



The material facts are undisputed. Swedish operates two independently licensed hospitals in Seattle—First Hill and Cherry Hill—located approximately eight blocks from each other. Currently, Swedish’s cardiology program is consolidated in its Cherry Hill location. When First Hill patients require cardiac care, Swedish transfers them to Cherry Hill.

Swedish decided to reestablish a cardiology program at First Hill. Accordingly, Swedish applied for a certificate of need from the Department to perform elective percutaneous coronary interventions (PCIs) at First Hill. PCIs are “invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries.”<sup>2</sup> These procedures can be elective or non-elective, but a hospital must obtain a certificate of need to provide elective PCIs.

The Department’s regulations prohibit granting a certificate of need for elective PCIs to a new program if existing PCI programs in the identified planning area perform fewer than 300 PCI procedures a year.<sup>3</sup> It is undisputed that two existing programs in the planning area where Swedish sought the certificate of need perform fewer than 300 PCI procedures a year. These programs are at University of Washington Medical Center and Northwest Hospital. Accordingly, the Department denied Swedish’s application.

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<sup>2</sup> WAC 246-310-705(4).

<sup>3</sup> WAC 246-310-720.

Swedish commenced an adjudicative proceeding. A health law judge granted summary judgment in favor of the Department, upholding its denial of this application for a certificate of need. Swedish sought review of this order, and the Department's review officer denied relief, adopting the health law judge's order as the final order and entering additional conclusions of law.

Swedish sought judicial review in King County Superior Court. The court affirmed the denial of the certificate of need.

Swedish appeals.

### **CERTIFICATE OF NEED**

Swedish argues that the Department erroneously denied its application for a certificate of need. Swedish concedes that it failed to meet the regulatory requirements of WAC 246-310-720. But it claims the Department should have considered whether special circumstances entitled Swedish to a certificate. We hold that the Department properly denied the application.

"The standards of review in certificate of need cases stem from the Administrative Procedure Act (APA), chapter 34.05 RCW."<sup>4</sup> The party challenging the decision bears the burden to show that the agency action is invalid.<sup>5</sup>

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<sup>4</sup> King County Pub. Hosp. Dist. No. 2 v. Dep't of Health, 178 Wn.2d 363, 371, 309 P.3d 416 (2013).

<sup>5</sup> RCW 34.05.570(1)(a).

This court substantially defers to the Department's interpretation of law, "particularly where the agency has special expertise."<sup>6</sup> We also defer to the Department's interpretation of its regulations, as "[it] has expertise and insight gained from administering the regulation that the reviewing court does not possess."<sup>7</sup>

We interpret agency regulations using the principles of statutory interpretation.<sup>8</sup> We first look to the regulation's plain language.<sup>9</sup> If the meaning is clear, we apply that meaning.<sup>10</sup>

RCW 34.05.570(3) provides several grounds for which a reviewing court may reverse an administrative order. The reviewing court may grant relief from an agency decision if it determines that the Department erroneously interpreted or applied the law, or if the Department failed to decide all issues requiring resolution.<sup>11</sup> These are the sole bases on which Swedish seeks reversal in this case.

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<sup>6</sup> King County Pub. Hosp. Dist. No. 2, 178 Wn.2d at 372.

<sup>7</sup> Overlake Hosp. Ass'n v. Dep't of Health, 170 Wn.2d 43, 56, 239 P.3d 1095 (2010).

<sup>8</sup> Id. at 51-52.

<sup>9</sup> Id. at 52.

<sup>10</sup> Id.

<sup>11</sup> RCW 34.05.570(3)(d), (f).

*Erroneous Interpretation or Application of Law*

We first consider whether the Department erroneously interpreted or applied the law. We hold that the Department properly interpreted and applied the applicable law.

Under RCW 70.38.128, the Department must promulgate “rules establishing criteria for the issuance of a certificate of need under this chapter for the performance of elective [PCIs] at hospitals that do not otherwise provide on-site cardiac surgery.”

To fulfill this statutory mandate, the Department promulgated WAC 246-310-700, which lists the standards a hospital must meet to obtain a certificate of need to perform elective PCIs. One such standard is WAC 246-310-720.

Under that regulation:

The department ***shall only*** grant a certificate of need to new programs within the identified planning area if:

(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and

(b) ***All existing PCI programs*** in that planning area ***are meeting or exceeding*** the minimum volume standard.<sup>[12]</sup>

The minimum volume standard for an existing program is 300 PCIs per year.<sup>13</sup>

Here, the validity of this regulation is not at issue. Moreover, it is undisputed that two other existing PCI programs in the identified planning area

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<sup>12</sup> WAC 246-310-720(2) (emphasis added).

<sup>13</sup> WAC 246-310-720(1).

where Swedish seeks a certificate of need fall below the 300 PCI minimum threshold. Swedish acknowledges this.<sup>14</sup> Thus, the question is whether the Department correctly interpreted and applied the law in view of these undisputed facts.

The plain text of the Department's regulations establishes that its standards are mandatory. Under WAC 246-310-700, "To be granted a certificate of need, an adult elective PCI program **must** meet the standards in [the Department's regulations]."<sup>15</sup> And under WAC 246-310-720, "The department **shall only** grant a certificate of need to new programs within the identified planning area if: . . . **All existing PCI programs** in that planning area are meeting or exceeding the minimum volume standard."<sup>16</sup> Thus, satisfying the minimum volume standard is an essential prerequisite for a certificate of need.

Swedish concedes that two hospitals in its area fail to meet the minimum volume standard—300 PCI procedures per year. But it argues that the Department's decision is incorrect based on case authority in this and other jurisdictions. This argument is without merit.

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<sup>14</sup> Opening Brief of Swedish Health Services at 12 n.1 ("Because it is undisputed that UWMC and Northwest each are performing fewer than 300 PCIs per year, Swedish's application may only be approved based on special circumstances, irrespective of whether or not there is a projected need for an additional PCI program in the planning area.").

<sup>15</sup> (Emphasis added.)

<sup>16</sup> Id.

Swedish primarily relies on King County Public Hospital District No. 2 v. Department of Health.<sup>17</sup> Because that case is distinguishable, it does not control this one.

There, Odyssey Healthcare Operating B LP and Odyssey Healthcare Inc., (collectively “Odyssey”), hospice care agencies, sought a certificate of need.<sup>18</sup> When determining whether to grant such a certificate, the Department considers need for the proposed project as well as three other criteria.<sup>19</sup> The Department forecasts future need based on regulatory criteria.<sup>20</sup> For example, the relevant data includes hospice care use rates, the number of resident deaths in the applicable planning area, the projected population growth, and the current hospice care capacity.<sup>21</sup> Another factor is whether existing hospice care providers in the applicable planning area will be unable to provide such care above a minimum threshold.<sup>22</sup>

Traditionally, applications for certificates of need were due in October, based on the Department’s assumption that the required data for determining

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<sup>17</sup> Opening Brief of Swedish Health Services at 20-23 (citing King County Pub. Hosp. Dist. No. 2 v. Dep’t of Health, 178 Wn.2d 363, 309 P.3d 416 (2013)).

<sup>18</sup> King County Pub. Hosp. Dist. No. 2, 178 Wn.2d. at 367-68.

<sup>19</sup> Id. at 367.

<sup>20</sup> Id.

<sup>21</sup> Id.

<sup>22</sup> Id.

need would be available by that time.<sup>23</sup> In fact, such data was not generally available by the October application deadline.<sup>24</sup> Thus, applicants were required to apply and pay large fees without knowing whether there would be a need for additional hospice care agencies.<sup>25</sup>

Odyssey applied in both 2003 and 2006 for certificates of need.<sup>26</sup> The Department denied both applications based on its determination that there was no need for additional services.<sup>27</sup> Odyssey challenged the 2006 denial in an adjudicative proceeding.<sup>28</sup> While that proceeding was pending, the Department released its 2008 hospice need projections.<sup>29</sup> The projections, based on data after the October application deadline, showed that one additional hospice care agency was needed in 2009 and two in 2013.<sup>30</sup> Odyssey asked the Department to grant its application in light of the new need calculations.<sup>31</sup> The Department

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<sup>23</sup> Id.

<sup>24</sup> Id.

<sup>25</sup> Id.

<sup>26</sup> Id. at 368.

<sup>27</sup> Id.

<sup>28</sup> Id.

<sup>29</sup> Id. at 368-69.

<sup>30</sup> Id. at 369.

<sup>31</sup> Id.



refused on the grounds that its policy was to review applications based on the data that existed at the time of the application, not later.<sup>32</sup>

Odyssey commenced a federal lawsuit against the Department, alleging violations of 42 U.S.C. § 1983; the Sherman Act; and the Commerce Clause of the United States Constitution.<sup>33</sup> The Department maintained that its policy was to evaluate need based on the data available at the time of the application.<sup>34</sup>

Nevertheless, Odyssey and the Department agreed to settle both the federal lawsuit and Odyssey's pending adjudicative proceeding.<sup>35</sup> Specifically, the Department agreed to consider stipulating to the approval of Odyssey's certificate of need application based on the new need calculations for the applicable planning area, subject to notice to other interested entities.<sup>36</sup> It did so under what it described as "special circumstances."<sup>37</sup>

Specifically, these circumstances were that Odyssey did not know of the need finding until after the 2008 application deadline.<sup>38</sup> Moreover, the new calculation showed need for a provider in 2009, which was within the three-year

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<sup>32</sup> Id.

<sup>33</sup> Id.

<sup>34</sup> Id.

<sup>35</sup> Id. at 369-70.

<sup>36</sup> Id. at 370.

<sup>37</sup> Id.

<sup>38</sup> Id.

window included in Odyssey's prior application.<sup>39</sup> Finally, no other providers were likely to be prejudiced by granting Odyssey's application.<sup>40</sup>

After providing notice to other interested parties of the settlement, the Department submitted the proposed settlement to the health law judge presiding over the adjudicative proceeding.<sup>41</sup> That judge, after considering objections by other interested parties, approved the settlement.<sup>42</sup> In doing so, the judge stated "[i]n the exercise of discretion," the December 2008 need calculation data could be used in evaluating need for Odyssey's proposed service.<sup>43</sup> Thereafter, the Department issued a certificate of need to Odyssey.<sup>44</sup>

Other interested parties in the adjudicative proceeding petitioned for judicial review of the grant of the certificate of need.<sup>45</sup> The superior court reversed the health law judge's order approving the settlement and remanded for reconsideration without consideration of the new data considered in connection

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<sup>39</sup> Id.

<sup>40</sup> Id.

<sup>41</sup> Id. at 370-71.

<sup>42</sup> Id. at 371.

<sup>43</sup> Id. (alteration in original).

<sup>44</sup> Id.

<sup>45</sup> Id.

with the settlement.<sup>46</sup> This court reversed the superior court's order, and the supreme court granted the petition for review of the other interested parties.<sup>47</sup>

The supreme court affirmed this court's decision. Notably, the court characterized the issue as whether the health law judge abused his discretion by considering the new finding of need under the circumstances of that case.<sup>48</sup> In concluding that the judge had not abused his discretion in considering the new evidence, the court based its decision on what it stated were "the special circumstances described by the [D]epartment."<sup>49</sup> The court noted that need applications are due in October, and the 2008 need finding was not available until December 2008.<sup>50</sup> Thus, Odyssey was unable to apply for a certificate in 2008 after the Department found need in the identified planning area.<sup>51</sup>

The court acknowledged that Odyssey could have applied for a certificate of need in October 2008.<sup>52</sup> But it would have done so without knowing if a need existed, expending a substantial expense for a benefit that was far from certain.<sup>53</sup>

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<sup>46</sup> Id.

<sup>47</sup> Id.

<sup>48</sup> Id. at 374.

<sup>49</sup> Id.

<sup>50</sup> Id.

<sup>51</sup> Id.

<sup>52</sup> Id.

<sup>53</sup> Id. at 374.

Lastly, the court stated:

We also find it significant that no certificate of need applicants were prejudiced by the department's decision to rely on the later need finding. If another entity had applied for a certificate of need to offer hospice care in King County in 2007, our analysis might have been different.<sup>[54]</sup>

King County Public Hospital District No. 2 is not analogous to the present case. Significantly, the special circumstances in that case have no relationship to the facts of this case. First, Swedish has not been disadvantaged by a lack of relevant data to permit a determination of need for the identified planning area. To the contrary, the data for determining need for an additional PCI program confirms there is no need. That is because two other PCI programs fall below the minimum volume standard of 300 PCIs per year. Second, the duly promulgated and valid regulation at issue here plainly states two of the required criteria for issuance of a certificate of need. And it is undisputed that Swedish fails to meet the minimum volume standard.

This is distinct from the Department's policy in *Odyssey*, a policy based on the fallacious assumption that need data would be available before the application deadline. Finally, if the Department were to grant a certificate of need to Swedish, despite the plain language of its regulation that specifies minimum volume standards for existing PCI programs, it is fair to assume prejudice to those existing programs. Otherwise, minimum volume levels of existing programs would be irrelevant to forecasting need.

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<sup>54</sup> Id. at 375.

The supreme court expressly stated in King County Public Hospital District No. 2 that the lack of a showing of any prejudice to certificate of need applicants was important to its decision.<sup>55</sup> Indeed, it might have decided otherwise in the absence of such a showing.<sup>56</sup>

Here, there presumably would be prejudice to existing programs falling below the 300 PCI procedures per year because additional capacity without need could further diminish the performance of existing providers. This further supports the Department's decision to deny the application.

For all these reasons, Swedish's reliance on King County Public Hospital District No. 2 is misplaced.

Swedish points to the Department's regulations for certificates of need for different procedures or services. Swedish argues that these regulations "contain[] numerous exceptions, exemptions, and caveats which allow for [the] approval of various types of projects which may not otherwise satisfy applicable criteria."<sup>57</sup> But the fact that those other regulations contain exemptions is not material to the issues before us.

The PCI regulations lack such language, indicating that their standards are mandatory and not subject to exemption. We reject the argument that the fact that other certificates of need may be granted without meeting all the

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<sup>55</sup> Id.

<sup>56</sup> Id.

<sup>57</sup> Opening Brief of Swedish Health Services at 18.

identified criteria establishes that PCI certificates of need can also be granted without meeting the governing criteria.

Swedish also relies on out of state case law. These cases are distinguishable because they are from states with regulatory schemes that differ from Washington's. Thus, they are not helpful.

Swedish cites Marion Hospital Corp. v. Illinois Health Facilities Planning Board.<sup>58</sup> In that case, an Illinois appellate court held that the Illinois Board had authority to grant a certificate of need to a hospital that failed to meet all the regulatory requirements.<sup>59</sup> But Illinois's regulations explicitly stated that "[t]he failure of a project to meet one or more [of the identified] review criteria . . . shall not prohibit the issuance of a permit."<sup>60</sup>

Here, no comparable law provides any exception to the Department's regulations that we previously discussed. Accordingly, that case is not persuasive.

Swedish also relies on University Community Hospital v. Department of Health and Rehabilitative Services.<sup>61</sup> In that case, a Florida hospital had received a certificate of need "after it demonstrated the existence of 'special circumstances' arising from the fact that its facility was intended to serve a

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<sup>58</sup> 324 Ill. App. 3d 451, 753 N.E.2d 1104 (2001).

<sup>59</sup> Id. at 454-55.

<sup>60</sup> Id. at 455 (quoting ILL. ADMIN. CODE tit. 77, § 1130.660 (1998)) (some alterations in original).

<sup>61</sup> 472 So.2d 756, 10 Fla. L. Weekly 1318 (Dist. Ct. App. 1985).

substantial number of persons from Latin America.”<sup>62</sup> But Florida’s regulations allowed for the consideration of “[s]pecial needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas . . . .”<sup>63</sup>

Here, no similar regulation allows the Department to consider special circumstances and waive the express requirements of the governing regulations. Thus, University Community Hospital is also not helpful.

In sum, the Department did not erroneously interpret or apply the law when it denied Swedish’s application for a certificate of need.

*Failure to Decide All Issues Requiring Resolution*

We next consider whether the Department failed to decide all issues requiring resolution. We hold that there was no such failure.

Swedish appears to argue that the Department failed to decide whether the special circumstances that Swedish cites merited issuance of a certificate of need, despite the failure to meet an essential criterion for issuance. Because the regulation clearly requires fulfillment of the minimum volume criterion, and it is undisputed that this criterion is not met in this case, the Department did not need to decide whether the special circumstances advanced by Swedish merited

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<sup>62</sup> Id. at 758.

<sup>63</sup> Farmworker Rights Org., Inc. v. Dep’t of Health and Rehabilitative Servs., 430 So.2d 1, 2 n.1 (Fla. Dist. Ct. App. 1983) (quoting Former FLA. ADMIN. CODE 10-5.11(9) (1981)).

issuance of a certificate of need. Swedish's arguments to the contrary are unpersuasive for the reasons we explained earlier in this opinion.

Swedish also makes an argument based on the APA's standards for judicial review. Under RCW 34.05.570(3)(h), a reviewing court may grant relief if "[t]he order is inconsistent with a rule of the agency unless the agency explains the inconsistency by stating facts and reasons to demonstrate a rational basis for inconsistency." Thus, Swedish argues that if an agency does "stat[e] facts and reasons to demonstrate a rational basis," it may issue an order that is inconsistent with its rules. Accordingly, the Department could have granted Swedish a certificate of need, despite the failure to meet the regulatory requirements, if the Department demonstrated a rational basis for doing so.

Swedish fails to cite any case law supporting this interpretation of the APA. Moreover, even assuming the Department could have issued an order inconsistent with its rules, nothing indicates that it was required to consider doing so before denying Swedish's application. Thus, the Department did not fail to decide all issues requiring resolution.

We affirm the superior court order that affirms the decision of the Department.

Lox, J.

WE CONCUR:

Dryden, J.

Schindler, J.