensure that patients are admitted to the ASC without regard to age, race, color, religion, sex, national origin, handicap, or sexual preference and will be treated with respect and dignity.

Provided that TDC agrees to the charity care condition and submits a revised admission policy as required on page 4 of this evaluation, this sub-criterion is met.

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

Based on the source information reviewed, the department determines that The Doctors Clinic application meets the structure and process (quality) 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.
- (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.
- (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.
- (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.
- (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.

Initial Evaluation Summary

In its March 28, 2008, initial evaluation, the department concluded that TDC's project met four of the five sub-criteria outlined above. [source: Initial evaluation, pp12-14] The sub-criterion not met—(4) above—related to the project's failure to meet the need criteria.

Reconsideration Evaluation

Based on information provided during the reconsideration review, the department concludes that TDC's application meets all applicable need criteria. As a result, the department's conclusion under (4) above would be met, along with the other four sub-criteria.

C. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that The Doctors Clinic application meets the cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

Initial Evaluation Summary

In the initial evaluation, the department concluded that TDC's project failed this sub-criterion. The rationale for this denial was based on the department's conclusion that the project failed to meet the need and financial feasibility criteria. The department's conclusion under this sub-criterion stated:

"The department concludes that the best available alternative for this project is TDC's continuous operation as an exempt ASC in the planning area. Based on the discussion above, the department concludes that this project is not the best alternative for the community, and this sub-criterion is not met."

[source: Initial evaluation, p15]

Reconsideration Evaluation

Documentation provided during this reconsideration review indicates that TDC's project meets the criteria of need and financial feasibility. Based on this reconsideration review, the department concludes the establishment of another ASC in Kitsap County is the best available option for the community. This sub-criterion is met.