

October 22, 2012

CERTIFIED MAIL # 7011 1570 0002 7809 5377

Heidi Aylsworth, Vice President Performance Improvement and Strategic Development Swedish Health Services 747 Broadway Seattle, Washington 98122

Re: CN12-32

Dear Ms. Aylsworth:

We have completed review of the Certificate of Need application submitted by Swedish Health Services proposing to amend Certificate of Need (CN) #1330R to change the approved site. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has denied the project because CN #1330R expired on October 1, 2012. As a result, Certificate of Need #1330R could not be amended.

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

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Appeal Option 2:

You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Other Than By Mail
Adjudicative Clerk Office
111 Israel Road SE
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,

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

Enclosure

cc: Department of Health, Investigations and Inspections Office

EVALUATION DATED OCTOBER 22, 2012, OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY SWEDISH HEALTH SERVICES PROPOSING TO AMEND CERTIFICATE OF NEED #1330R BECAUSE OF A CHANGE IN THE APPROVED SITE

APPLICANT DESCRIPTION

Swedish Health Services (SHS) is a not-for-profit corporation and a 501(c)(3) exempt organization with 100% ownership of Swedish Medical Center. Swedish Medical Center is also a Washington private, not-for-profit corporation and a 501(c)(3) exempt organization. Swedish Medical Center provides Medicare and Medicaid acute care services at the following four campuses.

SHS-First Hill Campus	747 Broadway, Seattle	King County
SHS-Ballard Campus	5300 Tallman Avenue Northwest, Seattle	King County
SHS-Cherry Hill Campus	500 – 17 th Avenue, Seattle	King County
SHS-Issaquah Campus ²	751 Northeast Blakely Drive, Issaquah	King County
SHS Edmonds ³	21601 76th Avenue West, Edmonds	Snohomish County

BACKGROUND INFORMATION AND INITIAL APPROVAL

This project focuses on CNs #1330 and #1330R issued to SHS May 26, 2006, and May 7, 2008, respectively. CN #1330 approved the establishment of a three-operating room ambulatory surgery center to be located in Issaquah, within East King County. Subsequent to the issuance of CN #1330, Overlake Hospital and Medical Center [OHMC] filed an adjudicative appeal of the approval.⁴ At the completion of the adjudicative appeal process, the department issued CN #1330R confirming the approval of CN #1330.

In response, to the issuance of CN #1330R, OHMC filed three judicial appeals, which began with the Superior Court appeal filed on May 16, 2008. During the course of the three judicial appeals, on April 6, 2009, the Department of Health's health law judge [HLJ] signed an "Order Tolling Commencement Period Deadline." Once the order was signed, SHS was permitted to commence the project, but was not required to do so until two years after all administrative and judicial appeals of the department's decision were exhausted. Essentially, the tolling order allowed SHS to maintain the approval of CN #1330R, but stayed the two-year validity period of the issued CN to allow for completion of the appeals.

On October 1, 2010, the HLJ signed the "Stipulation and Order Dismissing Adjudicative Proceeding" which recognized the September 23, 2010, Supreme Court decision in Overlake Hospital Association, et al. v. Department of Health, et al. No 82728-1 that resolved the legal issue in dispute.

² CN #1379 was issued on May 31, 2007, approving the establishment of a 175 bed hospital in Issaquah. The first phase-80 acute care beds-became operational and licensed on October 27, 2011.

¹ Swedish Health Services also has ownership percentages in a variety of other healthcare entities, such as home health, ambulatory surgery, and urgent care clinics. Since these entities are not pertinent to this project, they will not be discussed in this evaluation.

³ On February 26, 2010, SHS created a separate corporation known as Swedish Edmonds, where SHS is 100% sole member. On August 26, 2010, CN #1426 was issued to Swedish Edmonds approving a long-term lease agreement with Public Hospital District #3-Stevens Hospital located in Edmonds, within Snohomish County. The lease agreement became effective September 1, 2010, and is expected to continue for 30 years, with two 10-year options to renew.

⁴ Docket #06-06-C-2003CN and Master Case #M2008-118037.

⁵ The judicial appeal process included Superior Court, Appellant Court, and Supreme Court.

The order also provided the following timeline related to the validity period of CN #1330R. "Consistent with the Presiding Officer's April 6, 2009, Order Tolling Commencement Period Deadline, the project commencement deadline for CN #1330R shall be two years after entry of this dismissal order."

Based on the October 1, 2010, "Stipulation and Order Dismissing Adjudicative Proceeding," CN #1330R's validity period is October 1, 2010, to October 1, 2012.

HISTORY AND VALIDITY OF CN# 1330R

SHS submitted this amendment application to change the approved site of the ambulatory surgery center (ASC) from Issaquah to Redmond. Both sites are located within the east King planning area as defined in WAC 246-310-270. In addition to the amendment application, SHS also submitted a request for a sixmonth extension to the validity of CN #1330R as allowed under WAC 246-310-580. If the extension request was approved, the validity of CN #1330R would extend from October 1, 2012, to April 1, 2013.

WAC 246-310-580 allows for one six-month extension provided an applicant can demonstrate that substantial and ongoing progress toward commencement of the project has been made. CN #1330R approved the construction of a new ASC at a particular site in Issaquah. Subsection (2) of WAC 246-310-580 provides the following statements regarding substantial and ongoing progress toward commencement for a project involving construction.

- (2) In the case of a project involving construction, substantial and continuing progress shall include one of the following:
 - (a) When review and approval by the department of the final plans for construction is required, the submission of working drawings;
 - (b) When plan approval is not required by the department, receipt of copies of the working drawings for construction; or
 - (c) In the event working drawings have not been submitted, the applicant must demonstrate that he or she has made continuous progress toward commencement of the project.

WAC 246-310-590 requires the department to monitor approved projects through completion. The department fulfills this requirement through the review of quarterly progress reports that are completed and submitted each quarter covering the months of January through March, April through June, July through September, and October through December.

A review of the quarterly progress reports completed and submitted by SHS for CN #1330R from October 1, 2010, through June 30, 2012, did not demonstrate substantial and ongoing progress toward commencement of CN #1330R. On August 30, 2012, the department denied SHS's request for a sixmonth extension to the validity of CN #1330R. As a result, CN #1330R remained valid from October 1, 2010 through October 1, 2012.

The remainder of this evaluation focuses on the timing of submission of this amendment application and recognizes that CN #1330R expired on October 1, 2012.

⁶ DOR #12-37 submitted on May 29, 2012.

AMENDMENT PROJECT DESCRIPTION

With this application, SHS proposes to amend CN#1330R because of a change in the approved site. CN #1330 approved the establishment of the ASC to be located at 2005 Northwest Sammamish Road in Issaquah. This application proposes to relocate the facility within space at SHS's Redmond Campus located at 18100 Northeast Union Hill Road in Redmond. In December 2010, SHS opened an 85,000 square foot freestanding emergency department at the Redmond site that has space to accommodate an ASC. Both sites are located in the east King County planning area as identified in WAC 246-310-270(3).

In the initial application, SHS stated the ASC would provide the following ambulatory surgical services: gastroenterology, orthopedic, ENT, urology, ophthalmology, and gynecology. [source: Initial evaluation, p7] This amendment application does not propose to change the scope of services to be provided. [source: August 3, 2012, supplemental information, p1]

Additionally, CN #1330 was issued with an approved capital expenditure of \$7,640,000.8 This amendment application does not propose any increase or decrease to the capital expenditure for the project. [source: Application, p16]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to review under WAC 246-310-570(1)(f) because the site for the project has changed.

EVALUATION CRITERIA

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

In the event the 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;

⁷ Issuance of CN #1330R did not change the location of the ASC.

⁸ Issuance of CN #1330R did not change the approved capital expenditure for the project.

- (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."

The review for an amendment project is limited to only those criteria that would be affected by the amendment, <u>provided</u> that the amendment does not significantly alter the project. While SHS's initial project was significantly delayed, the project was not significantly altered under CN rules. As a result, the department's review will focus on applicable portions of financial feasibility (WAC 246-310-220) and cost containment (WAC 246-310-240).

CNs #1330 and #1330R were issued with two conditions. One condition related to the provision of charity care to be provided at the ASC as required under WAC 246-310-210(2) and WAC 246-310-270(7). Because significant time has lapsed between the initial approval and the conclusion of the appeals, if this project is approved this condition would be revised to reflect current charity care requirements.

The second condition required SHS to maintain Medicare certification and a Medicaid contract at the ASC. If this project is approved, this condition would also be attached to the approval.

TYPE OF REVIEW

As allowed under WAC 246-310-570 the department accepted this project as an amendment to an existing Certificate of Need. This application was reviewed under an expedited review timeline as outlined in WAC 246-310-150.

APPLICATION CHRONOLOGY

Action	Due Date	Actual Action Date	
Letter of Intent Submitted	n/a	April 27, 2012	
Application Submitted	May 29, 2012	May 29, 2012	
Department's 1 st Screening Letter	June 19, 2012	June 19, 2012	
Applicant's 1 st Screening Responses	August 3, 2012	August 3, 2012	
Department's 2 nd Screening Letter ⁹	August 24, 2012	August 24, 2012	
Beginning of Review	August 31, 2012	August 28, 2012	
Applicant's Supplemental Information Submitted	September 7, 2012	September 7, 2012	
End of Public Comment	September 17, 2012	September 17, 2012	
CN #1330R Expires at Midnight on this Date	October 1, 2012	October 1, 2012	
Rebuttal Comments Submitted	October 2, 2012	October 2, 2012	
Department's Anticipated Decision Date	October 22, 2012	October 22, 2012	

⁹ Within the 1st screening responses, Swedish Health Services requested a second screening of the application. No further questions were submitted to Swedish Health Services, so the department began formal review of the project two working days later.

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."

Throughout the review of this project, two hospitals sought and received affected person status under WAC 246-310-010(2):

- Evergreen Healthcare an acute care hospital located at 12040 Northeast 128th Street in Kirkland, within King County.
- Overlake Hospital and Medical Center an acute care hospital located at 1135 116th Avenue Northeast in Bellevue, within King County.

SOURCE INFORMATION REVIEWED

- Swedish Health Services' Certificate of Need application submitted April 29, 2012
- Swedish Health Services' supplemental information received August 3, 2012, and September 7, 2012
- Public comments received by 5:00 pm September 17, 2012
- Rebuttal comments from Swedish Health Services received on October 2, 2012
- Certificate of Need #1330 issued on May 26, 2006
- The department's May 12, 2006, evaluation approving the issuance of CN #1330
- Certificate of Need #1330R issued on May 7, 2008, replacing CN #1330 and providing a new twoyear validity period from May 7, 2008, to May 7, 2010
- 'Order Tolling commencement Period Deadline' issued April 6, 2009 by the HLJ
- 'Stipulation and Order Dismissing Adjudicative Proceeding' issued October 1, 2010, by the HLJ allowing a new two-year validity period from October 1, 2010, to October 1, 2012
- The department's August 30, 2012, decision related to DOR #12-37 submitted by Swedish Health Services requesting a six-month extension to the validity of CN #1330R

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Swedish Health Services proposing to amend Certificate of Need #1330R to change the approved site is denied. Certificate of Need #1330R expired on October 1, 2012, prior to the end of the rebuttal period and the department's scheduled due date for release of this decision. As a result, Certificate of Need #1330R is no longer valid and cannot be amended.

EVALUATION AND VALIDITY OF CN #1330R

On December 5, 2011, SHS submitted its September 2011 progress report related to CN #1330R. In the September report, SHS stated that it "has shifted its attention to this CofN." In response to SHS's September progress report, on March 1, 2012, the department reminded SHS that CN #1330R is valid until October 1, 2012, and the project must commence before the expiration of the issued certificate. The department also stated that to qualify for an extension, SHS must submit the extension request a minimum

of 120 days before the expiration date—or by June 1, 2012. This notification to SHS was approximately three months prior to SHS's submission of its extension request and the amendment application.

SHS submitted its letter of intent for this amendment application on April 27, 2012. On May 1, 2012, the department notified SHS that the amendment application must be submitted, reviewed, and an amended CN issued prior to the October 1, 2012, expiration date of CN #1330R. Based on the expedited review timelines, the department suggested that the amendment CN be submitted no later than May 29, 2012. This amendment application was submitted on May 29, 2012.

Even though the amendment application was submitted only 122 days before the expiration of CN #1330R, the department could have reviewed the project and an amended CN may have been issued prior to the October 1, 2012, expiration date if SHS would have been timelier in responding to the department's 11 screening questions. Under WAC 246-310-090, an applicant has 45 calendar days to respond to the department's screening letter. An applicant can submit responses at any time during the 45 calendar days; this fact is demonstrated in past applications submitted by SHS where screening responses were submitted before the 45-day due date. The table below shows the timelines for the four most recent applications submitted by SHS and reviewed under an expedited review timeline. ¹⁰

	App #10-26	App #10-32	App #11-02	App #11-30
Date of Department's Screening letter	03/01/10	05/21/10	08/24/10	05/10/11
Screening Response Due Date	04/15/10	07/06/10	10/07/10	06/24/11
Date Responses Submitted	03/24/10	06/11/10	09/27/10	05/11/10
# of Days	23 days	21 days	34 days	1 day

As noted in the 'Application Chronology' portion of this evaluation, SHS provided a response to the department's 1st screening letter on the 45th day.

Another 'slow-down' for this review process is when SHS requested a second screening of the application in its 1st screening responses. The department must review the 1st screening responses and request additional information within 15 working days of receipt of a second screening request. The department notified SHS on the 15th working day that no further questions would be asked, and began formal review of the project within 2 working days, rather than the 5 working days allowed under WAC 246-310-170(2)(a)(ii). Once formal review of the project began, the remaining timelines are identified in rule.

SHS's lack of timeliness in its 1st screening responses was a significant factor in this CN expiring before the department's decision could be released. As noted in the 'Application Chronology' portion of this evaluation, CN #1330R expired one day after the end of the rebuttal period. As a result, Certificate of Need #1330R is no longer valid and cannot be amended.

Application #10-26 proposed an amendment to CN #1379 because of a change in site. Application #10-32 proposed a long-term lease of Stevens Hospital located in Edmonds. Application #11-02 proposed a second amendment to CN #1379 because of a change in the approved financing. Application #11-30 proposed an amendment to CN #1264R2 because of a change in the site.