IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

SOUTH ANCHORAGE AMBULATORY
SURGERY CENTER,

Appellant,

STATE OF ALASKA, DEPARTMENT OF
HEALTH AND SOCIAL SERVICES,

Appellee.

Case No. 3AN-07-10738 CI
OAH No. 06-0152-DHS

Decision on Appeal

A certificate of need is required to spend more than a million dollars on construction of a health care facility,[1] and the Department of Health and Social Services is charged with evaluating whether a proposed expenditure is needed to maintain good health for Alaskans.[2] A joint venture of medical care providers sought a CON to build a new surgery center in Anchorage, and an administrative law judge found that the quality of medical care could suffer if the application were denied.[3] The Commissioner, however, concluded that the regulations[4] did not allow for use of the trend analysis relied upon by the ALJ, and so denied the application.[5] The joint venture appealed,[6] and the parties argued their positions two weeks ago.[7]

[1] AS 18.07.031. (An automatic increase of $50.000 per year in the triggering amount began 7/1/05.)
[2] AS 18.07.041.
[3] Decision and Order, 5/24/07; R. 189-208.
[4] *See* 7 AAC 07.025.
[5] Decision and Order, 7/5/07; R. 45-48.

Decision of the Administrative Law Judge.

These proceedings began with a letter of intent written in late 2004; the JV hoped to be operational with four new operating rooms by 2006.[8] After some delay,[9] the Commissioner denied the application,[10] and a hearing was requested.[11] Commission staff examined the need-related data under both the standard criteria and using "trend analysis,"[12] and the distinction between the two is at the heart of this appeal.

Under the standard methodology, the need for additional surgery suites

> is calculated using prescribed formulas in which projected population and general surgery use rates are the variables that dictate whether anticipated demand for surgery services might outpace supply. The general surgery use rate is an average from the three preceding years and remains static throughout the projection. Projected future growth in surgery demand is solely a function of growth in overall population. The standard methodology, therefore, does not take into account whether other factors, such as an aging population or changed approaches to medical care, cause the three year average to underestimate likely future rate of usage for surgery services.[13]

The parties agree that use of this methodology showed a surplus rather than a deficit of operating suites, while the trend analysis showed a need for 3% suites by 2011.[14] Chief ALJ Thurbon concluded, however, that trend analysis "is a more

[6] Brief of Appellant [At. br.] filed 1/30/08, Brief of Appellee [Ae. br.] filed 4/1/08, and Reply filed 4/21/08.
[7] Media 3DIA08-93, 2:27-3:27 (6/20/08).
[8] R. 1229.
[9] *See* At. br. at 6-8.
[10] R. 1150.
[11] R. 1149; 7 AAC 07.080.
[12] R. 191.
[13] R. 191-92 (internal footnotes omitted); *see* At. br. at 10-11.
[14] R. 193, 196.

reliable predictor of future need than the standard methodology."[15] The information was developed during the agency appeal process, which Chief Judge Thurbon described as a means "to allow the executive branch decisionmaker an opportunity to correct errors" at the agency level, with "errors" defined loosely to mean anything that gets in the way of reaching the correct result.[16] Accordingly, the evidence on trend analysis was evaluated to see if "the availability, quality, or accessibility of existing healthcare services creates an unreasonable barrier to services."[17] The ALJ concluded that there were several such barriers:

- Scheduling for routine procedures can be difficult because block time is in short supply and reliance on hospital suites increases the likelihood of routine procedures being postponed to accommodate emergencies.

- Procedures take longer than necessary, in part because of the time spent changing equipment and surgical teams, and because non-specialized support personnel are less efficient.

- Procedures that do not require a hospital must still be performed there.

- The risk of infection may be greater in a hospital setting and increases if a wound must be left open due to a delay in surgery.

- Exposure to unnecessarily high levels of general anesthesia occurs more often in hospitals than ambulatory surgery centers, where specialists rely more heavily on regional blocks.

[15] R. 196.
[16] R. 200-202.
[17] *Id*, citing 7 AAC 07.025(b).

•Operating at 90% of capacity in a hospital setting is taxing and operating above 85% can be a problem. Providence Alaska Medical Center's general surgery suites now operates at 98% of capacity.[18]

Chief ALJ Thurbon found that "Collectively, these facts show that more likely than not some patients' medical care is being adversely affected by current limitations on surgery suites available for non-hospital outpatient procedures."[19] She therefore concluded that the JV had shown that barriers existed to receiving a desirable quality of health care, that the barriers were unreasonable, and that application of trend analysis justified making an exception to the standard methodology.[20] The trend analysis demonstrated that the rate of surgical procedures has been increasing and is likely to continue to do so, and, as noted earlier, Judge Thurbon concluded that the linear regression analysis was a more reliable predictor of future need than the standard methodology.[21] Also noted were potential problems in using a dedicated endoscopy suite for general surgery,[22] scheduling difficulties and a perception that patients simply do better in an outpatient surgery center than in a hospital.[23]

The Commissioner's decision.

Commissioner Jackson began by stating that "(1) the findings and conclusions in the May 24, 2007 decision and order are hereby adopted, except as

[18] R. 205, citing the record in interna! footnotes 81-88.
[19] R. 206.
[20] *Id*
[21] R. 196.
[22] *See* At. br. at 11-12 for record citations.
[23] R. 196-97. *See also* At. br. at 17-19 (discussing qualitative advantages of proposed suites).

provided in (2) and (3) below."[24] Neither of the conclusions which followed disputed the ALJ's findings, but part (2) rejected the conclusion "that an exception can be allowed under 7 AAC 07.025 to use of the standard methodology for calculating need for general surgery services."[25] The Commissioner determined that the department did not intend to allow exceptions to the methodologies, but only the standards, even though the language, read literally, might suggest otherwise.[26] She acknowledged that, "Over time, more methodologies might be authorized," but at present there was only the one.[27]

The Commissioner did not address Chief Judge Thurbon's reasoning that a methodology is an inseparable part of the standard itself.[28] The regulation incorporates by reference a 40 page document titled *Alaska Certificate of Need Review Standards and Methodologies,* dated December 9, 2005,[29] which does distinguish between the two terms.[30] The general standard is set forth on page 2, and speaks to whether the applicant has documented the need for the project, coordination with other stakeholders, anticipated impact, accessibility and the like[31] while the review methodology is specific for each type of medical care being evaluated. And indeed the methodolgy for surgical care employs the

[24] R.51.
[25] *Id*
[26] R. 52.
[27] R. 52-53.
[28] R. 203. *See also* Reply at 13-14.
[29] *See* R. 348 and http://www.hss.state.ak.us/publicnoticc/PDF/l33.pdf.
[30] *Id*. at 1, 3.
[31] *Id.* at 2.

formula recited by the parties in their briefing,[32] and described by the ALJ[33] as inferior to trend analysis in meeting the statutory goal.

Standard of review.

There are four different standards of review:

> (1) the "substantial evidence" test applies to questions of fact; (2) the "reasonable basis" test applies to questions of law involving agency expertise; (3) the "substitution of judgment" test applies to questions of law where no expertise is involved; and (4) the "reasonable and not arbitrary" test applies to questions of about agency regulations and the agency's interpretation of those regulations.[34]

The State emphasizes the second of these,[35] and indeed there certainly would appear to be agency expertise involved in the lengthy and complicated regulation at issue. But the real question may be whether the regulation as interpreted by the State is consistent with and reasonably necessary to implement the statutes under which it is authorized.[36] As the Alaska Court of Appeals put it (in a different context),

> To the extent that a regulation is inconsistent with statutory law, the executive branch agency that promulgated the regulation has exceeded the rule-making power delegated by the legislature. Thus "when a regulation conflicts with a statute, it is the regulation which must yield."[37]

[32] *Id* at 30-31; At. br. at 10-11, Ae. br. at 5-6.
[33] *See* text accompanying note 13, *supra*
[34] *Lakloey, Inc.* v. *University of Alaska,* 157 P.3d 1041, 1045 (Alaska 2007).
[35] Ae. br. at 16. citing *Rose* v. *Commercial Fisheries Entry Commission,* 647 P.2d 154, 161 (Alaska 1982), *Lauth* v. *State,* 12 P.3d 181, 184 (Alaska 2000), and *State* v. *Greenpeace,* 96 P.3d 1056, 1061 (Alaska 2004).
[36] *Wilber v. State, Commercial Fisheries Entry Commission,* _P.3d _, 2008 WL 2551082 (Alaska 6/27/08), citing *Grunert* v. *State,* 109 P.3d 924, 929 (Alaska 2005). *See also* AS 44.62.030.
[37] *Frank* v. *State, 97* P.3d 86, 91 (Alaska App. 2004), quoting *Gudmundson* v. *State,* 763 P.2d 1360, 1363 (Alaska App. I988)(other footnotes omitted).

Although agency expertise is implicated in the regulation, there are parallels between the issue posed in this case and that presented in *O 'Callaghan* v. *Rue.*[38] As in that case, the issue of whether the regulation is consistent with the law is one of statutory construction, which a court may decide using independent judgment, while whether the regulation is necessary to implement it involves fundamental policy determinations, which are reviewed on a rational basis standard.[39] The "reasonable not arbitrary" review is also deferential.

Is 7 AAC 07.025 as applied by the Commissioner consistent with the statute?

There is no dispute about the agency's authority to promulgate the regulation;[40] the question is whether it is consistent with the legislative directive, when construed to exclude application of trend analysis as it has been in this case. And of course we reach this issue only if the regulation is interpreted in the manner that Commissioner Jackson did, which is in conflict with the decision of Chief Judge Thurbon. It makes sense to begin with what the evidence revealed about application of the standard methodology.

The JV emphasizes that the uncontested facts show a need for more surgery suites,[41] while the result produced by the standard method is that there are 7 1/2 too many already.[42] The witnesses agreed that Alaska, like the rest of the country, was getting older, and that this, and a new approach to certain medical problems, were

[38] 996 P.2d 88, 94 (Alaska 2000).
[39] *Id.* at 94-95.
[40] *See* Ae. br at 18, Reply at 5.
[41] *See also* R. 689 (21 needed by 2011).
[42] *R.* 193; Ae. br. at 9.

resulting in much more use of day surgery dial can be done in an ambulatory center.[43] Appellant argues that the result of the standard method is flawed because you can't use an average rate of surgery when it is apparent that the rate is accelerating rapidly,[44] and it notes that the Department's own expert agreed that the alternative methodology was superior for this reason.[45] The JV's expert, Professor Goldsmith, was, naturally enough, even more definite, calling use of the standard method a mistake, inappropriate and misleading.[46] And, as noted, Chief Judge Thurbon found this evidence compelling.[47]

The Department defends the standard methodology in several ways. First of all, it was developed by a task force charged with increasing efficiency and objectivity in the CON process, putting everyone on the same footing.[48] Secondly, the Department viewed the increase in the surgery rate as resulting from its own previous allowance of CONs—if you build it they will come.[49] Third, the methodology seemed to work in a recent Fairbanks application.[50] It perceives the issue as simply "whether the regulation can be excepted or waived...a legal question to which much of the testimony is not relevant. The court should not be enticed by the JV's statements and inferences in looking at these simple and

[43] *See* At br. at 20-22 (quoting testimony).
[44] *See* example in At, br. at 13.
[45] Tr. 213-14, *261-71; see* R. 637, 688-89.
[46] Tr. 300-302.
[47] R. 196-97.
[48] Ae. br. at 3-4.
[49] Ae. br. at 13-14.

straightforward legal issues."[51] And, it points out, a properly adopted regulation is presumed to be valid.[52]

But although the Department eventually gets around to stating the issue directly,[53] it never responds to the Joint Venture's argument that the standard methodology is fatally flawed, calling its position "sour grapes," and an end-around that would cause the process to lose neutrality and predictability.[54] It then concludes that the regulation is valid and moves on to the issue that it believes this appeal "begins and ends with"—is the standard methodology subject to an exception or waiver. If no, end of story and decision below affirmed.[55] It took the same approach at oral argument.

But while I find the two views of the regulatory language intriguing, 1 disagree that this is the key issue raised in this appeal. That issue is instead whether the regulation, read as the Commissioner did, is consistent with the statute. And the State has at no time explained how a method that fails to take into account an increasing rate of surgical procedures satisfies a statute that commands issuance of a CON "if the availability or quality of existing...resources is less than the current or projected requirement...to maintain the good health" of Alaskans.[56] While consistency and objectivity are laudable goals for an administrative agency,

[51] *Id. See also* Ae. br. at 16.
[52] Ae. br. at 17, citing *Interior Alaska Airboat Ass'n v. State Board of Game,* 18 P.3d 686, 689 (Alaska 2001).
[53] Ae. br. at 19.
[54] Ae. br. at 21.
[55] Ae. br. at 22.
[56] AS 18.07.04 1

the main idea is to serve the statute, to get the job done. The mathematical argument here is not complex, and if the regulation needs to be rewritten to meet conditions on the ground, then this will have to be done. Having adopted all of the findings made by the ALJ,[57] the Department cannot defend its regulation without showing that it yields a result that is consistent with the law as written by the legislature. It has not even attempted to do that in this case.

The Department is entitled to deference on the interpretation of its regulation, and it has determined that what appears to be a relief valve in 7 AAC 07.025(b) is unavailing to the JV. But in closing this door, it has left itself open to the argument that the regulation is not consistent with the statute. The goal is to predict health care needs,[58] and the regulation as construed fails to do this under the facts of this case. Based on the uncontested evidence accepted by the Commission, the JV is entitled to a certificate of need.

Conclusion.

The parties also litigated the question of whether, if the JV prevailed, it could "shell in" another two suites for possible use later.[59] It appears that this matter was settled at oral argument. The JV recognizes that a CON is required to construct surgery suites,[60] and that it cannot be heard to argue estoppel or waiver of some sort if it builds space ultimately rejected in a future application. It further recognizes that it can't argue that if the additional cost to convert the space to an

[57] R. 51, Ae. br. at 11.
[58] Ae. br. at 20.
[59] At. br. at 40-42, Ae. br. at 30-33, Reply at 18-20.
[60] R. 208.

operating room is less than the $1.2 million, or whatever threshold is applicable at the time, that it would not require a CON to add two more suites. With the agreement that it will have to re-apply should it seek to convert the space, it appears that the parties no longer have any dispute in this regard.

The Commissioner's decision is reversed and remanded with instructions to grant the certificate of need.

Dated 7/2/08 Fred Torrisi, Judge

I certify that on 7/2/08
a copy of this document was sent to
the attorneys of record or other:

Peter Gruenstein
Peter Maassen
Stacie Kraly

JM, Clerk

BEFORE THE STATE OF ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL FROM THE COMMISSIONER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

In the Matter of the South Anchorage
Ambulatory Surgery Center Joint Venture — OAH No. 06-0152-DHS

DECISION

This matter is back before me following return to the administrative law judge under AS 44.64.060(e)(2) and remand to the Department of Health and Social Services' certificate of need program staff under my July 5, 2007 Decision and Order. Having considered the staff's report filed on October 5, 2007, and in light of the September 14, 2007 stipulation of the parties to the effect that the recalculation of need ordered by me on July 5, 2007, would have no effect on my decision, I hereby enter a final decision in this matter.

The final decision in this matter consists of (1) the May 24, 2007 proposed decision prepared by the administrative law judge, as modified by my July 5, 2007 Decision and Order; (2) my July 5, 2007 Decision and Order; and (3) this document. For the reasons stated in those documents, I affirm my January 19, 2006 denial of the South Anchorage Ambulatory Surgery Center Joint Venture's May 5, 2005 application for a certificate of need.

Pursuant to AS 44.62.520(a)(2), my final decision takes effect immediately.

DATED this 5th day of October, 2007.

By: Karleen Jackson, Commissioner
Department of Health and Social Services

BEFORE THE STATE OF ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL FROM THE COMMISSIONER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

In the Matter of the South Anchorage
Ambulatory Surgery Center Joint Venture — OAH No. 06-0152-DHS

NOTICE TRANSMITTING COMMISSIONER'S DECISION

Attached is the decision by the Commissioner of the Department of Health and Social Services in this matter. The decision includes a remand to department staff. Though the remand is effective immediately, under AS 44.62.520(a)(3) the effectiveness of the decision as a whole is stayed until **October 13, 2007.** Unless the commissioner issues a different final decision and order following from the remand prior to October 13, 2007, the attached decision and order will become final on that date, at which point the parties' rights to request reconsideration by filing a petition under AS 44.62.540 and to appeal to the superior court under AS 44.62.560 will attach, regardless of whether an additional notice concerning finality of the decision and order is distributed.

Further filings in this matter, including the report required under the remand, and any petition for reconsideration must be sent to the following address:

Office of Administrative Hearings
Attn. Commissioner of Dept. of Health & Social Services
P.O. Box 110231
Juneau, Alaska 99811-0231

At the same time, the filing party must send a copy of the filing or petition to the opposing party's legal counsel.

DATED this 5th day of July, 2007.

By: Neil Roberts
Office of Administrative Hearings

The undersigned certifies that this date an exact copy of the foregoing was provided to the following individuals: (via e-mail, hard copy to follow by 1st class mail)

Peter Gruenstein
Stacie Kraly, AAG
S. Rose
Elmer Lindstrom (Courtesy copy)

7/5/07

BEFORE THE STATE OF ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL FROM THE COMMISSIONER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

In the Matter of the South Anchorage
Ambulatory Surgery Center Joint Venture — OAH No. 06-0152-DHS

DECISION AND ORDER

Pursuant to AS 44.64.060(e)(2)(3) & (5), I enter the following decision and order in the matter of the South Anchorage Ambulatory Surgery Center Joint Venture's appeal of my previous denial of its application for a certificate of need:

(1) the findings and conclusions in the May 24, 2007 proposed decision and order are hereby adopted, except as provided in (2) and (3) below;

(2) the conclusion in part III.B.2.i of the proposed decision and order that an exception can be allowed under 7 AAC 07.025 to use of the standard methodology for calculating need for general surgery services, and the interpretation of 7 AAC 07.025(b) embodied in that conclusion, are rejected for the reasons specified below;

(3) the conclusion in part III.B.3 of the proposed decision and order that a remand to the department's certificate of need staff is not the best remedy in this case is rejected for the reasons below;

(4) this matter is remanded to the department's certificate of need staff, which shall

(a) recalculate the need for additional general surgery operating rooms using the standard methodology but excluding from both the supply and demand projections such operating rooms, and the data on procedures performed in those rooms, as are unsuitable for general surgery,

(b) collect such additional information on existing and authorized future operating rooms as is necessary to perform the recalculation of need,

(c) evaluate whether one or more methodologies (including a trend analysis) other than the standard methodology would predict future need for general surgery services as well or better than the standard methodology such that it/they should be added to the approved methodologies in the *Alaska Certificate of Need Review Standards and Methodologies* document, and

(d) report to me in writing within 90 days after issuance of this decision and order the results of the recalculation and evaluation, and include recommendations on whether

(i) the joint venture's application to construct an ambulatory surgery center in South Anchorage should be approved in light of the recalculation using the standard methodology,

(ii) other methodologies should be approved for determining future need for general surgery services, and

(iii) the department's regulation would have to be amended (and if so, how) to allow use of such other methodologies in general and with regard to the joint venture's application;

(5) if within 45 days after issuance of this decision and order the department's certificate of need staff determines that the level of cooperation from facilities is insufficient to determine whether those facilities' operating rooms are suitable for general surgery, this matter is returned to the administrative law judge under AS 44.64.060(e)(2) for the limited purpose of issuing subpoenas and, if necessary, conducting a supplemental hearing to gather necessary information from uncooperative facilities and make appropriate findings;

(6) this decision and order shall become final for all purposes, including further appeals, 100 days after its issuance if I have not by then issued a final decision on the staff's recommendation required by (4)(d) above.

Department's Intent Regarding Exceptions Under 7 AAC 07.025. In adopting the exception language in 7 AAC 07.025(b), the department did not intend to allow exceptions to methodologies prescribed in the December 9, 2005 *Alaska Certificate of Need Review Standards and Methodologies* document incorporated by reference in the regulation. The text of the exceptions regulation itself (7 AAC 07.025(b)) allows exceptions only to "standards." Though the "Review Standards" paragraph under the General Surgery Services subpart, read literally, may suggest that the prescribed methodology is part of the standard, and thus that an exception to it can be made, the department's intent was and is to use (and require applicants to use) the prescribed methodology without exception.

The incorporated Standards and Methodologies document presently contains only one methodology for determining need for general surgery services. Over time, more methodologies

might be authorized for this or other service categories. To construe methodologies as indistinguishable from standards would be inconsistent with the possibility of multiple methodologies for a single standard. Use of the word "methodology" in the "Review Standards" paragraph, and even seemingly interchangeable use of words like "standards," "methodologies" and "considerations" elsewhere in the document, should not be allowed to thwart the department's intent. The Standards and Methodologies document was written by non-lawyers, for non-lawyers. Unlike the language of the 7 AAC 07 regulations themselves, the language of the incorporated technical document was not subjected to the same rigor as is applied to review of proposed regulations.

For these reasons, I conclude that the "Review Standard" in the General Surgery Services section of the Standards and Methodologies document does not itself contain a "methodology" for which a 7 AAC 07.025(b) exception can be allowed. Rather, the methodology prescribed under the heading "Review Methodology" (the so-called "standard methodology") is the only methodology presently available for use in determining need for general surgery services.

Remand on Suitability of Operating Rooms for General Surgery. The evidence brought out during the hearing showed that some of the operating rooms included in the staffs calculation of need are not suitable for general surgery. For instance, while an endoscopic procedure could be performed in any class of operating room, a room designed specifically for endoscopic procedures may be too small or ill-equipped for many other general surgery procedures. The record developed by the parties through the hearing process, however, did not provide all of the information needed to definitively rule in or out each of the operating rooms staff included in its calculations.

The proposed decision concluded that a remand to answer such questions would not provide a better remedy than allowing a 7 AAC 07.025(b) exception to the methodology. Since I have rejected the proposed decision's conclusion that such an exception is available, I am remanding this matter to the certificate of need staff to recalculate projected need with the unsuitable operating rooms excluded from the calculation on both the supply and demand sides. That is, if a particular operating room is found to be too small or otherwise unsuitable for general surgery, it will not be counted in the projection of future capacity and the number of procedures performed in that room during the three preceding years will not be counted when projecting future demand for surgery services.

The record shows that depositions were taken from representatives of several facilities to gather facts that might bear upon the suitability of the rooms at those facilities for general surgery procedures, but that some facilities may not have cooperated in the hearing-related information gathering effort. The department's certificate of need staff is instructed to try to work with facilities that previously have been non-responsive to requests for information, in an effort to fill information gaps. Facilities that do not cooperate may risk being barred from challenging certificate of need decisions with which they disagree.[1] If cooperation is not forthcoming within 45 days from the date of this order, staff is instructed to inform the administrative law judge and the joint venture of the need to resort to the additional proceedings described in paragraph (5) above.

DATED this 5th day of July, 2007.

By: Karleen Jackson, Commissioner
Department of Health and Social Services

The undersigned certifies that this date an exact copy of the foregoing was provided to the following individuals: (via e-mail, hard copy to follow by 1st class mail)

Peter Gruenstein
Stacie Kraly, AAG
S. Rose
Elmer Lindstrom (Courtesy copy)

7/5/07

[1] If a person does not meaningfully participate in the administrative processes leading to an agency authorization of an activity, that person may be barred from objecting to the agency's authorization. *See, e.g., Trustees for Alaska v. State,* 865 P.2d 745, 748 (Alaska 1993) (citing the U.S. Supreme Court's meaningful participation rule from *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519 (1978) when discussing whether interest group could raise an issue before the court).

BEFORE THE STATE OF ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL FROM THE COMMISSIONER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

In the Matter of the South Anchorage
Ambulatory Surgery Center Joint Venture[1] OAH No. 06-0152-DHS

DECISION AND ORDER

I. Introduction

The South Anchorage Ambulatory Surgery Center joint venture ("joint venture") appealed a decision by the Commissioner of the Department of Health and Social Services ("department") denying the joint venture's application for a certificate of need to construct six surgery suites—four complete suites and two shelled-in suites to be completed later. The denial was based on a conclusion by the department's certificate of need staff that future need for the suites during the planning horizon (i.e., five years out from proposed project completion) had not been demonstrated under the standard methodology for calculating need. Evidence in the agency record, as supplemented through the adjudicatory hearing process, shows that more likely than not a need for 3.5 suites will exist, and that without additional suites being added to the supply the availability and quality of medical care could suffer. Accordingly, the joint venture's application should be approved as to the four suites intended to be completed in the initial phase of the project, but conditions should be placed on that approval requiring the joint venture to demonstrate need for additional suites before it expends funds to complete the proposed shelled-in suites.

II. Facts

A. THE APPLICATION

On May 5, 2005, the joint venture applied for a certificate of need to construct an ambulatory surgery center (ASC) in South Anchorage.[2] As proposed, the ASC would consist of

[1] Prior orders and notices in this case were captioned as "In the Matter of Providence Health System Alaska." The caption has been changed to reflect the fact that the South Anchorage facility is proposed as a joint venture between Providence Health System Alaska and several physicians, including some doing business as Advanced Pain Centers of Alaska. *See* May 2005 Certificate of Need Application for the Operation of an Ambulatory Surgery Center (hereinafter "2005 CON Application") at p. 3 (Agency Rec. 7); August 15, 2006 Testimony of Thomas Vasileff, M.D. ("Vasileff Testimony") (describing the make up of the joint venture).

[2] May 5, 2005 Letter from Wolf to Pierce (Agency Rec. 143) (transmitting application); 2005 CON Application at p. ii (Agency Rec. 2). The application was submitted following a determination by the department's certificate of need staff that the proposed ASC would require a certificate of need due to the nature of the proposed facility and its expected cost. *See* March 7, 2005 Letter from Pierce to Wolf (Agency Rec. 144).

six operating suites.[3] The application calls for four operating suites to be fully functional upon opening of the ASC and the remaining two to be "shelled in" but not functional until 2009.[4]

The joint venture's application included a detailed "Demonstration of Need" section.[5] The application asserted that in 2004 the fourteen general operating rooms at Providence Alaska Medical Center "ran at 90 percent capacity, based on 94,248 minutes per room."[6] The joint venture used minutes-per-room to calculate capacity because the department's then-draft guidelines set operating room capacity in terms of minutes used.[7] Using the total minutes per year for the fourteen general operating rooms from the five-year period 2000-2004, the joint venture projected a demand "growth rate for the next 5 years" (2005-2009) for the fourteen operating rooms of 1.47 percent per year.[8]

The application's "Demonstration of Need" went on to illustrate in Table G that addition of the four proposed ASC suites, operating at 65% of capacity, to the supply would reduce the demand on the fourteen Providence general operating rooms to 76% of capacity.[9] It also spoke to the desire of physicians to be able to get more blocks of surgical time, to the increased efficiencies that might be obtained with the addition of "an off-campus" ASC, and to the increase in minutes devoted to outpatient pain management procedures.[10] Finally, it presented a great deal of information on the population the joint venturers expect would be served by the ASC.[11]

The application did not address the availability of facilities other than Providence Alaska Medical Center to serve the population sought to be served by the proposed ASC.[12] It also did not differentiate between types of procedures, other than by presenting the minutes used data in

[3] *Id.* at pp. ii & 3 (Agency Rec. 2 & 7).

[4] *Id.* at pp. ii, 4 & 17 (Agency Rec. 2, 8 & 21).

[5] *See id.* at pp. 8-19 (Agency Rec. 12-23).

[6] *Id.* at p. 8 (Agency Rec. 12). Providence Alaska Medical Center also has two dedicated operating rooms (one for cardiac surgery and one for cystoscopy) that were not included in the need demonstration calculations. *Id.* at pp. 8-9 (Agency Rec. 12-13).

[7] *Id.* at p. 9 (Agency Rec. 13).

[8] 2005 CON Application at p. 9 (Agency Rec. 13). The 1.47% per year increase is an average for the five-year period 2000-2004. *Id.* (dividing a 7.35% overall increase for those years by five to yield a 1.47% average). The increase over that period was not steady from year to year, but the figures show a significant increase (more than 5% per year) in minutes demanded between 2000 and 2002, a slight decrease for 2003 and a small (less than 2%) increase for 2004. *Compare* Total Minutes in Table F for each year *with* Total Minutes in Table F for the succeeding year (showing increases of 5.8% between 2000 and 2001, of 5.5% between 2001 and 2002, a decrease of slightly more than 1,000 minutes between 2002 and 2003, and a 1.8% increase between 2003 and 2004).

[9] 2005 CON Application at p. 10 (Agency Rec. 14).

[10] *Id.* at pp. 11-12 (Agency Rec. 15-16).

[11] *Id.* at pp. 12-17 (Agency Rec. 16-21) (narrative and tables on Anchorage and Alaska population; age, race and gender of the populations; and Providence Alaska Medical Center's patient demographics).

[12] *See generally* 2005 CON Application at pp. 8-19 (Agency Rec. 12-23).

terms of inpatient and outpatient procedures.[13] The application did not ask the department to approve any kind of exception or waive any certificate of need approval requirement.[14]

B. THE REVIEW PROCESS

The department's certificate of need staff asked the joint venture to provide additional information, including "a list of other surgery facilities that provide pain management services in Anchorage" and the number of pain management procedures and patients for 2002-2004 associated with the surgery minutes data for the Advanced Pain Centers of Alaska physicians.[15] The joint venture complied and the application was deemed complete as of June 30, 2005.[16]

In responding to the staff's request for additional information, the joint venture identified five facilities as providing pain management in Anchorage: Health South; Alaska Regional Hospital; Providence Alaska Medical Center; Alaska Spine Center; and Alaska Spine Institute.[17] It also indicated that the proposed ASC would "provide pain management and orthopedic services" and that the "[p]hysicians providing services will be members of the joint venture."[18]

As part of the review process, the department solicited public comments on the joint venture's proposal and held a public hearing.[19]

The certificate of need staff examined the need-related (i.e., supply and demand) data under "the standard in [the department's] review criteria" and also under an "alternative method that uses the trend (linear regression analysis based on [the] four most recent years' experience) ...."[20] The first is referred to as the "standard methodology" and the second as the "trend analysis."

Under the standard methodology, need for general surgery suites is calculated using prescribed formulas in which projected population and general surgery use rates are the variables

[14] *See generally* 2005 CON Application (Agency Rec. 1-35).

[15] May 25, 2005 Letter from Pierce to Wolf (Agency Rec. 142); *also* June 10, 2005 Letter from Wolf to Pierce at p. 1 (Agency Rec. 78) (repeating staff's questions when responding to them).

[16] *Id.;* June 30, 2006 Letter from Pierce to Wolf at p. 1 (Agency Rec. 72).

[17] June 10, 2006 Letter from Wolf to Pierce at p. 1 (Agency Rec. 72).

[18] *Id.* at p. 2 (Agency Rec. 79).

[19] Notice of Public Comment for Certificate of Need Applications to Build Ambulatory Surgery Centers in Anchorage (Agency Rec. 150). The notice covered the joint venture's proposal and a separate one from Doctors Surgery Center.

[20] December 30, 2005 Email from Rarig to Pierce (Agency Rec. 159); *also* July 28, 2006 Deposition Testimony of Alice Rarig ("Rarig Depo.") at pp. 103-105 (explaining that the trend analysis was used, in addition to ihe standard methodology, in anticipation of the applicant's arguments about increasing demand); August 15-16, 2006 Hearing Testimony of Alice Rarig ("Rarig Testimony").

that dictate whether anticipated demand for surgery services might outpace supply.[21] The general surgery use rate is an average from the three preceding years and remains static throughout the projection. Projected future growth in surgery demand is solely a function of growth in overall population. The standard methodology, therefore, does not take into account whether other factors, such as an aging population or changed approaches to medical care, cause the three-year average to underestimate likely future rate of usage for surgery services.[22] The trend analysis projects the general surgery use rates in a manner that takes account of historic data suggesting a positive (upward) trend in use.[23]

To forecast supply, the staff gathered data on "surgeries" performed at following facilities:

- Providence Alaska Medical Center;
- Alaska Regional Hospital;
- Alaska Surgery Center (Health South);
- Geneva Woods;
- Alaska Spine Center;
- Alaska Spine Institute;
- Alaska Digestive Center;
- Alaska (or Anchorage) Endoscopy Center;
- Alaska Native Medical Center; and
- Valley Hospital.[24]

[21] *Alaska Certificate of Need Review Standards and Methodologies* at pp. 30-31 (Dec. 9, 2005) (prescribing a three-step process that determines projected caseload as a product of projected population and general surgery use rate (cases per 1,000 persons) and calculates future need for operating rooms by dividing the projected caseload by an assumed number of surgical cases each operating room can handle).

[22] *Alaska Certificate of Need Review Standards and Methodologies* at p. 30 (Dec. 9, 2005) (defining general surgery use rate "as the average number of general surgery cases provided over the preceding three years per 1,000 (persons)); August 16, 2006 Testimony of Oliver Goldsmith, Ph.D. ("Goldsmith Testimony") (contrasting the standard methodology with the trend analysis).

[23] Goldsmith Testimony (discussing the trend analysis and concluding that it is a more appropriate approach when historical data suggests a positive trend, the observed positive trend is logical and consistent with what is happening—e.g., an aging population requiring more surgeries, and there is no reason to believe the historical patterns are likely to change).

[24] Untitled Spreadsheets (Agency Rec. 161-165, 178-181 & 190-192) & Valley Hospital Surgery Data Utilization Data (Agency Rec. 168-169). The spreadsheets refer to an "Alaska Endoscopy Center," but elsewhere the record speaks of an "Anchorage Endoscopy Center." *E.g.,* Agency Rec. 239; Rarig Depo. at pp. 18-19. These appear to be one and the same facilities.

During the review, the staff made an effort to differentiate between inpatient and outpatient procedures that were endoscopic or were performed in endoscopy rooms.[25] Staff included some endoscopy suites in the projection of supply in the belief that those suites were available for other procedures as well.[26] In its final need calculation, staff projected operating room supply figures of 27 combined inpatient/outpatient rooms and 21 outpatient rooms through 2011.[27]

Over the course of a few days at the end of December 2005, the staff reviewed evolving data and ran need calculations three times, using the standard methodology or the trend analysis, or both.[28] Each time, the results projected no need for additional surgery capacity until 2010 or 2011.[29] For the critical year 2011, the standard methodology showed a surplus of 7.4 suites but the trend analysis showed a need for 3.5 suites.[30]

C. THE STAFF RECOMMENDATION

The staff ultimately recommended that the commissioner deny the joint venture's application because, according to the staff, excess surgery capacity existed and the trends

[25] *See* December 27, 2005 Email from Rarig to Pierce and table following titled "Bartlett Regional Hospital" (Agency Rec. 205-206) (asking about whether the Bartlett endoscopies took place "in the endoscopy room" and listing procedure totals for five years according to whether they were endoscopy procedures of other surgery); *also* Request for Surgery Statistics in Support of the Alaska Certificate of Need Program for Valley Hospital (Agency Rec. 202) (asking respondent to list the number of endoscopy procedures if not included elsewhere—presumably in the columns used to report inpatient and outpatient procedures).

[26] Rarig Depo. at pp. 38-46.

[27] Anchorage Area Demand for Operating Suites Projected to 2010 [sic] - Model 1 (Agency Rec. 160). *See also* Untitled spreadsheet attached as Rarig Depo. Exhibit 2A (identifying 14 surgery suites at Providence Alaska Medical Center and 10 at Alaska Regional Hospital, and 21 to 23 outpatient suites at seven or eight facilities); Untitled table attached as Rarig Depo. Exhibit 2 (identifying 21 outpatient "operating suites" at seven "ASC Facilities,]" specifically: Health South (6 suites); Geneva Woods (2 suites); Alaska Spine Center (3 suites); Alaska Spine Institute (4 suites); Alaska Digestive Center (2 suites); Alaska Endoscopy Center (2 suites); and Valley/Susitna Center (2 suites)). Though the spreadsheet at Rarig Depo. Exhibit 2A suggests that Valley Hospital and Susitna Center each has two suites, the deposition testimony of Ms. Rarig and other documents show that staff counted those two facilities as collectively supplying two suites together.

[28] December 29, 2005 2:37 p.m. Email from Rarig to Pierce and accompanying Anchorage Area Demand for Operating Suites Projected to 2010 [sic] - Model 1 (trend analysis only) (Agency Rec. 185-186); December 29, 2005 4:22 p.m. Email from Rarig to Pierce and accompanying Anchorage Area Demand for Operating Suites Projected to 2010 [sic] - Model 1 (trend analysis; missing Valley Hospital data) (Agency Rec. 173-174); December 30, 2005 Email from Rarig to Pierce and accompanying Anchorage Area Demand for Operating Suites Projected to 2010 [sic] - Model 1 (using both standard methodology and trend analysis) (Agency Rec. 159-160).

[29] Three versions of Anchorage Area Demand for Operating Suites Projected to 2010 [sic] - Model 1 (Agency Rec. 160, 174 & 186) (projecting a need in 2010 and 2011 of 0.02, 0.18, 1.85, 1.89, 2.25, and 4.09 additional operating rooms).

[30] *See Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. 10 (January 6, 2005) (Agency Rec. 242).

suggested that no additional surgery suites would be needed until 2011.[31] The staff's explanation to the commissioner was as follows:

> There are currently 26 hospital based surgery suites in the Anchorage/Mat-Su Valley region that serve both inpatients and outpatients. The capacity is expected to increase to 27 in 2006 as the one additional surgery suite approved in the Mat-Su Valley certificate of need application comes on line. The number of freestanding ambulatory surgery center (ASC) suites serving the region increased from 15 to 21 in 2004. Applying the new need methodology from review standards filed December 9, 2005 to the data available indicates that there are about 10 surgery suites more than needed to meet the "target use rate" in 2005. Although population growth over the next five years is expected to result in more procedures and use some of that available capacity, both the adopted standard methodology and a more liberal trend-based estimation procedure consistent with the patterns relied upon by the applicants indicate that the available capacity is sufficient to meet increased demand for the next five years. See appendices for calculations.[32]

The appendices show that in calculating surgery capacity, the staff did not include surgery suites at the Alaska Native Medical Center, Elmendorf Hospital, Alaska Women's Center, and Pacific Cataract and Laser Institute.[33] Staff did include data on Anchorage Endoscopy Center, reasoning that "its services overlap with those provided in general surgery suites."[34] It also "included as available resources" the Mat-Su Valley Hospital facilities.[35]

The appendices also show that for user population staff subtracted the native population but not military populations, because the latter could use either military or civilian medical facilities.[36] Staff included, in addition to the Anchorage and Mat-Su populations, the Valdez-

[31] January 6, 2006 Memorandum from Rarig to Commissioner Jackson (Agency Rec. 70), stating the following recommendation: "It is recommended that a Certificate of Need be denied. There is currently excess surgery capacity of about 10 surgery suites in the region. Based on current data and recent trends, there will be no need for additional suites until 2011. At that time, need is forecast for only two suites." *Accord Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. ii (January 6, 2005) (Agency Rec. 228) (recommending denial and reasoning that "the adopted standard methodology indicates that the available capacity is sufficient to meet increased demand for the next five years [and a] trend-based estimation procedure … suggests that existing suites would on average meet the 'target use rate' in four years (2010)").

[32] *Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. ii (January 6, 2005) (Agency Rec. 228).

[33] *Id.* at p. 8 (Agency Rec. 239) (explaining that Alaska Women's Center was excluded because the department did not have data on the volume of services for any period more recent than 1994-1996).

[34] *Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. 8 (January 6, 2006) (Agency Rec. 239) (also attached as Exhibit 1 to Rarig Depo.).

[35] *Id.*

[36] *Id.* The joint venture has not taken issue with the exclusion of the native population which, like the military populations, could choose to use facilities other than the Alaska Native Medical Center. Indeed, this appeal raised no issues concerning the population figures used.

Cordova Census Area population, reasoning that "routine surgeries travel to Anchorage" because "the small rural hospitals in Valdez and Cordova appear to be handling only emergency surgery ..."[37]

With this data, staff projected demand for operating suites to 2011 for the "Greater Anchorage Service Area," noting that "'capacity' in rural areas is not truly available to the greater Anchorage population...[38] Applying a use rate of 109.69 surgeries per thousand population and projected population ranging from 345,902.0 in 2007 to 370,031.1 in 2011, staff projected demand using the standard methodology at 40,588.19 surgeries in 2011.[39] Starting from the same 109.69 per thousand population use rate, but applying an alternative method "taking into account [an] increasing trend" in population growth, staff projected demand of 53,746.4 surgeries in 2011.[40] Using the standard methodology, staff projected an increase of almost 12,000 surgeries per year by 2011, compared to the last year (2004) for which it had actual data.[41] The alternative method (trend analysis) projected more than 13,000 additional surgeries over the standard methodology, for an aggregate increase of about 25,000 surgeries compared to the 2004 data.

D. THE DECISION

On January 19, 2006, the commissioner denied the joint venture's application for a certificate of need, concluding that the application "has not met the provisions of A.S. 18.07.031¬111 and 7 AAC 07.010-130 to the satisfaction of the department ...,"[42] The rationale for the denial was stated as follows:

> There is currently excess surgery capacity in the region, and based on current data and recent trends, capacity is sufficient to meet increased demand for the next five years.[43]

[37] *Id.*

[38] *Id.* at p. 10 (Agency Rec. 241).

[39] *Id.*

[40] *Id.* Appendix C of the staff analysis recites in several places that the increase in population growth used for the projections was precisely or was "about" 1.6%. The figures in column "B" of the first Appendix C table, however, increase by approximately 7.7% from year to year. This decision expresses no opinion and makes no finding about whether 1.6% or 1.7% was the correct population increase to use for the staff's projections at the time those projections were made.

[41] *Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. 10 (January 6, 2005) (Agency Rec. 241).

[42] January 19, 2006 Letter from Commissioner Jackson to Kuykendall at p. 1 (Agency Rec. 68).

[43] *Id.; accord* January 29, 2006 Notice of Commissioner's Decision on an Application for a Certificate of Need (Agency Rec. 149) (stating, in the Summary of Decision section: "There is currently excess surgery capacity of approximately 8 surgery suites in the region. Based on current data and recent trends, available capacity is sufficient to meet increased demand for the next five years").

E. THE APPEAL

The joint venture appealed.[44] An evidentiary hearing was held in August 2006. Prior to the hearing, deposition testimony was taken from nine witnesses.[45] The parties agreed that the deposition testimony would be made part of the record. The deposition and hearing testimony, together with the documentary exhibits admitted into evidence at the hearing or as part of the depositions, shows that more likely than not the following facts are true:

- The number of surgical procedures in the area likely to be serviced by the proposed ASC has been increasing and likely will continue to increase;[46]
- When an increasing trend exists in the demand for surgical procedures, the linear regression (or trend) analysis is a more reliable predictor of future need than the standard methodology;[47]
- Using the standard methodology, existing and already approved surgery suites will have remaining capacity in 2011, but under the trend analysis, an additional 3.5 surgery suites will be needed by 2011;[48]
- A dedicated endoscopy suite typically will be too small, and possibly not sanitary enough, for use in general surgeries such as orthopedic procedures, which require maneuvering room for large pieces of equipment and may involve open wounds;[49]

[44] February 15, 2006 Letter from Humphrey-Barnett to Commissioner Jackson (Agency Rec. 67).

[45] Six of the nine were record depositions taken from staff of ambulatory surgery centers to gather information on existing centers. *See generally* Transcripts for Depositions of Nancy Stover, Tammy Ham, Orville Johnson, Lesa Johnson, Bruce Jayne, and Vicki Crumpton. Appellant's Exhibit lsummarizes in table form some of the information provided by these depositions.

The other three were depositions of department staff who worked on the certificate of need review. *See generally* Transcripts for Depositions of Alice Rarig, David Pierce and Shelbert Larson.

[46] *See* "Trend in Surgery Use Rates, Anchorage-Mat-Su Area 2002-2004" and "Projections of Total Surgeries for Anchorage-Mat-Su Area to 2011" graphs included as part of Department's Exhibit E.

[47] Goldsmith Testimony; Rarig Testimony. Drs. Goldsmith and Rarig were in agreement that a methodology such as the standard methodology, which uses a past average to project a future number, is not "statistically invalid," but they also acknowledged that when existing data shows a trend, the trend is probably a better predictor of the future than the average. Dr. Goldsmith opined that using the average, instead of the trend, would be a mistake if the historical data suggests a positive trend, the observed trend is logical and consistent with what is occurring at the time, and there is no reason to believe the trend is likely to change).

[48] *Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. 10 (January 6, 2005) (Agency Rec. 242).

[49] Vasileff Testimony (opining that it is not the standard of care to use endoscopy rooms for orthopedic procedures); August 16, 2006 Testimony of Richard McEvoy, M.D. ("McEvoy Testimony") (explaining that at Providence endoscopies normally are done in a separate room that is not kept as clean as the general surgery suites and pointing out that orthopedic surgeons want the cleanest environment possible to minimize the risk of bone infections); August 17, 2006 Testimony of Gregory Polston, M.D. ("Polston Testimony") (explaining the need for large equipment and room to position patients for required examinations and treatment).

- At least one, and probably four but possibly six more, of the outpatient suites that were included in the staff's need calculation, on both the supply and demand side, are not suitable for use in all types of general surgery;[50]
- Some joint venture participants currently have trouble scheduling procedures when they or their patients desire, primarily because of the high demand for suites at Providence Alaska Medical Center and limited availability of outpatient suites;[51]
- Patients for whom an outpatient procedure is appropriate generally "do better" in an outpatient setting in that they spend less time waiting, experience less stress than in a hospital setting, find outpatient facilities to be more convenient, usually experience less overexposure to general anesthesia, and may suffer less exposure to risks such as from infection and other complications of delaying treatment or taking longer to complete procedures;[52]
- Some joint venture participants are committed to continuing to treat Medicare, Medicaid and indigent patients at the ASC;[53]

[50] The deposition testimony, as summarized in Appellant's Exhibit 1, shows that one of the Geneva Woods suites is a small (approximately 144 square feet) class A suite in which only local anesthesia can be used, and that the other Geneva Woods suite, both Alaska Digestive Center suites, and one of the Alaska Spine Center suites are all class B suites 320 square feet or smaller in size. Evidence on the size and class of Alaska Endoscopy Center's two suites was not produced, but testimony from Drs. Vasileff and Polston established that endoscopy suites typically are not suitable for some types of general surgery such as orthopedic procedures requiring large equipment and sanitary conditions. Thus, more likely than not the two Alaska Endoscopy Center suites, the two Alaska Digestive Center suites, as well as the too-small, class A suite at Geneva Woods are not suitable for all types of general surgery. Whether the other Geneva Woods suite (268 square feet, class B) and the smallest of the Alaska Spine Center suites (320 square feet, class B) are unsuitable for general surgery cannot be determined definitively from the record in this case.

[51] Vasileff Testimony (explaining that he presently does 80 percent of his surgeries in a combination suite at Providence Alaska Medical Center and cannot get as much block time as he would like at HealthSouth).

[52] Vasileff Testimony (explaining that it can take 50 percent longer to perform a procedure in a hospital surgery suite than in an outpatient suite due to the lack of specialization of the medical support team); Polston Testimony (stating that infection rates for outpatient procedures at ASCs appear to be lower than for hospital patients and observing that patients will chronic conditions are given lower priority at hospitals than trauma or other emergency matters); *also* McEvoy Testimony.

[53] Vasileff Testimony (stating that Medicare, Medicaid and Project Access patients will be treated at the proposed ASC). Through Project Access volunteer physicians provide care to indigent persons who do not qualify for health care under other programs. *Id.; also* McEvoy Testimony. Though Dr. Vasileff testified about the general expectations for the joint venture facility to be used to continue providing care to indigents and Medicare and Medicaid recipients, and Dr. McEvoy testified that his practice group provides lots of free medical service in conjunction with Providence Alaska Medical Center, such testimony is insufficient to establish that all participants in the joint venture will provide such care, but it does indicate that the medical care access needs of indigent persons will be addressed to some extent by practitioners using the proposed ASC. Dr. Polston testified that Medicare, Medicaid and charity patients have trouble getting care from some healthcare providers in the Anchorage area.

- The ASC's surgery suites will be suitable (though not necessarily available) for procedures other than the orthopedic and pain management procedures for which the joint venture wishes to use them.[54]

Following the hearing, the record was held open to allow the parties to file post-hearing briefs. After post-hearing briefs were filed, the joint venture moved to strike a portion of the department staff's argument.[55] The department staff opposed the motion.[56] The motion is, in effect, a partial reply to the department staff's post-hearing brief. It has been treated as such and the department staff's opposition has been treated as a surreply. The post-hearing briefs have been given due consideration and no part of the department staff's brief has been stricken.

III. Discussion

A certificate of need from the department is a prerequisite to making expenditures equal to or exceeding a threshold amount for construction of a health care facility.[58] An ambulatory surgical facility is a "health care facility" for purposes of the certification requirement.[59] The department must issue a certificate of need

> [i]f the availability and quality of existing health care resources or the accessibility to those resources is less than the current or projected requirements for health services required to maintain the good health of citizens of [Alaska].[60]

A certificate of need application must meet the applicable requirements of AS 18.07 and 7 AAC 07, as well as "meet the standards and use the methodologies set out in the department's [Standards and Methodologies] document ...."[61]

The decision denying the joint venture's application found insufficient "Documented Need" for the proposed additional ambulatory surgery suites under the Standards and

[54] *E.g.,* Polston Testimony (explaining that the joint venture would welcome other orthopedic surgeons and would hope to be able to develop the ASC so that it could accommodate others, but that availability of suites for other users would depend on how efficiently the venturers are able to operate).

[55] September 5, 2006 Motion to Strike.

[56] September 6, 2006 Opposition to Motion to Strike.

[57] The Motion to Strike is denied.

[58] AS 18.07.031(a)&(d) (requiring a certificate of need for expenditure of $1,000,000 or more, with the base $1,000,000 trigger increasing $50,000 each year, beginning July 1, 2005, until July 1, 2014).

[59] AS 18.07.111(8) (defining "health care facility" as including "a private, municipal, state, or federal ... ambulatory surgical facility").

[60] AS 18.07.041 (setting standard for issuing certificates of need for facilities other than nursing homes).

[61] 7 AAC 07.025(a) (incorporating the *Alaska Certificate of Need Review Standards and Methodologies* (Dec. 9. 2005) as the source for Standards and Methodologies that must be met by and used in the application).

Methodologies.[62] The joint venture disagreed on several grounds which collectively question whether the department was required by the statutory and regulatory standards to grant it a certificate of need because projected demand for surgery suites in Anchorage may be higher than the demand calculations on which the department based its denial. The joint venture also asserts that the commissioner has discretion to grant the certificate of need under the department's regulations, and should exercise that discretion to ameliorate the effect of questionable demand calculations and thereby better ensure that necessary health care services will be available.

This decision first addresses whether the joint venture's application should have been granted based on the record before the department at the time the application was denied. Next, this decision addresses whether the application can and should be granted in light of new information and arguments brought out during the adjudicatory hearing process.

A. THE DEPARTMENT DID NOT ERR IN DENYING THE JOINT VENTURE'S APPLICATION BASED ON THE RECORD BEFORE IT WHEN THE DENIAL DECISION WAS MADE.

Unless the applicant for a certificate of need "shows to the department's satisfaction that the availability, quality, or accessibility of existing healthcare services creates a barrier to services in the service area" the department is under no obligation to consider making an exception to the standards adopted by reference in 7 AAC 07.025(a).[63] Instead, it must enforce the requirement that an applicant "meet the standards and use the methodologies set out in the department's [Standards and Methodologies document]."[64] This is what the department did with respect to the determination of need, based on the information available to it at the time of the decision and the joint venture's showing in the application.

The Standards and Methodologies document prescribes a "formula to determine need for general surgery capacityf.]"[65] One component of that formula is "general surgery use rate" (or GSUR) which is "defined as the average number of general surgery cases provided over the

[62] *Review of Certificate of Need Application to Expand Ambulatory Surgery in Anchorage* at p. iii (January 6, 2005). "Documented Need" is one of six general review standards that were considered. The review document noted one other problem with a general review standard but recommended granting an exception. *Id.* (recommending exception to "Relationship to Applicable Plans" standard because "there are no state, local or regional plans that related to ambulatory surgery centers").

[63] 7 AAC 07.025(b) (requiring the department to recommend to the commissioner that an exception be made if the applicant makes the necessary showing).

[64] 7 AAC 07.025(a) (placing the burden on the applicant to meet the review standards and use the review methodologies in the department's document as a prerequisite to the commissioner approving the application for a certificate of need).

[65] *Alaska Certificate of Need Review Standards and Methodologies* at pp. 30-31 (Dec. 9, 2005).

preceding three years per 1,000 (persons)."[66] As such, the formula attempts to predict whether general surgery capacity will be sufficient to meet need five years in the future considering the average use rate for the three immediately preceding years but not any upward or downward trend in use rate that might be evident in the data for the three years, or for a longer period if such data is available. This is the core concern raised by the joint venture's appeal.

Though the department staff's analysis found more than sufficient capacity for the planning horizon using the three-year average use rate, it also showed that additional surgery capacity likely would be needed by 2011 if the increasing trend in GSUR continued. The staff nonetheless recommended that the application be denied because the joint venture had failed to demonstrate need for the proposed ASC suites using the methodology that includes a GSUR derived from the three-year average use rate. This recommendation was sound when made, and when acted upon by the commissioner, because the joint venture then had yet to make the case for allowing an exception under 7 AAC 07.025(b), to take account of the increasing trend in general surgery use rate.

B. THE DEPARTMENT HAS THE DISCRETION TO GRANT THE JOINT VENTURE'S APPLICATION BASED ON THE ADDITIONAL INFORMATION AND ARGUMENTS FROM THE HEARING.

1. Role of the adjudicatory hearing process

The department's certificate of need program is like other agencies' permit programs: it starts with an application from the project proponent, goes through a public review process in which public comment sometimes provides additional fact information, personal or expert opinion, or both, and culminates in an agency decision that can be appealed by an aggrieved party. Fact information and opinion offered through public comment or "testimony" at a public hearing usually is not taken under oath, but staff can consider such information and opinion, along with the information provided in the application materials and gathered through staff research, when making a recommendation to the commissioner.

The appeal process is different: testimony is taken under oath; opinions are subject to cross examination or other refutation; previously unidentified legal issues are raised for the first time because the rationale for the decision is now known. The oft-stated purpose of affording an aggrieved party the right to an agency-level appeal is to allow the executive branch

[66] *Id.* at p. 30.

decisionmaker an opportunity to correct errors while the matter remains with the executive branch. The term "errors" can be misleading, however.

Correcting "errors" aptly describes what occurs when the appeal reveals that the agency made a mistake of fact or law based on the record as it existed when the decision was made. When the adjudication allows the aggrieved party to bring in new facts or opinion to show that the decision certainly or arguably (in the exercise of discretion) should have been different, "error" is not a particularly apt term. If the adjudication process allows the aggrieved party to, in effect, supplement the record that was before the decisionmaker, and the supplemental information changes the result, it can hardly be said that the challenged decision was erroneous.

In sum, an adjudication that allows new information to come in through an evidentiary hearing is not simply about correcting "errors." It is about making the best decision possible at the executive branch level, irrespective of whether fault lies with the project proponent's application, the staff analysis, or the legal predicates for the decision, or whether no fault exists at all but a better informed exercise of discretion yields a different result.

Under some circumstances, an agency-level "appeal" will be just that—a pure appeal limited to challenging the decision on the existing record. When the "appeal" includes an evidentiary hearing component, however, the neutral adjudicator looks beyond the record that existed when the challenged decision was made, and exercises any discretion allowed to the final decisionmaker based on the full record, including the evidence and arguments brought out during the appeal.

By regulation, the department has established that an applicant "who is dissatisfied with … a decision of the commissioner to … deny … a certificate of need, is entitled to a hearing" if the applicant timely requests one.[67] The hearing must be conducted under the adjudication provisions of the Administrative Procedures Act (APA).[68] The APA adjudication provisions allow for evidentiary hearings.[69] Indeed, nothing about the APA adjudication provisions make them well suited to a pure, on-the-record appeal.[70] Nothing in the APA provisions or in the

[67] 7 AAC 07.080(a).

[68] 7 AAC 07.080(b) (providing that the hearings will be conducted "in accordance with AS 44.62.330 - 44.62.640"; those sections of AS 44.62 govern adjudications).

[69] *See* AS 44.62.410(b) (providing for witness participation); AS 44.62.430 (providing for subpoenas to compel witnesses to testify); AS 44.62.450(b) (including in the powers decisions on admission and exclusion of evidence); AS 44.62.460(a)-(d) (requiring oath taking for oral evidence, providing for the parties to examine and cross-examine witnesses, and exempting the hearing from the technical requirements of evidence but addressing admissibility of evidence and use of hearsay evidence); AS 44.62.470 (allowing for evidence by affidavit).

[70] *See generally* AS 44.62.330 - AS 44.62.640.

department's regulation referencing them suggests that a party aggrieved by a certificate of need decision cannot use the evidentiary hearing process afforded to the party to place before the final decisionmaker (i.e., the commissioner) facts to support an exception under 7 AAC 07.025(b).[71]

Ideally, a request and the accompanying showing of justification for an exception should not be left to the adjudicatory hearing process. The request and the showing should be made at the application stage. When, as here, however, the application was filed several months before the governing regulations were adopted, it is not surprising that some critical facts concerning the availability and quality of surgery suites were brought out through the adjudicatory hearing process rather than during the public hearing and associated application process. No one in this case has advocated that the commissioner should ignore facts brought out at the adjudicatory hearing stage, nor should she. To do so would have the effect of making a nullity out of the department's regulation that provides for an evidentiary-type adjudicatory hearing. Accordingly, the joint venture's request, made through the adjudicatory hearing process, for an exception under 7 AAC 07.025(b) must be given full and fair consideration.

2. *An exception to the standard to allow use of a different methodology is warranted in this case*

Ordinarily, an applicant for a certificate of need must "meet the standards and use the methodologies set out in the department's [Standards and Methodologies] document[.]"[72] Exceptions can be made, however,

> if the applicant shows to the department's satisfaction that the availability, quality, or accessibility of existing healthcare services creates an unreasonable barrier to services in the service area.[73]

What constitutes an "unreasonable barrier" remains undefined in the department's regulations. Additionally, the department staff has taken the position that exceptions can be made only to a "standard" and not to a "methodology."[74] Thus, it is necessary to determine whether an exception can be granted under 7 AAC 07.025(b) to allow the future need projection to take account of the

[71] Though 7 AAC 07.025(b) places the burden on the applicant to show that an exception is in order, it does not require that that demonstration be made at any particular point in the process.

[72] 7 AAC 07.025(a).

[73] 7 AAC 07.025(b).

[74] *See* September 1, 2006 Posthearing Brief (by counsel for staff) at p. 10 (asserting that "the regulation only allows for recommending an exception of [sic] a *standard,* not a *use methodology"); accord* August 17, 2006 Closing Argument (by counsel for staff).

increasing trend in general surgery use rate, and if so whether the joint venture has, though the hearing process, now demonstrated that absent the grant of such an exception an unreasonable barrier to healthcare services would be created.

i. Methodology as an inseparable part of the standard

When taken together, out of context from the Standards and Methodologies document, the phrases "exception to one or more of the standards" and "must ... meet the standards and use the methodologies" in 7 AAC 07.025 suggest that "standards" and "methodologies" are two different things, and that the department may allow an exception only to the thing called a "standard." In context with the Standards and Methodologies document incorporated in the regulation, however, the exception phrase cannot fairly be read so narrowly.

The formula using the three-year average use rate appears under the subheading "Review Methodology" in the part of the Standards and Methodologies document titled "VIII. Surgical Care: Review Standards and Methodology."[75] That part is divided into two subparts: "A. General Surgery Services" and "B. Open-heart Surgery."[76] Only the first subpart applies to the joint venture's proposal.

The phrase "general surgery" appears ten times in the Standards and Methodologies document: once in the table of contents reference to part VIII, subpart A, and the other nine times in that subpart. Nowhere else in the entire document has the department undertaken to establish "standards" for general surgery services for which a 7 AAC 07.025(b) exception could be allowed.

Subpart A includes two subheadings, one "Review Standards" and the other "Review Methodology." At first glance, these may appear to be separate things: one "standards" and the other a "methodology." When one looks past the subheadings, to the textual content, it becomes indisputable that the "Review Standards" are nothing without the "Review Methodology" incorporated by reference in the first of two "Review Standards" paragraphs. In its entirety, the text under the first "Review Standards" paragraph reads as follows:

> After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standard in its evaluation of an application for a certificate of need for general surgery services: **<u>The</u>**

75 *Alaska Certificate of Need Review Standards and Methodologies* at p. 30 (Dec. 9, 2005)
76 *Id.* at pp. 30-33.

<u>applicant demonstrates need in accordance with the following review methodology.</u>[77]

(Emphasis added.)

The only "standard" in the general surgery services Review Standards is that the applicant must demonstrate need using the methodology set out below the "standard." The standard is meaningless without the methodology it incorporates and the methodology would be useless if not incorporated in the standard. They are inseparable. The department, therefore, can allow an exception under 7 AAC 07.025(b) to permit the demonstration of need to be based on another methodology—e.g., one using the trend analysis. To conclude otherwise would be to say that the Standards and Methodologies document contains no standards whatsoever, within the meaning of 7 AAC 07.025, for general surgery services. That would leave the department in the position of having to enforce use of the standard methodology in all cases, no matter how strong the showing that another methodology is a better predictor of the future under the circumstances in question, or granting a 7 AAC 07.025(b) exception to the standard, freeing the applicant from the burden of demonstrating need at all, if the 025(b) test for an exception is met.

ii. <u>The joint venture's showing of unreasonable barrier</u>

An exception to a standard is allowed only if the applicant shows that the availability, or the quality, or the accessibility of existing services "creates an unreasonable barrier to services in the service area."[78] Certainly, the joint venture's application did not make such a showing. In Section V, the application briefly addresses quality concerns.[79] The focus was on what the proposed ASC could do to ensure quality of care at the facility, not how having the additional surgery suites up and running would affect patient care in the service area generally.[80]

Through the evidence presented during the adjudicatory hearing process, however, the joint venture showed that within the subset of area patients being serviced by the venture partners already, the following barriers exist:

[77] *Id.* at p. 30. The second paragraph under "Review Standards" excludes certain kinds of procedures (i.e., open-heart surgery, birth-related surgery, and eye surgery) from the standards applicable to general surgery services. *Id.*

[78] 7 AAC 07.025(b).

[79] *See* 2005 CON Application at pp. 20-22 (Agency Rec. 24-26).

[80] *Id.*

- Scheduling for routine procedures can be difficult, especially insofar as block time is in short supply and reliance on hospital suites increases the likelihood of routine procedures being rescheduled to accommodate emergency ones;[81]
- Procedures take longer than necessary, in part because of the time required to change out equipment and surgical teams, and because procedures using non-specialized support personnel are less efficient;[82]
- Procedures that could be performed in outpatient settings, in which the outcomes might be better for some patients, must be performed in a hospital setting;[83]
- The risk of infection may be greater in the hospital setting and, in any event, increases when wounds must be left open longer than necessary due to delays;[84]
- Exposure to unnecessarily-high levels of general anesthesia occurs more often in the hospital setting than in ASCs, where specialists can rely more heavily on regional blocks;[85]
- Some of suites in the existing outpatient surgery inventory for the area are, or might be, unsuitable for many general surgery procedures;[86]
- Using the 900 surgeries per year factor for combination suites,[87] Providence Alaska Medical Center's general surgery suites already operate at 98% of capacity; operating at 90% capacity in a hospital setting is taxing and anything above 85% of capacity can be a problem.[88]

[81] Vasileff Testimony; Polston Testimony.

[82] *Id.*

[83] *E.g.,* Polston Testimony (explaining that in his practice the physicians have to resort to use of the hospital when ASCs are preferred); *accord* Vasileff Testimony.

[84] Vasileff Testimony; Polston Testimony. In addition to describing the increased risk of infection due to hospitalization, these witnesses spoke about a phenomenon referred to by Dr. Polston as "sick role" in which hospital patients come to react as if "sick," and therefore recover more slowly, simply because they are being treated as "sick" by hospital staff. Since neither witness was qualified as an expert on this matter, this decision makes no finding about this phenomenon and reaches no conclusion about whether such a phenomenon is indicative of patients receiving better quality care in an outpatient setting.

[85] Vasileff Testimony.

[86] *Compare* Polston Testimony (describing in general terms the size needs for orthopedic procedures) *with* Appellant's Exhibit 1 (summarizing records deposition testimony revealing that five of the outpatient suites included by the staff in the supply inventory are small than 400 square feet, and one is as small as 144 square feet).

[87] The department's formula uses 900 surgical cases per year for suites that handle a combination of inpatient and outpatient procedures when calculating capacity supplied by existing and proposed facilities. *See Alaska Certificate of Need Review Standards and Methodologies* at p. 31 (Dec. 9, 2005). For outpatient-only suites, the formula assumes each suite can handle 1200 surgical cases per year. *Id.*

[88] August 15, 2006 Testimony of Susan Humphrey-Barnett; August 15, 2006 Testimony of Colleen Bridge.

Collectively, these facts show that more likely than not some patients' medical care is being adversely affected by current limitations on surgery suites available for non-hospital outpatient procedures. The joint venture, therefore, has shown that barriers to receiving a desirable quality of healthcare services exist. If the barriers are unreasonable, the commissioner can allow an exception under 7 AAC 07.025(b). The regulations do not prescribe a test for determining whether a barrier is "unreasonable." An increased risk of infection or overexposure to anesthesia likely would be unreasonable if allowed to persist when a remedy might be found in authorizing more ASC suites to relieve some of the pressure on hospital suites. When, as here, the trend analysis shows that the general surgery use rate is likely to increase in the Anchorage area, and some barriers already exist, an exception to the standard methodology is in order.

Accordingly, an exception should be allowed so that the need calculation using the trend analysis, and yielding a result that 3.5 more suites will be required within the planning horizon, can be substituted for the standard methodology. The joint venture's application should be approved, but only to the extent of constructing four completed suites. No expenditures to convert the proposed shelled-in suites to complete, operable suites should be allowed absent a showing that these two additional suites are needed.

3. Why remand is not the best remedy in this case

The department staff took the position that if it "was wrong to include all licensed general surgery suites [including endoscopy rooms], the hearing officer must recommend a remand to the CON staff to 're-run' the methodology and potentially the regression [trend] analysis."[89] Staff noted that the analyses "could be very different" if the smaller suites were removed from the supply side because "they generate a lot of surgery ...."[90] That may be true. The results almost certainly would be somewhat different if the not-suitable-for-general-surgery suites, and the procedures performed in them, were removed from the supply side and the demand side of the analysis. This does not show that remand is the best remedy, however.

On remand, to parse which suites and which procedures should be removed from the calculation, staff would have to make at least the following determinations:

- Is the larger of the Geneva Woods suites too small or otherwise ill-suited to a broad range of general surgery, or is only the smallest one to be counted out?

[89] September 1, 2006 Posthearing Brief at p. 15, note 29.
[90] *Id.*

- If only the smallest of the Geneva Woods suites it to be counted out, what portion of the 1626 to 1660 surgical procedures performed by the facility each year between 2002 and 2004 should be attributed to the smallest facility and thus excluded from the demand side of the analysis?
- Is the smaller (320 square feet) Alaska Spine Center suite in or out of the count, and if it is out, what portion of the 1812 to 2754 procedures performed by the facility each year between 2002 and 2004 should be attributed to that suite?
- Are the two (273 square feet) suites at Alaska Digestive Center in or out of the count? Are the suites of sufficient size and versatility, and maintained to an adequate level of sanitation, to be used for a broad range of general surgery?
- What are the size and condition of the two Alaska Endoscopy Center suites? Is either suitable for use in a broad range of general surgery? If only one is suitable, how should the 2611 to 2963 procedures performed by the facility each year between 2002 and 2004 be apportioned between the suites?

The department's success in obtaining detailed information from facilities during the initial review of the joint venture's application was somewhat limited, arguably at least in part by the degree of cooperation the facilities were willing to give.[91] During the hearing process, the joint venture resorted to subpoenas and records depositions to gather details from five of the six outpatient facilities whose surgery use and suite count data the staff included in its analyses. Even then, no details beyond what was in the initial agency record were forthcoming for Alaska Endoscopy Center. With these information gaps and no assurance that the joint venture's prospective competitors would be quick to cooperate in further inquires, it is difficult to see how a remand would yield a better remedy than that of granting the conditional exception described above.

IV. Conclusion

The department staff was not wrong to recommend denial of the joint venture's application, and the commissioner did not err in accepting that recommendation. At the time of the decision, the joint venture had not made the requisite showing for an exception from the

[91] The agency record as a whole evidences many attempts to obtain information through email inquiries and distribution of forms to medical facilities seeking detailed information, as well as inquires within the department (e.g., to employees knowledgeable about licensing of surgery suites). Corresponding responses do not appear in the record to all such inquiries, suggesting that not everybody was willing or able to cooperate in providing information.

general surgery standard that bases projection of future need, in part, on a three-year average use rate, without regard to whether the use rate for surgery services is trending upward. Due to the unusual circumstances in this case—particularly the fact that the application was submitted months before the key guidance document was in force—it is not surprising that the showing necessary for an exception was made through the adjudicatory hearing process. However atypical the timing and manner of making the showing may have been, the joint venture has now made the necessary showing. An exception should be allowed so that the more reliable predictor of future events under these circumstances—i.e., the trend analysis—can be used to calculate need.

Accordingly, the January 19, 2006 decision to deny the joint venture's application is vacated. A certificate of need for **FOUR** ambulatory surgery suites will be granted **ON THE CONDITION** that if the joint venture's construction of the South Anchorage ASC includes one or two shelled in but incomplete suites in addition to the four approved suites, no funds will be expended to complete the shelled-in suites unless and until the department approves an amendment to the certificate of need, upon a demonstration by the joint venture of the need for the shelled-in suites to be completed.

DATED this 24th day of May, 2007.

By: Terry L. Thurbon
Chief Administrative Law Judge

[92] The joint venture did not obtain a subpoena for Alaska Endoscopy Center's records. Thus, no conclusion about whether that facility would cooperate is intended by the observation that details were not forthcoming.