BEFORE THE COMMISSIONER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

In the Matter of: ALASKA MEDICAL DEVELOPMENT - FAIRBANKS, LLC	)	OAH No. 06-0744-DHS
In the Matter of: KOBUK VENTURES, LLC	)	OAH No. 06-0745-DHS
In the Matter of: FAIRBANKS MEMORIAL HOSPITAL	)	OAH No. 06-0746-DHS

DECISION AFTER REMAND

On May 31, 2007, as authorized by AS 44.64.060(e)(2), I declined to adopt the proposed decision issued in this case on April 18, 2007, and I returned this matter to the administrative law judge (ALJ) to conduct further proceedings in three areas. Broadly speaking, these were:

1. An evaluation of whether the Fairbanks Memorial Hospital's OR H, or its proposed replacement, should be counted or processed as "general surgery operating rooms" in connection with these certificate of need applications.

2. A process to obtain, and then review, a staff recommendation as to which applicant or applicants would be best suited to supply the two additional general surgery operating rooms needed in Fairbanks.

3. Revision of the interpretation of a department regulation, 7 AAC 07.025(b), which had played a limited role in the proposed decision.

After consultation with me, the ALJ has recommended and I now issue the following decision to resolve these three issues. This decision amends the proposed decision of April 18, 2007. The final decision in these consolidated appeals consists of (1) the proposed Decision and Order dated April 18, 2007 as modified herein; (2) the Order of Remand dated May 31, 2007; and (3) this document.

I. Fairbanks Memorial Hospital's Surge Capacity Application

Fairbanks Memorial Hospital (FMH) applied for a certificate of need in May of 2006 for "replacement and upgrade" of a "'surge capacity' operating room suite."[1] FMH stated in the application that "No new services will be provided by the proposed project."[2]

The suite being replaced had never been counted toward general surgery capacity in the Fairbanks area, and in its application to build a replacement, FMH continued to treat both the existing and the proposed suite as facilities having no impact on general surgery capacity in the community.[3] This approach to the project continued during the evidentiary hearing in this appeal: FMH presented an impressive array of experts on the issue of general surgery capacity and need in the Fairbanks area, and none of them testified that the existing or the proposed surge room was part, or potentially part, of general surgery capacity.

At the proposal for action stage of this appeal, FMH's counsel briefly seemed to take a different tack. He argued that the failure of the proposed decision to include the surge suite in future general surgery capacity was "inexplicable."[4] This suggested that FMH intended to use the surge room for a purpose—general surgery—that FMH had not identified in its CON application. Kobuk Ventures, the appellant in case number 06-0745-DHS (the case relating to the surge capacity suite), objected to this apparent change of position.[5] The matter was remanded to the ALJ to evaluate whether the existing and proposed surge capacity suites are, or will be, general surgery operating rooms. If they were, the medical need for the new suite would have to be justified under the general surgery services methodology and other aspects of the original recommended decision might need to be adjusted.

On remand, all four parties agreed that the present-day surge capacity room, OR H, is not part of the existing or future general surgery capacity for Fairbanks. Its location and facilities make it wholly impractical to use it as part of FMH's general operating room pool.

As to the proposed suite, the staff observed on remand that "only an applicant may identify the nature and scope of a proposed project."[6] The staff is correct. An applicant defines

1 Agency Record at 1364.
2 Agency Record at 1384.
3 *See, e.g.*, Agency Record at 1377, 1386 (calculating general surgery services capacity using the Alaska methodology; all calculations use only six ORs (corresponding to ORs A-F) prior to 2005 and seven ORs (corresponding to ORs A-F plus OR1) from 2005 onward).
4 Fairbanks Memorial Hospital's Proposal for Action, at 14.
5 Kobuk Ventures Motion to Strike Portions of Fairbanks Memorial Hospital's Proposal for Action, at 3-7. Because there is no legal provision for an administrative law judge to entertain or grant a motion to strike a proposal for action filed under AS 44.64.060(e), Kobuk's pleading was treated as an objection rather than a motion.
6 Staff's Response to Respondents' Opening Briefs Regarding Remand Issue Number 1, at 7.

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the nature and proposed use of a facility requiring a certificate of need. If a certificate is granted, it is a certificate to operate the facility as proposed. If the same facility is later to be shifted to a new type service, the applicant must first obtain an amendment to the certificate to demonstrate that it meets the need criteria for that service, applying any methodology the regulations prescribe for that service.

The essential question, therefore, is what proposed use FMH has designated for this project. At the oral argument addressing this issue on remand, counsel for FMH clarified that the hospital has "not deviated one iota from the language of the application" and "that the hospital is not attempting to justify that room on a demand/need basis."[7] He confirmed that "This is a surge application."[8] FMH does not seek a certificate of need to operate an additional general surgery operating room. Since the applicant defines the project, it was appropriate, and remains appropriate, for the department to evaluate the FMH application on the basis of need for surge capacity alone. There is no specific methodology for surge capacity; such an application is properly judged against the general criteria.

FMH argues convincingly, both in its application and in this appeal, that upgrading the surge capacity of the hospital is an important community service. At the same time, it would not be fair to other parties, nor faithful to the spirit of the CON program, if FMH were free to change the new OR into a general surgery operating room after having obtained a certificate without making the need showing required for new general surgery operating rooms. If a party could obtain a certificate of need for a project by defining its scope in a way that avoids a particular need methodology in the CON regulations, and then could later unilaterally redefine the scope of the project into something that would have required the use of that methodology had it been identified in the original application, there is a danger that the certificate of need process could be circumvented or manipulated.

To ensure the integrity of the process in this instance, conditions will be placed on FMH's certificate in addition to the single condition attached to the certificate issued on September 29, 2006.[9] The new conditions have been formulated using draft conditions submitted by the parties in July, 2007, with some alterations. They will read as follows:

> 2. The surge capacity suite may be used only during times of major emergencies involving large numbers of patients. It may only accommodate a

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7 Digital recording of oral argument (June 13, 2007) at 44:10, 47:00.

8 *Id.* at 49:20.

9 Agency Record at 1622-23.

surgery when all other operating rooms suitable for that type of surgery are occupied by emergent cases.

3. Except in an emergency described in condition 2, this certificate does not authorize Fairbanks Memorial Hospital to operate, or to hold in standing reserve, more than six (6) Class C operating suites.

4. Should Fairbanks Memorial Hospital wish to designate one of its existing Class C operating suites as the surge capacity suite and to place the surge capacity suite authorized by this certificate into service as a general surgery suite, it may apply to the department for a modification of this certificate to effect that change.

5. The designated surge capacity suite will not be considered a general surgery suite for purposes of determining capacity, utilization, or need in future Certificate of Need applications for general surgery facilities in the service area. No surgery performed in the designated surge capacity suite may be reported as or counted as part of the "general surgery cases provided" in calculating GSUR under the General Surgery Services review methodology.

Condition number 4 reflects the practical reality that FMH may find, in time, that it makes more sense (because of location, larger size, or superior equipment) to use the new suite for regular case loads and to designate one of the existing ORs A, B, C, D, E or F as the surge suite.[10] If this is done without increasing the overall general surgery capacity of the hospital, it is not fundamentally at odds with the rationale behind FMH's CON application or its approval. However, one Class C suite must be designated as a surge suite at all times, and each change in designation requires application to, and approval by, the department.

II. Choice of Applicant to Provide New General Surgery Capacity

A. Procedural Posture

The proposed decision in this matter determined, and I have accepted, that there is a medical need for two additional general surgery operating rooms in Fairbanks. Prior to the appeal, I had determined that single-suite ambulatory surgery centers are uneconomical, and my determination was not challenged in any of the three appeals presented at the hearing.[11]

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[10] FMH Chief Financial Officer Robert Gould explained this possibility during oral proceedings on June 13, 2007, and his explanation was not challenged by any party.

The flexibility granted in Condition 4 was not requested in FMH's surge suite application, but proceedings on remand showed it to be desirable to permit a more efficient allocation of health care resources. During the remand proceedings, FMH argued for even greater flexibility, going so far as to propose, for example, that it be allowed to change the designated surge room on a daily basis. These proposals are rejected as inconsistent with the spirit of the FMH application and as presenting an undue risk that the Certificate of Need process will be circumvented in a way that is unfair to other potential applicants.

[11] FMH did challenge this determination at an oral proceeding during the remand (June 13, 2007) and, more fully, in a motion for reconsideration filed on June 19, 2007, which was denied by the ALJ the following day. FMH's challenge came too late. FMH had not raised the issue of the viability of single-suite ASCs at any preliminary stage of its appeal (OAH No. 06-0746-DHS), had not presented any evidence on the subject at the 55-hour hearing held in February, and had not identified the issue in its AS 44.64.060(e) proposal for action to the

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Accordingly, if awarded to an ASC, the two suites must be awarded together to a single ASC applicant. Because FMH has not applied for, and will not receive, a certificate to create a general surgery operating room, the sole choice to be made is which ASC applicant—AMD-F or Kobuk—should be authorized to build a two-suite facility.

Following the order of remand on May 31, 2007, conferences with the parties ascertained that the staff had not previously made a comparison of the two ASC applications. A process was devised for the staff to gather any additional information it needed to create a comparison document. The staff filed its comparison document, called a "Staff Supplemental Recommendation,"[12] on August 6, 2007, recommending that a certificate be issued to Kobuk Ventures to build the two needed suites.

Over the following month, Kobuk and AMD-F submitted written responses to the staff's supplemental recommendation, each of them raising a number of criticisms. AMD-F disputed key factual findings in the recommendation and contended that, when corrected, the facts showed AMD-F to be the superior applicant. Kobuk agreed with the staff's outcome but likewise contended that certain factual findings were erroneous and should be corrected to further bolster the recommendation of Kobuk as the superior applicant.

The ALJ asked the staff to "file a brief response to the criticisms of its supplemental recommendation made by AMD-F and Kobuk."[13] The staff filed a short document on September 24, 2007 responding to one of approximately ten criticisms raised by AMD-F, and to none of a similar number of criticisms raised by Kobuk.[14]

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commissioner. Only after the final decisionmaker had acted on the ALJ's proposed decision, issuing a limited order of remand, did FMH raise this issue. The matter could not be entertained at that time because the issue was not within the scope of the "specific proceedings" mandated under the AS 44.64.060(e)(2) order of remand. Further, the failure to raise it prior to or at the hearing constituted a waiver of the issue. Finally, there is doubt that FMH has standing to raise this issue under 7 AAC 07.080, since FMH has not shown that it is "substantially affected" by the manner in which a fixed number of suites are allocated between two other entities.

[12] This three-word title was used on the cover pleading; the attached document bore the title "Supplement to the Concurrent Review of Kobuk and Alaska Medical Development Certificate of Need Applications for Ambulatory Surgery in Fairbanks." In footnotes hereafter, this decision will refer to the document as "Supplement."

[13] Order for Additional Submissions (September 6, 2007).

[14] The staff explained its decision to limit its response to only one issue by observing that the issue appeared to be the most "central" to the decision, and—with respect to Kobuk's arguments—by stating that "it is unclear what criticisms have been made by Kobuk." Staff's Response to the ALJ's Order Dated September 6, 2007 at 1 n.1 and 3 n.3. The latter explanation is especially puzzling, since Kobuk's detailed, 13-page critique of the staff's recommendation used phrases such as "This is not an accurate statement," "The Staff's analysis is incorrect when it states . . .," "Such is not the case," "There is no basis in the record . . .," "The Staff also erred in concluding . . .," and ". . . it is difficult to determine why the Staff claims . . . ."

B. Summary of Staff's Supplemental Recommendation

The department's Standards and Methodologies document contains six general review standards that every CON applicant must demonstrate it meets, and three additional "Considerations for Concurrent Review." The three additional considerations apply when two or more applications for the same service are reviewed concurrently, and the document requires the department to "*compare the extent* to which each applicant, including any parent organization" meets these additional considerations.[15] A notable—but not controversial—feature of the staff's supplemental recommendation is that it compared *the extent* to which AMD-F and Kobuk met, not only the three concurrent review considerations, but also the six general review standards.[16]

Concurrent Consideration 1 ("commitment to quality that is consistent with, or better than, that of existing services):

Overall, the staff found AMD-F superior on this criterion. The key elements of this determination were that AMD-F demonstrated greater commitment to quality by promising to apply for Joint Commission of Health Care Organizations (JCAHO) accreditation; that nearly all AMD-F physicians are board-certified and many have completed one or more fellowships, whereas the single Kobuk physician has two fellowships but no board certification; and that AMD-F is a larger organization with more staff to oversee quality. Kobuk was found superior only with respect to its commitment to ongoing quality improvement assessment through the Intermountain-Pacific Quality Health Foundation. A large number of additional service components related to quality were considered and judged roughly equal, including policy manuals, hours of operation, patient safety, ASC experience, and commitment to patient satisfaction. The overall sense of the staff's evaluation is that AMD-F is superior on Consideration 1, but only marginally so.[17]

Concurrent Consideration 2 ("pattern of licensure and accreditation surveys with few deficiencies and a consistent history of few verified complaints"):

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[15] Alaska Certificate of Need Review Standards and Methodologies (Dec. 9, 2005) at 3 (italics added).

[16] The text of the Standards and Methodologies neither requires nor precludes a comparative evaluation of the six general standards. No party to these appeals has contended, however, that a comparative weighing of the competing applications against these six standards is improper—that is, no party has argued that the six standards must be viewed as essentially pass/fail criteria even in the context of a concurrent review. It certainly seems logical that the staff should have the ability to consider differences between applicants on such key matters as accessibility (Standard 6) and impact on existing health care systems (Standard 5), and hence the unchallenged general approach used by the staff will not be disturbed here.

[17] *See* Supplement at 4-8.

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The staff found Kobuk superior on this criterion. Although it observed that both applicants appear to be able to meet licensing and accreditation standards, it judged Kobuk better in the following respects:

> "● Kobuk had fewer patient complaints than AMD-F with no settlements against Dr. Wade. Dr. James had one complaint, but he will not be operating in Fairbanks.
>
> "● Kobuk operated with fewer staff than AMD-F: 9.5 the first year compared to 17.
>
> "● AMD-F had some deficiencies that had to be corrected during the certification and licensing process for the Wasilla facility."[18]

The staff found the two applicants essentially equal, and somewhat unimpressive, in the areas of licensing experience (both with "one licensing survey under their belts") and adequacy of staffing plans with respect to quality assurance. The staff discounted some facts that the parties had deemed important: It noted "stellar performance" by Kobuk consultant Sharon Anderson when she was administrator of Alaska Regional Hospital, but gave her abilities no weight because she would be an advisor but would not have responsibility for implementing services. Conversely, the staff gave no weight to litigation surrounding AMD-F's sister facility in Wasilla, noting that the litigation "has not shown to date any indication of malfeasance on the part of AMD-F."[19]

Concurrent Consideration 3 ("applicant has consistently provided, or has a policy to provide, high levels of care to low-income and uninsured persons"):

The staff rated Kobuk superior on this criterion, finding that "[a]lthough both programs appear to be interested in serving low-income and uninsured patients Kobuk appears to have a greater interest."[20] The staff observed that Kobuk does not charge an up-front fee, whereas AMD-F does, a fee the staff felt could inhibit some patients from seeking treatment. The staff found that Kobuk has offered 2.95 percent charity care in the past (excluding bad debt writeoffs), whereas the comparable number for AMD-F is between 0.4 and 1.8 percent. The staff noted that AMD-F "proposes to actually serve more charity care cases," but found the claim speculative.

General Review Standard 1 ("need for the project by the population served"):

No difference between the applicants was noted on this criterion.

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18 *Id.* at 10.
19 *Id.* at 9.
20 Supplement at 11.

General Review Standard 2 ("project . . . augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery"):

No difference between the applicants was noted on this criterion.

General Review Standard 3 ("stakeholder participation in planning for the project and in the design and execution of services"):

No difference between the applicants was noted on this criterion.

General Review Standard 4 ("applicant . . . assessed alternative methods of providing the proposed services and . . . proposed services are the most suitable approach"):

No difference between the applicants was noted on this criterion.

General Review Standard 5 ("impact on existing health care systems within the project's service area . . . and . . . on the statewide health care system"):

The staff gave Kobuk the overall advantage on this criterion. The reasons were Kobuk's plan to phase in more slowly and expand support staff at a slower rate, thereby reducing disruption to the local system; the likelihood that Kobuk, in contrast to AMD-F, will not add cost to the system by moving procedures from doctors' offices into an ASC; and the expectation that Kobuk will serve more low-income patients, which benefits the overall delivery system.

General Review Standard 6 ("location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services"):

No difference between the applicants was noted on this criterion. The staff rejected Kobuk's request that it consider the lack of a transfer agreement at an AMD-F-affiliated facility in Wasilla as having "no bearing on the project at hand."[21]

Overall balance:

The staff observed that Kobuk rated higher than AMD-F on two out of three concurrent review considerations, and that Kobuk also had an advantage regarding the general standards. The staff recommended that Kobuk rather than AMD-F be awarded a certificate of need for the two required general surgery operating rooms.

C. Evaluation of Criticisms of Staff's Supplemental Recommendation

The choice between two qualified applicants to select the one best suited to supply additional surgical capacity in Fairbanks is difficult. Ideally, the comparison should be made by

[21] Supplement at 17; *see also* Kobuk Response to Staff Concurrent Review Questions at 12-13; Kobuk Response to Concurrent Review at 11-12.

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a team with extensive experience in this facet of health care administration, capable of evaluating and synthesizing a broad array of pluses and minuses of each proposal. Within the Department of Health and Social Services, the CON staff is in the best position to supply the time and expertise needed for this task.

I note that no party has quarreled with the overall approach the staff took in weighing the many factors that bear on this decision. Instead, there are a number of focused challenges to particular factual determinations and particular reasoning steps. With the assistance of the ALJ, I will evaluate each of these criticisms, generally deferring to my staff's professional judgments but correcting or adjusting the evaluation where there is a documented factual error or where the staff's approach to a particular issue diverges from the policy direction that seems most appropriate for the department.

Concurrent Consideration 1 ("commitment to quality that is consistent with, or better than, that of existing services):

With respect to Concurrent Consideration 1, AMD-F raises certain criticisms even though the overall finding on this criterion was in its favor; it believes the finding in its favor should have been stronger. AMD-F faults the supplemental recommendation for giving insufficient recognition to the fact that its ten physicians cover more specialty disciplines than Kobuk's two. AMD-F also faults the staff for failing to note that half (one) of Kobuk's members does not live in Fairbanks. These criticisms can be rejected because it was reasonable for the staff to deem them outside the scope of an evaluation of "commitment to quality."

AMD-F additionally questions the staff's finding that Kobuk's Dr. Wade has completed two fellowships. The staff's finding on this point is supported in the record by uncontroverted evidence.[22]

Kobuk disputes the overall outcome on Criterion 1. First, it criticizes the staff's finding that AMD-F, but not Kobuk, plans to apply for JCAHO accreditation. Kobuk is correct on this point; the staff apparently overlooked Kobuk's JCAHO commitment.[23] The staff's finding that AMD-F is superior in commitment to quality on account of a disparity in plans to seek this accreditation must be reversed.

Kobuk contends that the staff should have judged Kobuk superior in the area of experience in operating an ASC. Kobuk points out that its Anchorage partner, Dr. James has

[22] Affidavit of Dr. Mark Wade (July 12, 2007), ¶ 6 [Attached to Kobuk Ventures' Response to CON Staff's Concurrent Review Questions and Issues, submitted to the staff on July 12, 2007 and filed in this case on Sept. 4, 2007].

[23] Agency Record at 1303, 1331.

about six years of experience operating an ASC, whereas AMD-F has what Kobuk characterizes as a few months of experience. Kobuk's challenge misses the mark. The staff acknowledged Dr. James's superior experience, but declined to give Kobuk itself credit for more experience because Kobuk did not make it clear "exactly what role [Dr. James] will play in the administration of the facility."[24] This is a reasonable basis for the staff to discount the importance of Dr. James's experience, and Kobuk has not articulated any criticism of this reasoning.

The section of Kobuk's critique titled "Concurrent Review Standard 1" contains other points, but they are addressed to the staff's findings or reasoning regarding other standards.

In sum, the staff was wrong to accord AMD-F an advantage on the basis of planned JCAHO accreditation, but there is no basis to disturb the staff's other findings relating to Concurrent Consideration 1. The overall balance on this consideration was, and remains, marginally in favor of AMD-F.

Concurrent Consideration 2 ("pattern of licensure and accreditation surveys with few deficiencies and a consistent history of few verified complaints"):

Kobuk, the beneficiary of a favorable comparison on Consideration 2, is largely supportive of the staff's analysis. Kobuk does take issue with the staff's unwillingness to give weight to Sharon Anderson's expertise, asserting that she will "actively participate" in ensuring that the new facility meets licensing and certification standards.[25] Kobuk's criticism (which is not supported by any citations to the record) is beside the point, because Consideration 2 is solely about an applicant's *past* record of deficiencies and complaints.

AMD-F takes strong issue with the finding on Consideration 2 because of its heavy reliance on the supposed smaller number of malpractice complaints and settlements against Kobuk physicians than against AMD-F physicians.[26] AMD-F points out that it has ten physicians while Kobuk has only two; it challenges what it perceives as the staff's use of aggregate monetary settlement amounts in comparing the volume of "verified complaints" against each applicant; and it argues that the Kobuk disclosure of complaints and settlements to the staff was in any event less forthcoming than AMD-F's. There was considerable litigation between AMD-F and Kobuk on this issue during the latter portion of the remand proceeding, each alleging that the other had failed to disclose significant malpractice claims.

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[24] Supplement at 7.

[25] Kobuk Response at 5.

[26] This criticism, which appears on pages 2-3 of the AMD-F comments, is the sole criticism by either applicant to which the staff has responded. Staff's Response to the ALJ's Order Dated September 6, 2007, at 3-5.

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The resolution of this question does not turn on malpractice litigation. When Consideration 2 calls for "a consistent history of few verified complaints," the focus is on complaints verified by regulatory and licensing authorities. The staff initially recognized this, directing its information request to the applicants to "information regarding . . . professional licensure . . . [including] . . . any documented complaint."[27] Unfortunately, AMD-F read the staff's request too broadly and supplied civil litigation data, and the staff became sidetracked from the regulatory task when presented with this unnecessary information. What is relevant is that there were no substantiated regulatory/ licensing complaints against any physician of either applicant during the relevant period.[28]

AMD-F also attacks the second basis for the staff's finding on Consideration 2, which was the observation that "Kobuk operated with fewer staff than AMD-F." AMD-F asks "Why is this a plus?"[29] The question is a fair one. In the absence of a response from the staff, one can discern no basis for concluding that Kobuk was "'better' in the area of licensure, accreditation and deficiencies" because "Kobuk operated with fewer staff."[30]

AMD-F lastly attacks the third basis for the staff's finding on Consideration 2, which was the existence of deficiencies during the certification and licensing process for an affiliated facility in Wasilla. AMD-F suggests that the staff should have evaluated whether the deficiencies were minor or were typical for a newly-opened facility.[31]

The deficiencies at issue, which were identified by DHSS in an April 2007 inspection, are documented at Tab 2-A of AMD-F's Response to Staff Information Requests. They relate to such matters as evacuation planning and smoke barriers. The information is properly within the scope of Consideration 2. If there was ameliorating information, such as data to show that all new ASCs encounter similar issues in their first inspection, it was up to AMD-F to demonstrate that to the staff. AMD-F did not make that demonstration.[32] Hence, the third basis for the finding on Condition 2 stands.

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[27] The information request is quoted in Kobuk Response to Staff Concurrent Review Questions (July 12, 2007; filed with OAH Sept. 4, 2007) at 15.

[28] One complaint against Dr. James addressed to the Medicare quality improvement organization covering Alaska resulted in a very mild suggestion for improved procedure regarding releases, but did not find that his care or procedures fell below any standard. *Id.* at Tab 2-B-2.

[29] AMD-F Comments at 5.

[30] The quotations are from Supplement at 10.

The staff was given from September 6 to September 20 to respond to this criticism.

[31] AMD-F Comments at 5.

[32] On the contrary, there is some evidence that new ASCs do not universally encounter these problems. *See* Agency Record at 1605-07 (inspection of an ASC developed by one of the Kobuk partners).

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In conclusion, AMD-F has successfully shown that two of the three areas in which the staff found Kobuk superior in relation to Condition 2 should be disregarded. What remains is this: both applicants have an essentially unblemished record regarding verified complaints against their physicians, but an AMD-F affiliate has had some recent, substantiated, but correctable facility licensing issues in one newly-opened facility. The staff's determination that Kobuk was superior on Consideration 2 was accurate, but Kobuk's advantage is marginal.

Concurrent Consideration 3 ("applicant has consistently provided, or has a policy to provide, high levels of care to low-income and uninsured persons"):

Kobuk is wholly supportive of the staff's analysis on Consideration 3. AMD-F characterizes it as "ridiculous."[33]

AMD-F first suggests that, in its original 2006 recommendation to the commissioner, the staff found that AMD-F would provide charity care on 2 percent of its patient load whereas Kobuk would do so on only 1.8 percent. This is not a wholly fair characterization of what the staff did in 2006. At that time, the staff did not think it needed to compare or rank the competing applications,[34] and it simply noted the expectations of the applicants regarding future charity care and concluded, on a pass-fail basis, that they had "met" Consideration 3.[35] The staff did not adopt the exact percentages given to it by the applicants.

AMD-F next contends that while the percent of *patients* projected to receive charity care by the two applicants is similar (with AMD-F having an 0.2% advantage), as a percentage of *revenues* the AMD-F advantage is more dramatic. Comparing the parties' respective financial projections,[36] it asserts that AMD-F's charity care will be about 3.0% of total revenue billed, while Kobuk's will be about 1.8% of total revenue billed.[37] AMD-F then asks, "From this evidence in the record, how could the Staff reasonably conclude that the applicants' prior history shows that Kobuk has a greater interest in providing charity care?"[38]

The evidence AMD-F cites has nothing to do with "prior history." It is a financial projection for future years in a new facility. When the staff made its key conclusion about charity care "in the past," it had to rely on different evidence. With respect to AMD-F, there was

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[33] *Id.* at 3.

[34] *Cf.* April 18, 2007 Decision and Order at 16.

[35] Agency Record at 1559-60.

[36] Agency Record at 1494 (AMD-F) and 1343 (Kobuk).

[37] AMD-F Comments at 3-4. AMD-F also purports to compare charity care as a percentage of what it characterizes as "revenue minus bad debt," putting itself at 14.95% and Kobuk at 6%. *Id.* This calculation, which actually appears to be the percentage of billed revenue represented by the sum of charity care *plus* bad debt, has no demonstrated connection to Consideration 3.

[38] AMD-F Comments at 4.

evidence in the record on this point that agreed with the staff's finding. AMD-F's CON application showed charity care being offered to between 0.4% and 1.8% of its affiliates' patients over the previous five years.[39] As a percentage of revenues (a statistic AMD-F contends is more relevant[40]), the affiliates' past charity care never exceeded 1.2%.[41] With respect to Kobuk, however, *no evidence supported the staff's finding that Kobuk has extended charity care to 2.95% of patients in the past*.[42] Kobuk's CON application placed the percentage of patients of the two Kobuk partners who receive charity care at "[a]pproximately 2%," not 2.95%[43] Moreover, Kobuk did not provide charity care figures reaching far into the past. The only fair comparison offered by the limited evidence in the record is to compare AMD-F's most recent percent-of-patients charity care figure—1.8% in 2005—against Kobuk's corresponding figure—"[a]pproximately 2%." There is no significant difference between these figures.

Lastly, AMD-F argues that the staff's finding regarding up-front fees is irrelevant to the comparison.[44] This criticism is not well-taken: under Consideration 3, any "policy" that would tend to increase or decrease "care to low-income and uninsured persons" is relevant. It was reasonable for the staff to infer that the absence of a policy to collect an up-front fee for services would tend to increase service to these groups.

In conclusion, the staff's differentiation of the two applicants based on prior charity care was not supported. The remainder of the staff's reasoning was sound, but it supports only a finding that Kobuk was marginally superior on Consideration 3.

<u>*General Review Standard 1*</u> ("need for the project by the population served"):

Neither applicant disputed the staff's implicit finding that there was no difference between the applicants on this criterion.

<u>*General Review Standard 2*</u> ("project . . . augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery"):

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[39] Agency Record at 1502-03.

[40] AMD-F Comments at 4 ("Charity care based on percentage of revenue is the single most important measure of charity care . . . .").

[41] The percentages were 1.1% (2001 and 2002), 0.8% (2003), 0.9% (2004), and 1.2% (2005). Agency Record at 1502-03.

[42] The staff's figure of 2.95% seems to have come from a statement by Kobuk's attorney. *See* Kobuk's Response to Staff Concurrent Review Questions at 21; Kobuk's Proposal for Action at 31-32. However, the attorney's citations to the record do not support his claim.

[43] Agency Record at 1329-30.

[44] AMD-F Comments at 5-6.

Neither applicant disputed the staff's implicit finding that there was no difference between the applicants on this criterion.

General Review Standard 3 ("stakeholder participation in planning for the project and in the design and execution of services"):

Neither applicant disputed the staff's implicit finding that there was no difference between the applicants on this criterion.

General Review Standard 4 ("applicant . . . assessed alternative methods of providing the proposed services and . . . proposed services are the most suitable approach"):

Neither applicant disputed the staff's implicit finding that there was no difference between the applicants on this criterion.

General Review Standard 5 ("impact on existing health care systems within the project's service area . . . and . . . on the statewide health care system"):

Kobuk, as the beneficiary of a favorable finding on this standard, confines its criticism to disputing staff footnotes suggesting that Kobuk did not provide record support for parts of its assertion that AMD-F would add more cost to the system, while Kobuk would not.[45] Kobuk then supplies record cites for these points. Since the staff seems largely to have accepted Kobuk's contentions, finding record support on its own where necessary, there is no need to address this criticism.

AMD-F disputes the staff's finding that Kobuk has a greater commitment to charity care. As discussed above in connection with Concurrent Consideration 3, AMD-F is correct in pointing out that Kobuk has demonstrated no advantage over AMD-F on charity commitment. AMD-F's Comments do not contest the other two bases for the staff's determination on Standard 5 (slower phase-in/less staff demand for Kobuk; increased costs with AMD-F due to addition of a facility fee when minor surgeries are moved from doctors' offices to the ASC). These bases are well supported in the record,[46] and the finding on Standard 5 will be upheld.

General Review Standard 6 ("location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services"):

The staff found the applicants equal on Standard 6. Kobuk argues that the staff should have considered the failure of an ASC in Wasilla affiliated with AMD-F to secure a transfer agreement with a local hospital. It was reasonable, however, for the staff to avoid a detour into a potentially complex dispute about a distant facility, in the absence of any indication that AMD-F

[45] Kobuk Response to Concurrent Review at 8-11.

[46] *See, e.g.*, April 18, 2007 Decision and Order at 27-28.

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would fail to secure an appropriate transfer arrangement with FMH. The staff's finding on Standard 6 is upheld.

Overall balance:

As revised based on the critiques filed by the two ASC applicants, the staff's comparative review now yields:

- A marginal advantage for AMD-F on Concurrent Consideration 1.
- A marginal advantage for Kobuk on Concurrent Considerations 2 and 3.
- An advantage for Kobuk on General Review Standard 5.
- No advantage to either applicant on General Review Standards 1-4 and 6.

Concurrent Consideration 1 is not of such overriding significance that a marginal advantage in that area outweighs Kobuk's three areas of superiority. Accordingly, I accept the staff's recommendation that a certificate of need be awarded to Kobuk Ventures for two general surgery operating rooms.

III. Modification of Part III-C of Proposed Decision

The proposed Decision and Order issued April 18, 2007, interpreted 7 AAC 07.025(b) to permit the staff or the commissioner to grant exceptions to the methodologies contained in the Standards and Methodologies. The administrative law judge concluded that although 7 AAC 07.025 refers to "standards and . . . methodologies" and then permits exceptions only for "standards," the service-specific methodologies are themselves "standards" and thus are encompassed by the authorization for exceptions. I disagree with this interpretation for three reasons.

First, I note that the administrative law judge, when interpreting the relationship between 7 AAC 07.025(b) and the methodologies, gave significant weight to language contained in the General Surgery Services section of the Standards and Methodologies that appears to characterize the methodology for general surgery as a "service-specific review standard." As the staff has pointed out in its Proposal for Action, however, the language in the General Surgery Services section is anomalous. In all 13 other specific services covered in the Standards and Methodologies, standards are carefully separated from the review methodology for calculating need. Reading the Standards and Methodologies as a whole in conjunction with 7 AAC 07.025, I believe they reflect an effort to distinguish the methodologies from the standards.

Second, as I stated in a recent order in *In re South Anchorage Ambulatory Surgery Center Joint Venture*[47]:

> 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.

Third, as the chief executive of the Department of Health and Social Services, I have direct knowledge of the intent behind 7 AAC 07.025(b). It was not my department's intent in 7 AAC 07.025(b) to create a means to set aside the published methodologies. Instead, 7 AAC 07.025(b) was intended only to create a means to set aside or adjust, under exceptional circumstances, one or more of the six Review Standards and three Concurrent Review Standards appearing on pages 2 and 3 of the Alaska Certificate of Need Review Standards and Methodologies (December 9, 2005). In making this determination of the intent of the regulation at issue, I am deciding the matter myself rather than deferring to my staff's interpretation of 7 AAC 07.025(b); at the same time, however, I note my staff's agreement with my understanding of the department's intent, and I regard my staff's agreement as important confirmation of my own recollection of the intent.[48]

For these reasons, I reject Part III-C-1 of the proposed Decision and Order issued April 18, 2007. As to the remainder of Part III-C, I concur with the determination that *even if* exceptions to the methodology were permissible, AMD-F did not demonstrate a basis to recognize additional medical need of such magnitude that it could not be accommodated in the two suites already justified through the regular methodology. Inasmuch as they support this

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[47] OAH No. 06-0152-DHS (Decision and Order, July 5, 2007). That decision became final through an order issued on October 4, 2007.

[48] The staff's view on the interpretation of 7 AAC 07.025(b) is expressed at pages 4-9 of the Staff's Proposal for Action (May 7, 2007). I do not endorse the statement at page 6 of the staff's submission that the 7 AAC 07 regulations are "its own"—meaning the staff's own—regulations; I regard the regulations as the department's regulations rather than the staff's. The staff's views are helpful to me in determining the department's intent, however.

alternative holding, the findings and conclusions set out in Parts III-C-2 through III-C-7 are adopted.

For the same reasons, I reject the second full paragraph on page 19 of the proposed Decision and Order. That paragraph suggested the FMH surge capacity application *could* be viewed as an application for general surgery services that, because of a deficiency in available surge capacity in the service area, would be excepted from the published review methodology by applying 7 AAC 07.025(b). Because I hold that 7 AAC 07.025(b) does not authorize exceptions to the methodology, this characterization of the FMH surge capacity application is not viable. The staff's approach to the FMH surge capacity application, which is described in the first full paragraph on page 19, is the correct approach.

Also rejected for inconsistency with the above holding is the final text sentence on page 30 of the proposed Decision and Order.

IV. All Other Matters

Except as set forth above, the Decision and Order issued April 18, 2007 is adopted as the final decision in this matter.

V. Appeal

Judicial review of this decision, which consists of consists of (1) the proposed Decision and Order dated April 18, 2007 as modified herein, (2) the Order of Remand dated May 31, 2007, and (3) this document, may be obtained by filing an appeal in the Alaska Superior Court in accordance with Alaska Rule of Appellate Procedure 602(a)(2) within 30 days after the date this document is distributed.

DATED this 9th day of October, 2007.

Recommended by: *Signed*
Christopher Kennedy
Administrative Law Judge

Adopted by: *Signed*
Karleen Jackson
Commissioner

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BEFORE THE COMMISSIONER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

In the Matter of: ALASKA MEDICAL DEVELOPMENT - FAIRBANKS, LLC	)	OAH No. 06-0744-DHS
In the Matter of: KOBUK VENTURES, LLC	)	OAH No. 06-0745-DHS
In the Matter of: FAIRBANKS MEMORIAL HOSPITAL	)	OAH No. 06-0746-DHS

ORDER OF REMAND

Pursuant to AS 44.64.060(e)(2), I decline to adopt the proposed decision issued April 18, 2007, and return this matter to the administrative law judge (ALJ) to conduct the specific proceedings discussed below:

1. Fairbanks Memorial Hospital (FMH) advocates in its proposal for action that its proposed surge capacity suite be included in general surgery capacity calculations for Fairbanks. On remand, the ALJ shall conduct proceedings to evaluate the FMH application as an application for a general surgery operating room. These proceedings may include an evaluation of the nature of the existing and proposed surge capacity suites, their capabilities and licensing classifications, and whether those suites are, or will be, general surgery operating rooms. Calculations of existing or future general surgery capacity in Fairbanks may be adjusted as appropriate. The FMH application may be denied if it is found to be an application to construct a general surgery operating room and it does not meet the one or more standards for issuance of a certificate of need, or if it is found inferior under concurrent review to another pending application to construct general surgery operating rooms.

2. The ALJ shall conduct proceedings to compare the pending applications to build general surgery operating rooms to determine which application or applications should be granted to fill demonstrated need. If the FMH application is found to be an application to construct a general surgery operating room, it shall be included in the comparative review. The

ALJ shall require the staff to furnish the complete record of any comparative review it has already conducted to determine the relative ranking of the competing proposals. The ALJ may conduct proceedings, if necessary, to permit the staff to update or supplement its comparative analysis and to permit applicants to respond to any new evidence or reasoning offered. The ALJ may require the staff or any applicant to furnish data needed to apply the comparative review standards. The ALJ and the staff may consider any information offered in the proposals for action, motions, and letters of the parties submitted after the issuance of the proposed decision, as well as material previously admitted and new material developed or admitted after remand.

3. In consultation with the commissioner, the ALJ may revise the interpretation of 7 AAC 07.025 made in Part III-C of the proposed decision. No new evidence or argument will be taken in connection with this revision.

* * *

It is my desire that proceedings on remand be expedited. Although I do not formally limit the period of remand, I ask the ALJ, my staff, and the applicants to make every effort to complete the tasks above within 30 days.

DATED this 31st day of May, 2007.

By: *Signed*
Karleen Jackson
Commissioner

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

In the Matter of: ALASKA MEDICAL DEVELOPMENT - FAIRBANKS, LLC	)	OAH No. 06-0744-DHS
In the Matter of: KOBUK VENTURES, LLC	)	OAH No. 06-0745-DHS
In the Matter of: FAIRBANKS MEMORIAL HOSPITAL	)	OAH No. 06-0746-DHS

DECISION AND ORDER

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I. Introduction

A. Matters Presented for Review

In the first half of 2006, three applicants sought certificates of need under Title 18, Chapter 7 of the Alaska Statutes for the construction of new surgical suites in Fairbanks. Alaska Medical Development – Fairbanks, LLC (AMD-F) and Kobuk Ventures, LLC (Kobuk), both for-profit companies organized primarily by physicians, each requested a certificate to build ambulatory surgery centers (ASCs) in the city. AMD-F applied to build a three-suite center and Kobuk a two-suite center. Fairbanks Memorial Hospital (FMH), which operates all of the existing licensed surgery suites in Fairbanks, requested a certificate to relocate and upgrade an operating suite within the hospital that is dedicated to emergency surge capacity rather than to day-to-day surgery demand.

On September 29, 2006, following a concurrent review, the Commissioner of the Department of Health and Social Services (DHSS) issued certificates to all three applicants, reducing the AMD-F project by one suite so that it, like Kobuk, would build a two-suite ASC. The total cost of the three projects together is about $16 million.

The certificate of need regulations permit aggrieved parties to seek a formal administrative hearing to challenge certificate of need decisions. FMH requested a hearing to challenge the certificates issued to Kobuk and AMD-F. AMD-F requested a hearing to challenge the reduction of its own allowance to two suites and to challenge the certificate granted to Kobuk. Kobuk requested a hearing to contest the surge capacity certificate granted to FMH. All three appeals were referred to the Office of Administrative Hearings and, by consent of all concerned, have been heard together.

B. Purpose of the Certificate of Need Program

Alaska's certificate of need (CON) program dates from 1976, when this state became the 31st to establish such a mechanism for approval of certain categories of medical construction.[49] Originally implemented to fulfill a condition for receiving federal funds, the certificate of need program was conceived as a way of reducing unnecessary duplication in health care facilities and thereby to reduce the cost of care.[50] The federal incentive was effectively repealed in the Reagan

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[49] Agency Record at 1823 (MacQuest Consulting, *State of Alaska Certificate of Need Review Standards* (2005), Supporting Appendices at 3).

[50] *See Sisters of Providence in Washington, Inc. v. Dep't of Health and Soc. Serv.*, 648 P.2d 970, 972 n.2 (Alaska 1982); *Greater St. Louis Health Sys. Agency v. Teasdale*, 506 F. Supp. 23, 28 (D. Mo. 1980); J. Simpson, *State Certificate-of-Need Programs: The Current Status*, 75 Am. J. Pub. Health 1225 (1985).

administration, but most states, including Alaska, have retained certificate of need programs as a planning tool.[51]

Certificate of need planning is not, fundamentally, economic planning. A common misconception, espoused by some of the parties in this case, is that a CON evaluation focuses on whether new facilities will be filled to capacity, whether they will generate their own patient load without drawing from existing facilities, or whether they will be economically successful. These are not the central questions in the CON process. Instead, the essence of certificate of need programs today remains the perception that a planning tool is needed to ensure that providers of health care services build adequate capacity, but not excess capacity, to supply the *medical* needs of a community.[52]

In the U.S. economy, market forces generally limit supply by creating a disincentive to building excessive capacity, but the health care market is widely regarded as imperfect: price sensitivity among consumers is poor, there are strong informational disparities between consumers and suppliers, and those controlling supply can also affect demand by recommending more or different procedures, or changing the location where procedures are done, as capacity expands.[53] The theory is that in parts of the health care market, "'supply generates demand, putting traditional economic theory on its head[,]'" leading to "an inefficient allocation of health care resources and higher health care costs."[54] Additionally, CON programs are now viewed as a way of protecting the cross-subsidies that currently support unprofitable parts of the health care system, whereby, for example, hospital surgery departments produce revenue that offsets money-losing emergency room operations.[55] There is a fear that new entrants might "cherry-pick" the profitable services, leaving community hospitals without the resources to maintain quality service in the less desirable segments of the market and to supply largely uncompensated public goods such as disaster preparedness.[56] Finally, some have suggested that by maintaining a fairly tight supply, CON programs enhance quality by ensuring that facilities have the patient volumes

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51 *E.g.*, Michigan Certificate of Need Commission, Performance Audit of the Certificate of Need Program (2002) at 13.

52 *E.g.*, direct exam and AMD-F cross-exam of Caroline Watts (director of University of Washington's Resource Center for Health Policy; chair of Governor's Task Force on Certificates of Need (Washington)); U.S. Dep't of Justice and Federal Trade Commission, *Improving Health Care: A Dose of Competition* (2004) [FTC Report] at ch. 8, pp. 2-3; *see also* AS 18.07.041 (need is what is needed "to maintain the good health of the citizens of this state").

53 Direct exam of Watts; FTC Report at ch. 8, pp. 2-3; Agency Record at 1763-1766 (MacQuest Consulting, *State of Alaska Certificate of Need Comments and Observations* (2005), Att. C at 33-36).

54 FTC Report at ch. 8, p. 3 (quoting and paraphrasing Thomas R. Piper).

55 *Id.*; direct exam of Watts.

56 *E.g.*, direct and AMD-F cross-exam of Watts.

that optimize provider skills.[57] Alaska's current certificate of need review standards, adopted just over a year ago, reflect all of these concerns.[58]

The effectiveness of certificate of need programs to improve the operation of the health care market is debated, both nationally and in Alaska.[59] It is not the function of this decision to enter that debate. So long as certificates of need remain part of the law of Alaska, the role of decisions such as this one is to interpret the CON requirements in keeping with their overall objectives and to apply them fairly and uniformly.

C. How Certificate of Need Decisions Are Made

Alaska Statute 18.07.041 provides that, outside the context of certain specialized services not relevant here, a certificate of need should be granted "if the availability and quality of existing health care resources is less than the current or projected requirement for health services required to maintain the good health of citizens of this state." Apart from this general standard, which has remained essentially unchanged since 1976, the Legislature has left the details of the program for development through regulations.[60]

DHSS's regulations establish two tracks to obtain a certificate of need. The first track requires an applicant to show that the proposed project meets the "Alaska Certificate of Need Standards and Methodologies," the current version of which was adopted by regulation—and thus became a regulation in its own right—in early 2006.[61] On this track, all covered projects must meet six "General Review Standards" relating to (1) "need for the project by the population;" (2) the project's fit with existing plans; (3) stakeholder participation; (4) assessment of alternatives; (5) impact on existing health care systems in the community and on the statewide health care system; and (6) accessibility.[62] Three additional general standards apply when there are competing applications for the same service. These relate to quality of service and service to low income and uninsured persons; the department is to compare "the extent to which" the concurrent applicants meet these three standards.[63]

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57 FTC Report at ch. 8, p. 3.

58 Alaska Certificate of Need Review Standards and Methodologies (Dec. 9, 2005) [Standards and Methodologies]. It is not clear whether the last concern (sufficient patient volume to maintain skills) is a basis for the general review standards, but it is identifiable in some service-specific standards, such cardiac catheterization standard 5.

59 *Compare, e.g.,* FTC Report *with* Agency Record at 1763-1766 (MacQuest Consulting, *State of Alaska Certificate of Need Comments and Observations* (2005), Att. C at 33-36).

60 *See* AS 18.07.101.

61 7 AAC 07.025(a).

62 Standards and Methodologies at 2.

63 *Id.* at 3.

For certain fields, an applicant following the first track to approval must also meet "service-specific review standards." There is a set of such standards, relevant in this case, for "General Surgery Services." These standards provide the "methodology" under which "[t]he applicant demonstrates need," that is, makes the core demonstration—"need"—required in General Review Standard number one. The first step listed in the methodology is to determine the "projected general surgery caseload" using a formula designed to yield a demand projection for the fifth year from the project implementation date. The next listed step is to develop the "projected number of operating rooms required" by dividing the projected caseload by a defined per-room capacity. Finally, one compares the existing number of operating rooms to the projected need to determine if there is an "unmet need." These steps have been laid out in the methodology in a somewhat counterintuitive way, and the experts and parties to this proceeding tended to approach the need formulas in a different order: determine the current supply and its rated capacity, and then determine the projected demand and see if it exceeds the rated capacity of the current supply. The result is the same.

Certificate of need applicants who fall short of one or more of the general or service-specific standards can follow a second track to approval: An exception can be made to one or more of the standards if the applicant shows "that the availability, quality, or accessibility of existing health care services creates an unreasonable barrier to services in the service area." This second track, which has some importance to this proceeding, is found in 7 AAC 07.025(b)[64] and will sometimes be referred to below as an "025(b)" exception.

Regardless of the track used, certificate of need decisions are addressed in the first instance by the DHSS CON staff, who conduct a public meeting on the application, accept written comments, and prepare an analysis and recommendation for the commissioner.[65] The commissioner then makes a decision to issue or deny the certificate or to require additional information or analysis.[66] The commissioner must explain in writing any departure from the staff's recommendation. In issuing a certificate, she has discretion to attach conditions.[67]

[64] At the commissioner level, there is a parallel provision for exceptional circumstances in 7 AAC 07.070(b)(7). Note, however, that 7 AAC 07.025 also applies to the commissioner and binds the commissioner to the standards and methodologies except as provided in section 07.025(b), so that to interpret these two sections in harmony one cannot read 070(b)(7) to authorize an independent basis for departing from the standards and methodologies. Sections 07.025(b) and 07.070(b)(7) are discussed further in section III-C-1 below.

[65] AS 18.07.045(a)(2); 7 AAC 07.052; 7 AAC 07.060(a). The comment process would ordinarily precede and factor into the staff recommendation, although the staff is not expressly required to consider the public input.

[66] 7 AAC 07.070. The commissioner has to consider the public comments, among other information.

[67] 7 AAC 07.070(b)(8).

D. Nature of Administrative Appeal in the Certificate of Need Program

Once a decision has been reached, the applicant or any other person substantially affected by any activities authorized is entitled to an administrative hearing conducted under Alaska's Administrative Procedure Act.[68] Unless there is a delegation (which has not occurred here), the matter returns to the commissioner after the hearing for final decision.

The DHSS certificate of need process follows the traditional path for agency permits in Alaska: it starts with an application from the projects proponent, progresses through public comment and staff review steps, and leads to an initial decision to grant or deny the permit. There is then an opportunity for an appeal through a formal hearing, and after the hearing the matter circles back to the head of the same agency for a final decision. In this case, the two-round process that is so typical of Alaska administrative decisions caused some dissention among the parties. Some made unusual proposals to put blinders on the commissioner's ability to consider evidence in the second round. Another proposal was to require the commissioner to "defer" to herself, unable to adjust her prior decision if she decided it was mistaken in some respect but, instead, bound to it unless she found it wholly unsupported by evidence. It will therefore be useful to review briefly the concepts behind Alaska's traditional administrative decisionmaking process.

The first round of decisionmaking is informal. Evidence and comments generally are not received under oath, and participants do not typically offer elaborate briefing on potential legal questions. Indeed, some stakeholders may not participate at all in the review of a particular application, perhaps because they do not foresee an outcome that will affect them.

In many cases, the first permitting decision will be the last, because no one will pursue an appeal. When an appeal is filed, however, it is not a repeat of the first round. Importantly, all aspects of the first-round decision that are not specifically challenged will stand, and the appeal therefore focuses more narrowly. Within that focus, evidence is taken under oath, allowing a more rigorous testing of factual matters that, allegedly, may have been presented inaccurately in the first round. The Administrative Procedure Act also places no constraints on parties raising "new matter," such as new factual rationales for the result they seek or new legal arguments. This is appropriate because only now is the general direction and rationale for the agency's decision understood.

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68 7 AAC 07.080.

The decision at the end of the second round will be a more rigorously tested version of the first decision. If it differs from the first, the difference may not stem from any "errors" in the initial round. Instead, it is simply a new decision made with a different and more complete body of evidence. The task is to make the best decision possible at the executive branch level.

In the course of making the best decision possible, the final decisionmaker in the second round may, for a variety of reasons, find it appropriate to defer to judgments made by the agency staff, particularly those that are based on a genuine application of specialized expertise in the field.[69] A commissioner or final decisionmaker is never bound to defer to staff, however.[70] As the agency's policy head, moreover, it is particularly appropriate for a commissioner to make an independent judgment about the best reading of the agency's regulations; an agency chief is never required to accept strained or problematic interpretations of the regulations advanced by the staff in the litigation process or elsewhere.[71]

E. Evidence Received at the Hearing

Because the principal focus of the hearing was the overall decision to permit construction of the two ASCs, by consent of the parties the hearing was organized with FMH as the appellant, presenting its evidence first and having an opportunity for rebuttal after the staff and the other private parties had made their own evidentiary presentations. There were no independent proceedings regarding AMD-F's appeal of the Kobuk certificate, AMD-F's appeal of the limitation on its own certificate, or Kobuk's appeal of FMH certificate for surge capacity. Evidence on these three matters, which was primarily documentary, unfolded in the course of the main proceeding, and the parties argued their views on the implications of that evidence during the overall final argument.

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[69] *See, e.g., Quality Sales Foodservice v. Dep't of Corrections,* OAH No. 06-0400-PRO (Commissioner of Administration, Sept. 21, 2006) at 11, 16 ("While there is no automatic deference . . . , the commissioner may, in appropriate circumstances, wish to extend some practical latitude to the judgments of agency staff;" giving deference "in recognition of the need to give procurement staff some latitude to manage a complex procurement").

[70] *Blasting v. New Jersey Dep't of Labor & Workforce Dev.*, 2005 WL 3071509, *4-5 (N.J. Super. App. Div. 2005) (under New Jersey's APA, similar to Alaska's, deference to staff's preliminary decisions is not required in administrative appeal process; administrative appeal is not like court review, where deference is indeed required); *Baffer v. Dep't of Human Serv.*, 553 A.2d 659, 662-3 (Maine 1989) ("the Commissioner [is] the final repository of discretion;" where final administrative decisionmaker thinks he "must defer" to prior exercises of discretion, "[t]his thwarts the purpose of the hearing procedure"); *In re Service Oil Delta Fuel Co.* (Commissioner of Administration, May 26, 1998), at 4 ("the Commissioner is not obligated to defer to the interpretation advanced by [the Division of General Services]").

[71] *See, e.g., In re Calista Corp.*, OAH No. 05-0889-SEC (Administrator of Securities, Sept. 25, 2006) at 9. (rejecting staff's longstanding but unworkable reading of securities regulation).

The hearing record encompasses about 50 hours of testimony from about 25 witnesses, including more than half a dozen physicians who do or have done surgical procedures in Fairbanks, several members of the DHSS certificate of need staff, a variety of FMH administrators, FMH nursing staff, and hospital foundation board members, as well as experts on the financial, demographic, and health care administration issues that bear on the certificate of need decision. The 1600-page record relied upon in the initial certificate of need decisions became part of the hearing record, along with several volumes of additional documentation. The admissibility of documents generated only a few disputes; those that did occur have been resolved in separate orders on evidentiary matters issued prior to this decision.

F. Summary of Ruling

The starting point of this decision is that regulations should be applied according to their plain intent as written. Proposals from the staff, the hospital, and the ASC applicants to apply the regulations in ways at odds with the sense an ordinary reader would draw from them have been rejected.

This decision concludes that, under the department's regulations, Fairbanks will have a medical need for two new outpatient general surgery suites in 2013. Because two qualified entities have applied to furnish this needed capacity, the regulations require the department to compare those applicants and make a reasoned choice between them. The matter will be remanded to the certificate of need staff to make that comparison. In addition, Fairbanks Memorial Hospital is entitled to a certificate of need for the single surge capacity suite that it seeks to build.

Part II of this decision sets the stage for the above decision, exploring the current general surgery capacity in Fairbanks, the proposals to augment that capacity, and the department's preliminary rulings on those proposals. Part III reevaluates the two ASC proposals with a particular focus on the challenges to the preliminary rulings that the parties have raised on appeal. It assesses the impact of new ASC construction on the health of the community hospital, concluding that the hospital is not fundamentally threatened by the ASC proposals. It also reviews in detail the proper rated capacity to be assigned to the existing surgery facilities, placing the rated capacity at 5400 surgeries per year notwithstanding FMH's ability to accommodate surgeries well in excess of rated capacity. With respect to the use rate and population figures to be used to project future need under the first track of the regulations, it concludes that when the methodology is properly applied the selected service area population base makes little difference

to the outcome. Critically, however, it determines that use rates for the methodology must be calculated from local statistics applicable to whatever service area population is selected. The regular methodology yields a need for two added surgery suites to comfortably accommodate the anticipated number of surgeries in 2013 that have a need for a sophisticated operating room.

At the end of Part III there is an exploration of the second track for CON approval, which requires special findings that were not considered in the preliminary decision. This decision concludes that the special findings are justified but that there is no net upward departure above the need projected through the first track methodology.

Part IV briefly reevaluates the less controversial FMH surge capacity proposal.

Because of the large number of discrete issues, this decision has not been divided into a preliminary set of factual findings followed by a separate analysis. Part II is comprised largely of findings of fact, but additional findings of a more specific nature have been made, as the context demands, throughout Parts III and IV.

II. Background

A. Existing Surgery Facilities in Fairbanks

All licensed operating rooms in Fairbanks are located at Fairbanks Memorial Hospital. FMH had five operating rooms (hereafter sometimes referred to as "ORs") until the mid-1990s, expanding to six ORs under a certificate of need granted in 1995.[72] These six ORs cluster around a central core. All are Class C suites under the Guidelines for Design and Construction of Health Care Facilities of the American Institute of Architects (AIA). Class C is the highest class in the AIA hierarchy and designates operating suites suitable for major surgery.

Although all six of the central suites fall in this highest classification, some are more ample than others. Joint replacement surgery, for example, which requires a lot of bulky equipment, can be performed comfortably in only two of the suites.[73]

In 1999, with these six suites in place, FMH and others applied for certificates of need to build additional surgical capacity in Fairbanks. After a concurrent review under the regulations then in effect, Commissioner Karen Purdue affirmed a staff recommendation to reject the applications on the basis that no additional capacity was needed in Fairbanks.[74] One of the criteria then examined for certificates of need was "the availability of less costly or more

[72] *E.g.,* Kobuk Ex. QQ at 17-18 (1999 Concurrent Review at 13-14).
[73] Direct exam of Dr. Mark Wade.
[74] *Id.*; FMH Ex. 39.

efficient alternatives," and one of several explanations for the rejection of the applications was the following observation:

> Fairbanks Memorial Hospital has one procedure room that is outfitted with medical gasses and air. This means that it could be used as a seventh operating room without any changes. The impact of adding some space to this one room to convert it to an operating room was not explored [by FMH].[75]

In January of 2006 FMH followed through on this suggestion. It made alterations to the referenced procedure room costing less than $5000 and began using it as a licensed operating suite denoted "OR1."[76] OR1 is located about 500 feet from the other operating suites.[77] It is an AIA Class A suite, usable for minor surgeries such as breast biopsies.[78] It is used only for outpatient surgeries and usage has been light—just over one surgery per business day in the first five months of 2006.[79] Some of the surgeons are unaware of OR1, which is unsuitable for many or all of the surgeries they perform,[80] but other surgeons use it and even maintain "block time" there.[81] One of the surgeons with OR1 block time is Dr. Teslow, vice president of AMD-F, who testified that he uses one of his block time days in OR1 "heavily" and that all of the procedures that he performs there are surgical procedures.[82] However, the FMH surgeons who testified at the hearing and who were aware of OR1, regardless of on whose behalf they were testifying,

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[75] Kobuk Ex. QQ at 26 (1999 Concurrent Review at 22). The importance of this observation to the final decision is underscored by a reference to it in the final paragraph of the 31-page staff analysis: "[T]here is no need for additional surgery capacity at this time. . . . Unexplored alternatives, however, do exist for . . . Fairbanks Memorial Hospital . . . to expand services without going through the certificate of need process." *Id.* at 35 (1999 Concurrent Review at 31).

[76] Direct exam and staff cross-exam of Michael K. Powers (chief executive of FMH and Denali Center).

[77] Staff cross-exam of Powers.

[78] *Id.* In this decision, operating room classes are used to describe the general nature of the rooms in question, and not as a regulatory concept. Class A operating rooms under the AIA Guidelines are designed to be suitable for surgeries performed under topical, local, or regional anesthesia without pre-operative sedation, excluding procedures needing intravenous, spinal, and epidural anesthesia routes.

Although there was much testimony at the hearing referring to operating room classes, the context and provenance of these classes was not fully developed in testimony and has been supplied here from library references. A party objecting to the taking of official notice of the characterization of Class A suites in this footnote may file an objection and submit evidence or authority to refute the officially noticed fact. Any such filing should be made at least five days prior to the date set in this case for submission of proposals for action under AS 44.64.060(e), and should be submitted separately from any proposal for action filed under that provision.

[79] *E.g.*, Agency Record at 1133 (letter from Powers to Rarig, 6/30/06) (105 surgeries in 103 business days).

[80] *E.g.*, Direct exam of Wade; cross-exam of Dr. Richard Hess.

[81] At FMH, block time is a pre-reserved period (*e.g.*, every Tuesday from 8 to 12) that is held for the surgeon's use and blocked from scheduling by other surgeons until about 48 hours beforehand. Three surgeons have block time in OR1. Direct exam of Robert Stetson (CON consultant); FMH redirect exam of Powers.

[82] FMH cross-exam of Dr. Timothy Teslow; Jt. Ex. 6 at 1445 (AMD CON Application at 5). Another AMD-F surgeon, Dr. Wennen, also has block time in OR1. FMH redirect of Powers.

made it clear that they did not think of OR1 as a real operating room; to them it is a procedure room in which some surgeries can be performed.[83]

In short, Fairbanks has seven licensed operating rooms, six of them suitable for major surgery and one—suitable only for minor surgery—that the surgeons generally think of as a procedure room. In addition, the city has numerous procedure rooms in which occur many minor surgeries[84] for which an operating room is not required.[85]

B. The Kobuk and AMD-F Proposals for New Capacity

1. Nature of the Projects

In February of 2006, Kobuk Ventures LLC became the first applicant to make an entry in the current round of proposals to expand surgery capacity in Fairbanks. Kobuk is a limited liability company with two members, Anchorage physician J. Michael James and Fairbanks surgeon Mark Wade. Kobuk originally planned to apply to build an ASC with three surgery suites. Based on a preliminary exchange with the certificate of need staff that it understood to be an indication that a three-suite facility could not be approved, however, it elected to develop a proposal for only two suites.[86] These would be placed in a 9,900 square-foot freestanding facility in northeast Fairbanks. The Kobuk application does not provide much detail about the nature of the suites to be built, but one can infer from Dr. Wade's references to the surgeries he could perform there that they would be Class B or C suites capable of handling a substantial range of orthopedic surgery.[87] Only outpatient surgery would be performed.

Alaska Medical Development – Fairbanks, a limited liability company consisting of nine physician investors and two others, submitted a proposal in May of 2006 to build a 22,500-square-foot ambulatory surgery center next to the Steese Highway in northeast Fairbanks. The

[83] AMD-F cross-exam of Dr. David Witham (orthopedist who did 413 surgeries at FMH in 2006; an FMH witness); Kobuk cross-exam of Dr. Richard Hess (Tanana Valley Clinic OB-GYN who does surgery in FMH Class C suites; an FMH witness); AMD-F cross-exam of Dr. Richard Raugust (ear-nose-throat surgeon with extensive surgery practice at FMH; an FMH witness); direct exam of Dr. Timothy Teslow (AMD-F investor with substantial general and thoracic surgery practice at FMH; an AMD-F witness); staff cross exam of Dr. Richard Cobden (AMD-F investor and vice chief of staff at FMH; an AMD-F witness); direct exam of Dr. Mark Wade (Kobuk investor with substantial orthopedic practice at FMH; a Kobuk witness).

[84] Among the medical procedures that physicians testifying at the hearing classified as "surgery" were closed reductions, cast changes for small infants, foreign body removals, and abscess drainage (Dr. Cobden); facet joint injections, epidural steroid injections, and joint blocks (Dr. Stinson); cyst aspirations and hemorrhoid procedures (Dr. Teslow).

[85] *E.g.*, direct exam of Robert D. Gould (FMH chief financial officer). FMH has seven procedure rooms. Some minor surgery that occurs in these rooms could be performed in OR1 or in one of the Class C suites, but the hospital does not place it in one of these facilities because it believes that doing so would not be a "responsible" use of a surgical suite. *Id*.

[86] Agency Record at 1581 (letter from Kobuk investors to Commissioner Jackson, Sept. 12, 2006).

[87] Direct and FMH cross-exam of Wade.

center would be operated by Advanced Pain Centers of Alaska, an entity currently operating several facilities in Alaska and affiliated with AMD-F by overlapping ownership. The facility would contain three 504-square-foot Class C surgery suites.[88] It would serve outpatients only, and would ordinarily be open from Monday through Friday from 8:00 a.m. to 5:00 p.m.

AMD-F has submitted alternative plans for a two-suite ASC, and would pursue the smaller project if given a certificate of need for only two suites.[89]

2. Public Hearing and Comment Process

In keeping with 7 AAC 07.052, once the applications were complete the certificate of need staff accepted public comments on the ASC applications in May and June of 2006 and held a public hearing in Fairbanks on June 12, 2006. The record contains a partial transcript of the public hearing and several hundred written comments. A large percentage, but certainly not all, of the written comments are identical or substantially identical forms or letters supplied by AMD-F or Kobuk to potential supporters.

a. The purpose of public hearings and public comment

Public hearings associated comment periods are held to inform the public about pending proposals, to let interested parties express their views, and to gather facts on which a final decision can be based. As a number of courts around the country have pointed out, however, a public hearing emphatically is not a plebiscite.[90] In the zoning context, judges and commentators caution that decisionmakers

> should [not] be controlled or even unduly influenced by opinions and desires expressed by interested persons at public hearings. . . . Public notice . . . is not given for the purpose of polling the neighborhood on the question involved, but to give interested persons an opportunity to present facts . . . . The [decisionmakers] should base their determination upon facts which they find to have been established, instead of upon the wishes of persons who appear for or against the granting of the application.[91]

The public hearing and comment process in the certificate of need context are no different. As former Commissioner Purdue testified in this proceeding, public hearings are often an inaccurate gauge of overall community sentiment, and they have not historically been used as a polling

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88 Agency Record at 1447, 1450 (AMD-F application).

89 Agency Record at 1572-1579.

90 *City of Apopka v. Orange County,* 299 So. 2d 657, 659 (Fla. App. 1974) (referencing authority from Maryland and Rhode Island); *see also, e.g., Basile v. Southington Zoning Bd. App.*, 1992 WL 49975 (Conn. Super. 1992); *Sexton v. Anderson County*, 587 S.W.2d 663 (Tenn. App. 1979) (public hearing not "a referendum").

91 *Id.* (quoting 3 Anderson, *American Law of Zoning*). *See also McGreavy v. Ferrazzano,* 2002 WL 220779 (R.I. Super. 2002) ("'[t]he purpose of a public hearing is not to conduct a poll'") (quoting prior authority).

mechanism in the certificate of need process.[92] The findings made below about what the public process demonstrated are drawn with these principles in mind.

b. What the public hearing and comments in this case showed

The staff accurately summarized the content of the live statements and written comments in its Concurrent Review.[93] The staff noted that many medical service recipients commented about their frustration with outpatient surgery at FMH or about their positive views of the physician investors in the proposed ASCs, and that some of the physicians commented about their own frustrations with scheduling surgeries. The staff also noted that some community leaders testified about concern that the hospital might be undermined financially if ASCs were built.

The staff seems to have drawn two conclusions from the comment process: that "scheduled outpatient surgeries regularly get delayed or bumped by more urgent inpatient procedures" and that the "testimony received generally supports the contention of the [ASC] applicants . . . that additional dedicated outpatient surgery suites are needed."[94] AMD-F, in its post-hearing brief, goes further: it advocates using the public hearing and comment in the nature of a plebiscite, offering precise percentage calculations purporting to show that "citizens of Fairbanks" overwhelmingly support the ASCs.

As observed in the preceding subsection, converting the public process to a poll or vote, as AMD-F seeks to do, is a misuse of the process. The staff's conclusions, on the other hand, were in keeping with the role of public hearings and comment periods and were supported by the comments received. Notably, however, they had no ultimate role in the staff's recommendation to the commissioner. This is because the conclusions the staff drew from the hearing and comments relate solely to "need." The staff, as will be discussed below, ultimately determined "need" through the General Surgery Services Review Methodology, a mathematical exercise. Had the staff decided it should depart from that methodology as permitted by 7 AAC 07.025(b), the subjective information about need developed through public comment could have played a role.

Since this decision will, unlike the staff recommendation, eventually explore a departure under 7 AAC 07.025(b) from the mechanical need methodology in Part VIII of the Standards and Methodologies, some further evaluation of the public comment record is appropriate. There was

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[92] ALJ exam of Purdue.

[93] Jt. Ex. 7 at 1560 (Concurrent Review at 16).

[94] *Id.*

extensive testimony in this proceeding about the nature of the public comment process and the accuracy of the information provided in it.

Both ASC applicants approached the public hearing and comment process as an exercise in political theater. Kobuk's public relations presentation at the hearing was particularly remarkable, at one point showing a slide depicting the entity that operates FMH as a large pig-shaped pit into which its employees were dumping money that they presumably had extracted from the good people of Fairbanks.[95] Kobuk worked harder to bring vocal supporters to the hearing than is perhaps typical in this kind of process: Kobuk investor Mark Wade had his staff solicit patients to attend the hearing, and gave away water bottles and T-shirts to supporters who did so.[96] AMD-F, for its part, collected hundreds of identical letters from supporters that can only have been obtained by means of some form of organized solicitation.[97] Some of the more dramatic anecdotes offered through unsworn "testimony" in the public hearing and comment process were shown in the adjudicatory hearing to have been inaccurate, with the ASC investors in some cases aware of the inaccuracies but failing to correct them.[98] These factors make the record of oral and written comments of quite limited value in assessing the medical need for new surgical capacity in Fairbanks.[99]

3. The Staff Review

a. Overall methodology

In its 22-page review and recommendation document, the staff first compared each application to General Review Standards 1 through 6. In a decision that is not challenged by any party in this appeal, the staff waived Standards 2 and 3 as inapplicable in the context of these

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[95] Agency Record at 665.

[96] *E.g.,* FMH cross-exam of Wade. Former Commissioner Purdue found the atmosphere at the hearing unusual for a CON proceeding. FMH redirect of Purdue. Cheryl Kilgore, the Executive Director of the Interior Community Health Center, felt the hearing had the tenor of "a political rally." FMH redirect of Kilgore.

[97] Agency Record at 158-458.

[98] *Compare* Agency Record at 727 (R. Clemens claim of 5-month wait for shoulder surgery) *with* direct exam of Elizabeth Wood, FMH cross-exam of Wade; *compare* Agency Record at 729 (A. Welch claim of half-day wait for surgery) *with* direct exam and staff cross-exam of Susan McLane and 11/8/05 record in FMH Ex. 14; *compare* Agency Record at 731 (F. Couney claim that FMH would not treat his mother unless he signed over his home) *with* direct, redirect, and Kobuk cross-exam of Shannon Hartke, FMH cross-exam of Wade, direct exam of Gould

[99] That the public hearing was likely approached by the ASC applicants as something other than an objective, truth-seeking exercise is reinforced by observations of some of the leading witnesses for those applicants at the adjudicatory hearing. A view that the certificate of need process was some sort of charade seemed to carry through into parts of that testimony. AMD-F investor Dr. Cobden, for example, punctuated his answers with a number of histrionic asides (*e.g.,* "Do you really want to know?"), and at one point had to be admonished to confine his testimony to the literal truth when his testimony about a supposed FMH "loyalty oath" proved, by his admission, to have been spoken "metaphorically." Kobuk investor Dr. Wade found his contempt for the process so difficult to conceal that he rolled his eyes when asked to raise his right hand to take the oath.

projects.[100] With respect to Standard 1, relating to "need," the staff referred only to the "service-specific review standard" for "General Surgery Services."

Because this was a concurrent review of multiple applications, the staff also addressed the three concurrent review standards. It determined that the ASC applicants "meet" all three standards. It did not compare the degree to which they met or exceeded the concurrent review standards.

The staff did not, at any point in the document, recommend a finding "that the availability, quality, or accessibility of existing health care services creates an unreasonable barrier to services in the service area," thereby justifying an "exception" to one or more of the standards. Hence the staff confined its analysis to the first track for certificate of need approval under 7 AAC 07.025(a). It did not advocate use of the "025(b)" track.[101]

The sections below focus on the key judgments made in the staff's review.

b. *Decision to exclude OR1 from the supply side*

In assessing the current supply of operating rooms in Fairbanks, the staff counted the six Class C operating suites at FMH but decided not to count OR1, the Class A room that is located in a different part of the hospital. In its concurrent review, the staff made two observations in explaining the exclusion of OR1 from the count. First, the staff noted that OR1

> was used for only 105 cases in nearly six months, January 1-June 29. The low level of use (averaging less than one case per day) suggests that OR1 may not be available for general surgery.[102]

The staff did not base its conclusion that OR1 "may not" be available on any factor other than its low reported usage and did not inquire further about the room's availability. Second, the staff observed that "[t]he A-B-C classification system is not recognized in current regulations."[103] The significance of this observation to the staff's reasoning was not explained in the review document. David Pierce has since explained that he did not believe OR1 was "a licensed operating room" and that his concern that it was unlicensed "has to do with – with, you know, whether you are going to count as capacity or not."[104] Hence, the staff appears to have excluded OR1 from Fairbanks capacity because the room was little-used and because the staff thought it

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[100] Kobuk did challenge the waiver of Standard 3 with respect to AMD-F at an earlier stage of the process, Agency Record at 1584-1586, but it did not appeal AMD-F's certificate or otherwise pursue the issue at this level.

[101] One of the parties noted and made a record of the staff's election not to resort to the 025(b) track. Agency Record at 1584 (letter from Kobuk investors to Commissioner Jackson, Sept. 12, 2006, at 5 n.5).

[102] Jt. Ex. 7 at 1562 (2006 Concurrent Review at 18).

[103] *Id.*

[104] David Pierce depo. at 24-25.

could not or should not count a room it believed to be unlicensed, regardless of whether it met an AIA classification threshold.

c. Decision to adopt a statewide use rate for the demand side

In selecting a use rate for calculation of demand, the staff made a decision not to use the use rate for the service area in which the ASCs would be located. The staff explained that, in Alaska, "[l]ocal use rates are . . . skewed" because Alaskans have historically had to travel to "one of the large cities" for surgery, particularly noting that the Anchorage rates include surgeries done on people from outside the area.[105] The staff decided to exclude from the statewide use rate three populations—Alaska Natives, members of the military, and residents of Southeast Alaska—and to exclude surgeries performed in facilities dedicated to those populations. The reason for excluding Natives and military was that these groups have separate health care systems and hence, in the staff's view, are not in the population "that might use the non-Native non-military services."[106] The reason for excluding Southeast from the statewide rate was the prevalence of out-of-state referrals from Southeast.[107]

As shorthand, the staff and CON experts at the hearing refer to this as a "civilian non-native" use rate for the state, excluding Southeast. The per capita use rate for this population averaged .09443 (94.43 per thousand) in the 2002-2004 period.[108]

d. Inconsistency in population assumptions for the demand side

Population is used in the methodology as part of the calculation of demand. It enters the calculation at two points. One use of population figures is in the calculation of a historical use rate—the average per capita usage of general surgery services over the preceding three years.[109] The number of general surgery services per year must be divided by the population to whom they were provided to arrive at this use rate. The second place population figures enter the calculation is as a projected population for the fifth year of the project. The use rate will be multiplied by this projected population to arrive at a projected caseload.

As noted above, the staff used a civilian non-native population in calculating the statewide use rate. When projecting population for the fifth year in order to calculate the Fairbanks caseload, the staff used a Fairbanks North Star Borough population figure that did not

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105 Agency Record at 1562.
106 Agency Record at 1562.
107 *Id.*
108 Agency Record at 1563.
109 This is discussed more fully in text accompanying note 106 and text accompanying notes 142-156 below.

exclude civilians and Natives. Certificate of Need staffer Alice Rarig has since described the inconsistency in population assumptions, which she did not discover until late December of 2006, as "an error."[110] The error increased one of the factors in the projected caseload calculation performed by the staff by 20.9 percent.[111]

e. Refusal to compare applicants

The Review Standards and Methodologies declare that, in a concurrent review, "the department will *compare the extent* to which each applicant, including any parent organization of the applicant" meets three standards relating to quality and low income/uninsured care (italics added). Notwithstanding this directive, the staff performed no comparison regarding these three standards. After determining a need level of three outpatient suites, the staff allocated two suites to AMD-F and one to Kobuk, without explanation. The same need could have been met by allocating three suites to AMD-F (which had applied for three) and none to Kobuk, or by allocating two to Kobuk and only one to AMD-F.[112] The reasons for rejecting these options were not explored.

f. Recommendation reached

The staff calculated that Fairbanks has an existing rated general surgery capacity of 5400 surgeries per year, and projected that demand in 2013 will be 9,006 cases, leaving a shortfall of 3,606 cases for which rated capacity does not exist. This translated to a "need" under the methodology for 3.00 dedicated outpatient suites.[113] As mentioned above, the staff recommended that certificates be granted for AMD-F to build two of the suites and for Kobuk to build one of them.

4. The Commissioner's First Decision

a. Overall methodology

After reviewing the staff recommendation, the commissioner asked Kobuk and AMD to submit information relevant to the reduction of each of their proposals by one suite. Upon

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[110] Dr. Alice Rarig depo. at 71.

[111] Agency Record at 1566; FMH Ex. 24. 95,367, the number used to calculate year 2013 caseload, is 20.9% more than 78,861, the civilian non-native population for Fairbanks North Star Borough.

If this error is removed, but no other adjustments are made to the staff methodology, the staff's need calculation yields a need of 1.70 outpatient suites in 2013, rather than the 3.00 reported in the staff recommendation.

[112] A fourth option might have been to invite Kobuk to submit a revised plan for three suites, and then to compare that proposal to AMD-F's on a head-to-head basis. Recall that Kobuk originally conceived of its project as a three-suite ASC, but apparently decided to apply for only two because the staff had told it the community did not have a need for three suites.

[113] Agency Record at 1566.

receipt of that information, she made the initial certificate of need decision. Like the staff recommendation, the decision used the regular 7 AAC 07.025(a) track to assess the proposals, making no "025(b)" finding to permit an exception from any of the listed standards.

b. *Importation of Anchorage use rate*

In applying the standard methodology to determine need, the commissioner, after further consultation with and advice from the CON staff, applied an Anchorage/Mat Su utilization rate to the Fairbanks population in calculating projected need. The Anchorage per capita utilization rate applied was .109, or 109 surgeries per 1000 population. By way of explanation, it was noted that the Anchorage use rate had increased substantially after ASCs were built.[114] There was no discussion of the staff's previous finding that the Anchorage use rate was "skewed." The higher utilization rate yielded a projected need of four new outpatient suites.

The Anchorage rate chosen was apparently a civilian non-Native rate, paralleling the modified statewide use rate used in the staff's recommendation.[115] The staff's 2013 population projection for Fairbanks was not adjusted (the error not having been discovered at that time nor brought to the commissioner's attention), and hence the inconsistency between inclusion and exclusion of Natives and military remained in the final need calculation. If this error had been removed and no other adjustments made, the commissioner's selected use rate would have yielded a need for between two and three outpatient suites.[116]

c. *Two suites needed for viability*

The commissioner determined from the additional submissions of the applicants that a single-suite ASC would be "at best, marginally economically efficient."[117] This finding was not used as a basis for a departure from the calculated "need" for new suites under the methodology, since need had already been reassessed at four ORs and the number of suites finally approved did not depart from that number. However, the finding that at least two suites are needed for viability provided an explanation, for the first time, of the basis for apportioning suites between

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[114] Agency Record at 1609.

[115] FMH Ex. 3 (Goldsmith Report).

[116] The commissioner's determination that four suites were needed was apparently reached by multiplying a per capita use rate of .109 by an unmodified Fairbanks North Star Borough 2013 population of 95,367 to yield a projected 2013 caseload of 10,395. Subtracting the current rated capacity of 5,400, there was an unmet need of 4,995. This unmet need represents the rated capacity of 4.16 outpatient suites. The commissioner rounded down to four. Had this calculation been done with the borough's 2013 projected civilian non-native population of 78,861, the projected 2013 caseload would have been 8,596 cases. Subtracting the current rated capacity of 5,400, there would have been an unmet need of 3,196. This unmet need represents the rated capacity of 2.66 outpatient suites.

[117] Agency Record at 1610.

the two applicants. The assessed need of four suites could not be divided by giving three suites to one applicant and one to the other; the only possible division to maintain viability was two suites to each.

d. Decision reached

The commissioner determined that the need assessed by the methodology as she applied it, four suites, should be addressed by approving two suites for each ASC applicant. This represents a 66% increase in surgery capacity for Fairbanks.[118] Concerned that the new facilities must serve low-income and uninsured Alaskans and must be integrated into the community's existing health care system, she added conditions relating to serving patients for whom care would not be fully compensated and developing a transfer agreement with FMH. The added conditions are not at issue in this appeal.

C. The FMH Proposal for Surge Capacity

In May of 2006, after the two ASC applications had been submitted but before the review of them was very far advanced, FMH requested a certificate of need for a much smaller project. FMH presently has a surge capacity OR for use in disasters, located on the second floor next to the room dedicated to birth-related surgeries. The hospital reported that disaster drills have shown that the room would function better in its intended role if relocated close to the clean core and the six general surgery ORs on the first floor. FMH proposed to build a rather large (800 square foot) operating room plus support spaces in the former laundry space across from existing ORs C and E. The cost of $1.7 million would be borne in cash by the hospital foundation.[119]

FMH assured in its application that the new construction "would not increase the number of rooms currently in service nor the number of rooms held as a standing reserve."[120] The hospital nonetheless observed that, owing to its convenient location, "this room may be brought into service from time to time to meet the ordinary peak load demands of the department."[121] The latter statement suggests that FMH management believes that "ordinary peak load" places some strain on existing capacity.

[118] It is an increase from six to ten suites capable of handling major surgeries. By rated capacity in raw numbers of surgeries the increase is 89%, but that comparison is somewhat misleading because it ignores the fact that, due to the inpatient component, the average surgery in the existing suites is likely to be more substantial and time-consuming than the average surgery in the new suites.

[119] Agency Record at 1364, 1387-8, 1422, 1427 (FMH CON application).

[120] Agency Record at 1366.

[121] *Id.*

The staff reviewed the FMH proposal under the six general standards. It did not apply any "service-specific review standards" because it felt that there are none for surge capacity suites (the only service-specific review standards in the surgery field are for general and open heart surgery). Although there was no concurrent application for surge capacity, the staff also touched on the three concurrent review standards.[122] The staff recommended approval.

There is an alternative way to conceptualize the handling of the surge capacity application. The hospital's counsel stated at final argument that the processing of this application should be viewed as an application of 7 AAC 07.025(b). Under this view, the application would be seen as one for general surgery services that, because of a deficiency in available surge capacity in the service area, has been excepted from the special review methodology.

The commissioner's preliminary decision granted the certificate of need as recommended, without discussion. The commissioner added a condition such that approval for the disaster-preparedness improvements would be withdrawn unless FMH certified that it had entered into, or entered into good faith negotiations for, written transfer agreements with the two proposed ASC entities.[123]

III. Revaluation of the AMD and Kobuk Proposals

This section reevaluates the AMD and Kobuk proposals in light of the fuller record developed at the hearing. Parts A and B assess whether the AMD and Kobuk proposals have met the presumptive review criteria under 7 AAC 07.025(a)(2), with Part A devoted to the "General Review Standards" and Part B devoted to the specific methodology for "General Surgery Services." Concluding that the two applicants have demonstrated a need—as defined by the review criteria—for only two additional operating suites, the reevaluation turns in Part C to whether they have established a basis for "an exception to one or more of the standards" permitted by 7 AAC 07.025(b), justifying a more generous allocation of new capacity. Although the basic predicate for an 025(b) exception has been met, Part C concludes that the overall need remains at two suites. Part D explains the need for a staff determination of which ASC applicant should be authorized to go forward.

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[122] Agency Record at 1549-51.

[123] Agency Record at 1611. This condition has not been appealed.

A. A Closer Look at the General Criteria

1. Most Criteria Not at Issue

All applications for certificates of need are subject to six General Review Standards set out on page 2 of the Alaska Certificate of Need Review Standards and Methodologies. In addition, in a concurrent review of multiple applications three further criteria are provided to assist in making any necessary choice between competing applications. This section of the present decision focuses on the six standards that all applications must meet, regardless of whether they have competitors.

The staff found that each of the six criteria had either been met or should be waived with respect to both the Kobuk and AMD-F applications, and the commissioner left these findings in place. On appeal, FMH does not quarrel with the findings on five of the six criteria. It challenges only the handling of General Review Standard 5, which provides that an applicant for a certificate of need "briefly describe[] the anticipated impact on existing health care systems within the project's service area that serve the target population in the service area, and the anticipated impact on the statewide health care system." Issues related to this criterion were quite intensively litigated at the hearing.

2. Nature of Standard 5

All but one of the General Review Standards expressly require that an applicant "document" or "demonstrate" something. Standard 5, relating to impact on health care systems, is the exception. It uses the phrase "briefly describes," which, if read literally, would be only a procedural requirement that an applicant touch the base of including a description of impact; there would be no substantive requirement that the impact be shown to be beneficial or acceptable.

The staff treated Standard 5 as a substantive standard like the other standards. Indeed, in summarizing the standard in its tables on pages 3 and 4 of its review document, the staff substituted the word "demonstrates" for the word that actually appears in the standard, "describes." No party has challenged this substantive reading of Standard 5.

The staff's reading of Standard 5 as a substantive criterion is appropriate. The commissioner has discretion to construe the department's regulations in keeping with their overall intent. Avoidance of unacceptable damage to other elements of the health care system is

among the core purpose of the certificate of need program.[124] To interpret the review standard directly addressed to this core purpose as merely a procedural check-off, rather than a basis for substantive evaluation, would allow the program to ignore one of its core purposes.

Standard 5 has two elements: "impact on existing health care systems within the project's service area" and "impact on the statewide health care system." These will be examined in turn in subsections 3 and 4 below.

3. Impact on Existing Health Care System in Fairbanks

The staff devoted minimal attention to Standard 5, finding only that the standard had been met and commenting that, because the ASCs would increase surgery demand in Fairbanks, the impact on the hospital should be "minimal." FMH contends that the staff incorrectly evaluated the impact of new ASCs on the existing health care system and specifically upon FMH itself as a community hospital.

Kobuk and AMD-F share the staff's view, and their defense of the view that impact would be minimal has not been passive at the hearing or at prior stages of the process: They have sought to show that FMH is a monopolist so profitable that it exports wealth to a national corporation, Banner Health, and thus one that requires no protection from their competition. In its presentation at the public hearing, for example, Kobuk displayed a slide asserting that "FMH revenues will be minimally affected because it is part of the $2 billion-dollar Banner Health System." Kobuk illustrated the slide with the previously mentioned cartoon showing people shoveling money into a large pit shaped like a pig and labeled "Banner Health."[125]

The specifics of this controversy are examined below. In general, Kobuk and AMD-F mischaracterize FMH, Banner Health, and the financial arrangements that support them, but the two ASC applicants are fundamentally correct that construction of new surgery capacity in Fairbanks does not greatly threaten the financial health of the community hospital.

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[124] *See, e.g.*, Agency Record at 1765 (MacQuest report at 35) (goal to "protect the critical health care infrastructure").

[125] Agency Record at 665. *See also, e.g.,* Agency Record at 725 (comments of consultant Chris Gates) ($2.0 to 4.8 million per year "exported . . . out of this state to . . . executives somewhere"; "hospital foundation actually earns--$26 billion [sic] average over the last seven years").

a. *The nature of FMH and Banner Health*

The owner of Fairbanks Memorial Hospital is the Greater Fairbanks Community Hospital Foundation.[126] Formed more than 35 years ago in response to a community health care crisis growing out of the 1967 Chena River flood, the foundation is still managed by a board of volunteer trustees from the local community. The board has managed the foundation conservatively, building investment reserves of more than $120 million in addition to medical real estate holdings in Fairbanks worth about $200 million. Notwithstanding the contrary impression given in promotional statements by the ASC applicants, the foundation is not part of Banner Health and the foundation's assets do not fund activities outside the Fairbanks region. As the owner of the hospital's physical plant, the foundation is responsible for capital improvements to the facility. Recent projects include a $45 million "BLT" (boiler-laundry-trash) upgrade. In 2007 the foundation expects to spend in the neighborhood of $40 million on health care in Fairbanks,[127] including $18 million on current construction projects, $8½ million on developing a cardiology center, $5 million on capital equipment, and $4½ million to service bonds for prior construction.

Considerable sophistication and experience are needed to run a large hospital in today's health care system, and a complete management team can be hard to recruit locally. The foundation feels it must use the services of an organization specializing in health care management, such as Providence Health System or Banner Health, to run the facility. For this reason, Fairbanks Memorial is leased to Banner Health, an Arizona nonprofit corporation that operates hospitals in many states. Banner is the successor entity to the Lutheran Hospital and Homes Society, and under these two names it has operated Fairbanks Memorial since 1972. Banner operates the facility subject to some general oversight from the foundation, including review and approval of the hospital's annual budget.

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[126] Unless otherwise indicated, the description of the nature of FMH and Banner Health is based on the testimony of Daniel Winfree, Executive Director of the foundation, and Cheryl Kilgore, a member of the foundation's board. Winfree, who came to the hearing expressly to testify on this financial relationship and who appeared to have prepared his testimony with care, is the source of the rent figures and other numbers used in this description. Winfree's numbers differ somewhat from financial statements that FMH has released and from the understanding of FMH Chief Executive Mike Powers; *cf., e.g.*, Ex. 6 to Powers depo.; Powers depo. at 50-52. For some of these differences there are potential explanations (such as the inclusion of both basic rent and additional rent in above-the-line expenses in the financial statements), but it is not necessary to delve into them for purposes of this decision.

[127] The testimony was slightly confusing on this figure; the number appears to be between $37½ and $43 million.

The financial arrangement between the foundation and Banner is complex. In general terms, Banner pays a basic rent per square foot, which in 2006 was $9.5 million and in 2007 will be $13.5 million. The basic rent is fixed and represents a floor for the foundation's income, and it has been climbing steadily as the hospital expands. If the hospital has a net "profit"[128] in any quarter and thereby generates excess cash as determined by a formula, Banner pays 82 percent of this cash as "additional rent." Banner retains the balance, subject to a cap. In six of the last seven years, the formula has caused Banner to pay additional rent. The hospital's net profit, if any, is thus ordinarily divided between the foundation and Banner. Net profit does not finance charity care nor subsidize low-revenue segments of the hospital's operation; these costs come out before profit is calculated.[129]

Banner also receives 3½ percent of net operating revenues[130] as an administrative fee for services beyond day-to-day running of the hospital, such as the handling of risk management and insurance. This fee, negotiated in 1993, is below the current norm for hospital administrative fees. With the percentage of net profit and the administrative fee, Banner's overall take from net operating revenues is capped at 4½ percent.

In 2006, this arrangement resulted in a total payment of $14 million from Banner to the foundation. The foundation has other sources of income (about $4.5 million from investments and $1 million from office leases and gifts), giving it an annual income that varies but would typically fall in the neighborhood of $20 million. Since the foundation expects to spend about $40 million in 2007 for the construction, capital equipment, and other expenses mentioned above, it will need to draw on its reserves. Once complete, some of these outlays will yield revenue-producing assets,[131] so that the draw on reserves could potentially be reimbursed in future years.

There are several general conclusions to be drawn from this structural and financial information. First, most profits generated at Fairbanks Memorial revert to the foundation and become seed money for improvements and upgrades to benefit Fairbanks citizens. Second,

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[128] The witnesses used the term "profit" with reference to an excess of revenues over expenses for the hospital itself. Both controlling entities, Banner and the foundation, are nonprofits.

[129] *See* Ex. 6 to Powers depo.

[130] In the case of FMH, "net operating revenues" excludes salaries, supplies, rent, and a number of other large cost items. In recent years it has been a little more than $100 million. Ex. 6 to Powers depo.

[131] FMH's certificate of need application for the cardiology center whose construction cost is part of the 2007 budget projects that the center will generate between $2.9 and $5.9 million in "contribution profit" per year. This does not become a direct contribution to the foundation, but through the various rent mechanisms it should largely inure to the benefit of the foundation.

lower profitability would, in most years, result in a lower contribution to the foundation. Third, the foundation presently has a large reserve.

There is a danger that the focus on the handling of profits will obscure another fundamental truth about FMH. The hospital foundation and Banner manage FMH, in important respects, as a community institution, not as a profit-maximizing entity. Although already a relatively low-cost provider among Alaska hospitals,[132] FMH has a particularly generous charity care policy, giving aid to patients with incomes up to 500 percent of the federal poverty level, or $82,500 per year for a family of four (in contrast, other large hospitals in Alaska cap aid eligibility at 200 percent of poverty).[133] In 2006, charity care at FMH amounted to $6.6 million.[134] Even AMD-F physician Richard Cobden, perhaps the most outspoken critic of the hospital to appear at the hearing, acknowledges that Fairbanks Memorial does "a wonderful service to the community" in the context of charity care.[135] It is notable that the charity care policy, insofar as it reduces net operating revenue, reduces the funds for distribution to both the foundation and to Banner Health under the 82%-18% additional rent formula.

b. Role of surgery revenue in financing FMH

There was general agreement among witnesses at the hearing that surgery is ordinarily one of the more profitable services at a hospital and is among the profit centers used to cross-subsidize unprofitable functions such as the emergency department. FMH expert Michelle Vest calculated that migration of surgeries to the new ASCs could reduce the hospital's net income by "over one million dollars," which "represents approximately 35% of the Hospital's entire annual net income which was $2.8 million in 2005."[136] Ms. Vest assumed that all of the surgeons currently practicing at FMH who are associated with the ASC applicants would move all of their outpatient surgeries to the ASCs, with the possible exception of unprofitable outpatient surgeries.

Ms. Vest went on to lay out potential consequences of the loss of 35% of net income. As examples, she suggested that the hospital's $6.6 million in charity care might be reduced by $1 million, or that services in departments that typically generate negative cash flows (*e.g.*, emergency, mental health) might be reduced.

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132 *E.g.*, direct exam of Purdue.
133 *E.g.,* direct and staff cross-exam of Hartke.
134 FMH Ex. 11; direct exam of Powers.
135 Cross-exam of Cobden.
136 FMH Ex. 11 at 2 (Michelle Vest Impact Analysis). Ms. Vest is a health care finance expert with strong credentials. FMH Ex. 10.

The Vest opinion on lost profitability has not been challenged by other evidence, and it is probably basically sound. Her exploration of potential consequences is somewhat misleading, however. One must recall that FMH does not finance charity care or the operating expenses of particular departments from net income. Instead, net income (subject to certain restrictions relating to cash accumulation) is divided between the hospital foundation and Banner, with the vast majority going to the foundation. The most likely effect of a $1 million reduction in net income is an eventual $820,000 reduction in additional rent payable to the foundation, which would, in a typical year, represent a reduction of about four percent of the hospital's payments to the foundation.

c. *Ability of FMH to withstand reduction in surgery revenue*

The surgery department at FMH generates a surplus of revenue over expenses. The amount of this surplus has not been established, but one can infer from Ms. Vest's calculations with respect to a small part of the surgery caseload that the surplus is at least several million dollars. The surplus, in the aggregate, is unquestionably important to FMH; were there no surplus at all from surgery, the lost net revenue could force the hospital to cut back on a variety of programs, including charity care, in order to remain in at least a break-even status after basic rent to the foundation and other expenses have been paid. The prospect in this case, however, is about a $1 million reduction in the annual surgery surplus, not elimination of the whole surplus. Looking at FMH's performance in recent years as a guide, this is not a sufficient reduction to eliminate the likelihood of an overall profit (excess of revenue over expenses), and hence its effect is a more subtle one, impacting the accumulation of funds in the foundation that are used primarily for capital improvements.[137] There is no evidence that a reduction of the foundation's annual income stream from approximately $20 million to approximately $19 million will threaten any vital component of the Fairbanks health care system.

d. *Staffing*

FMH employs eight full-time and five part-time nurses to staff operating rooms A through F.[138] The hospital finds it challenging to recruit trained OR nurses, and typically must use temporary or traveler staff, at increased expense, to supplement the permanent corps.[139] An

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[137] The foundation also funds some community programs directly, such as the Chronic Inebriate Program, and makes grants to other nonprofits such as the Interior Community Health Center. Direct and staff cross-exam of Purdue; direct and Kobuk cross-exam of Cheryl Kilgore (Exec. Director, Interior Community Health Ctr.).

[138] Direct exam of McLane; *cf.* direct exam of Wood (giving slightly different staffing numbers).

[139] *Id.*

unattractive feature of operating room nursing at FMH is that the nurses must allow themselves to be placed on call for night duty.[140] The hospital fears that any new ASCs will draw trained staff away from the hospital through their more attractive working hours (one surgeon referred to them as "banker's hours"), leaving FMH with high turnover and chronic understaffing.[141]

That development of ASCs in Fairbanks will have an effect on hospital recruitment and retention for operating room nurses is undeniable. FMH has not shown, however, that the overall effect on the "existing health care system" in Fairbanks would be anything more than marginal. The loss of nearly one thousand outpatient surgeries from the hospital—the loss FMH expert Michelle Vest has projected—would reduce the overall surgery load at the hospital by about 18 percent and thus would presumably make it easier to weather some staff losses. Moreover, a portion of the staffing needs of an AMD-F ASC would likely be met by nurses already working in the procedure room at the affiliated clinic already operating in Fairbanks.[142] Beyond that, the traditional way to address recruitment and retention problems in a labor market is to improve the compensation of those one seeks to recruit or retain. This entails expense, but the surgical nursing staff is small enough that even substantial compensation increases for these nurses would not multiply out to numbers that would have a major effect on the hospital's bottom line. Finally, to accept FMH's view that the staffing issue should be a driver in evaluation the Standard 5 analysis would, in effect, be to apply the certificate of need program with the express purpose of denying workers more attractive employment opportunities in an effort to keep them tied to their current employment. It is quite unlikely that this is the sort of management the legislature had in mind when it created the program. In short, the staffing challenges that one or more competing ASCs would create at FMH do not justify a finding that the ASC applicants fail to meet Standard 5.

e. *Benefits of competition*

As a counterweight to the staffing and financial ill-effects that FMH posited under Standard 5, the ASC applicants have argued that their projects would, through competition, cause the existing elements of the health care system in Fairbanks to improve their service to patients. For example, Kobuk investor Dr. Mark Wade observed that the only reason hospitals in Dallas

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[140] Direct exam of Wood.

[141] *Id.*

[142] Advanced Pain Centers of Alaska dba Advanced Medical Centers of Alaska currently operates a clinic in Fairbanks at which AMD-F investor Dr. Lawrence Stinson and two colleagues, assisted by an operating room nurse already in their employ, presently do 1200-1500 procedures per year, most or all of which they would move to the new ASC. Direct and FMH cross-exam of Stinson.

(where he used to practice) offer valet parking to patients is because they face competition from other surgery providers.[143] Because the adverse effects on the existing health care system have not been shown to be substantial, it is not necessary to evaluate the desirability of this kind of competition as an alleged counterweight.

4. Impact on Statewide Health Care System

Potential impact to the statewide health care system is the second element of Standard 5. The only impact to the statewide health care system explored at the hearing was the possibility of an added or lessened cost burden on the Medicare and Medicaid systems.

a. Direct Cost Savings

For government-reimbursed service, the ASC applicants have established that an ASC setting would likely be cheaper than FMH for a number of outpatient surgeries. For example, both Medicare and Medicaid reimbursement for an arthroscopic carpal tunnel release surgery would be substantially lower; illustrations presented at the hearing showed savings of between 15 and 60 percent.[144] AMD-F claims that the overall average Medicare/Medicaid reimbursement for surgeries in ASCs is about 38% lower than for hospital outpatient surgeries of the same type,[145] and the examples explored at the hearing indicate that this figure is in the correct range.

To the extent that ASCs are able to charge less than hospitals for particular surgeries, part of the reason is that they typically have lower overhead.[146] When an ASC takes away a portion of a hospital's surgeries, however, the hospital's overhead does not go away. If the community is to continue to have a hospital, its overhead must be supported by other means.[147] It may therefore be unwise to be too sanguine about localized cost savings, since cost increases for other hospital services or in other parts of the system may counterbalance them. FMH presently has the lowest overall charges of any major hospital in the state; a significant loss of revenue in the surgery area could cause some upward movement in other charges, which may eventually affect Medicaid payouts for the associated services.[148]

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143 AMD-F cross-exam of Wade.

144 Affidavit of Elizabeth Wood (admitted without objection at final argument); *cf*. direct exam of Sharon Anderson (Kobuk health care administration consultant).

145 Kobuk re-cross of Jeremy Hayes (AMD-F public relations and business consultant).

146 Direct exam of Hayes.

147 Direct exam of Watts.

148 *See* direct exam of Roderick Betit (CEO, Alaska State Hosp. & Nursing Home Ass'n; former director of Utah Dep't of Health); direct exam of Karen Purdue.

b. *Direct Cost Increases*

Advanced Pain Centers of Alaska dba Advanced Medical Centers of Alaska, which will be the operator of the proposed AMD-F facility and is affiliated with AMD-F by common ownership, currently operates a clinic in Fairbanks. AMD-F physician Dr. Stinson and two colleagues annually do between 1200 and 1500 pain management procedures, such as epidural steroid injections, in that clinic's procedure room. They would move most or all of them to the new ASC if it were built. Moving the procedures to an ASC will enable Stinson and his colleagues to get supplies reimbursed rather than having to pay for them out of their own fee, and it will also permit the recovery of a separate "facility fee." This is part of the perceived benefit to Dr. Stinson of opening an ASC: the ability to receive higher payments for these procedures.[149] The higher payments will represent cost increases to the statewide health delivery system.

The example provided by Dr. Stinson bears out more general testimony from Dr. Carolyn Watts, a nationally distinguished figure in health care economics, to the effect that overall prices would not fall as a result of the addition of two new ASCs in Fairbanks needing to recover investments of $15 million.[150] Among other effects, she noted the likelihood that procedures would be moved from doctors' offices to the ASC with a resulting addition of a facility fee.[151] Price competition, which works well to control prices in other markets, operates poorly in the health care field to constrain upward adjustments of this kind.[152]

c. *Overall Effect on Cost to Statewide Health Care System*

The evidence was inconclusive on whether the rate of increase in health care costs reimbursed by Medicare and Medicaid would, overall, be accelerated or retarded by the construction of ASCs in Fairbanks. There are significant immediate and direct cost savings that may or may not be offset or more than offset by countervailing tendencies to increase cost. With reference to Standard 5, it has not been shown that the staff's finding that the standard has been met was erroneous.

Regarding services *not* reimbursed by Medicare or Medicaid, AMD-F admits that data is insufficient for an outsider to determine whether its charges would be higher or lower than the

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[149] Direct and FMH cross-exam of Stinson.

[150] Direct exam of Watts. Dr. Watts, a University of Washington professor and administrator who is widely published in national journals on health policy and economics, chaired the Governor's Task Force on Certificate of Need in Washington in 2006. FMH Ex. 13.

[151] *Id.; cf.* re-direct of David Witham (surgeon-investor in proposed Seattle ASC) (ASCs attractive because they "can increase your income").

[152] Direct exam of Watts.

hospital's.[153] Kobuk has provided no information about its projected fee schedule. Increased or lowered costs to private payers are not, however, among of the standards on which certificate of need applications are judged.

B. Application of the Need Methodology

1. The Need Formula in the Regulations

The need methodology for general surgery is laid out in a series of three steps on pages 30 and 31 of the Standards and Methodologies.

Step one is to determine caseload ("C") for the fifth year after project implementation. This is done by multiplying projected population in that year ("P") by the average per-capita use rate[154] ("GSUR"). The formula is expressed as C = P x GSUR.

Step two is to determine the general operating rooms required ("GORR") to meet that caseload by dividing caseload by the target use capacity for operating rooms ("TU"). The formula is expressed as GORR = C/TU. TU is defined as 900 cases for ORs serving a mix of inpatients and outpatients, and 1200 cases for ORs dedicated to outpatients.

Step three is to subtract the number of existing and previously-approved general operating rooms from GORR; the difference is the projected need.

This way of conceiving the exercise is unwieldy in a community that is projected to have, in year five, a mix of ORs, some with rated capacities of 900 and some 1200, because the denominator in the C/TU formula must then be a pro-rated blend of the two capacity ratings. To avoid these complications, the staff and the CON experts at the hearing[155] generally addressed the question in the following mathematically equivalent but much more intuitive manner:

1. What is the total rated capacity of the present set of operating rooms?
2. What is the projected caseload five years hence?
3. If the number in 2 is greater than the number in 1, how many additional rooms (at 900 or 1200 surgeries each, depending on type) are needed to cover the shortfall?

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[153] FMH cross-exam of Hayes.

[154] The definition of GSUR has been written imprecisely in the methodology as "cases provided over the preceding three years per 1,000 persons." If this were read literally, it would overstate the intended figure by a factor of 3000. Step one would proceed as follows (using staff figures for surgery count and population):

GSUR = 18,899 (surgeries in past 3 years) ÷ 80.8 (thousands of people, 2005) = 233.9 cases provided over the preceding three years per 1,000 persons

C = 86,647 (2013 population) x 233.9 = 20,266,733

Continuing with the methodology, the community would then need at least 16,889 operating rooms in 2013. To avoid this absurdity, the administrative law judge has substituted the concept of average per-capita use rate—which is plainly what the drafter intended to describe—for the casually-written definition in the methodology. The staff and the expert witnesses have all done this as well, without saying so.

[155] *See, e.g.*, Agency Record at 1566 (Staff Review at 22); FMH Ex. 3 (Goldsmith report) at 6-11.

The analysis below will progress in this more intuitive order.

2. The Importance of Faithful Application of the Regulations as Written

The CON provisions in Title 7 of the Alaska Administrative Code, and the Standards and Methodologies they adopt by reference, are not mere policy guidance. They are law.[156] These laws must be interpreted "with due regard for the meaning the[ir] . . . language conveys to others."[157] It is the text of the regulations that has gone through a public review process; a departure from their text makes that process irrelevant. Further, when one adheres to the plain meaning that the text conveys to those who use it, the resulting consistency and predictability enable businesses to plan with a measure of certainty. Straightforward interpretation of the language also helps to avoid unnecessary court reversals and the disruption and delays that can attend them. Last and perhaps most important, it helps to avoid a public perception that the meaning of rules is being manipulated to achieve a preordained result.

This is a case in which all participants have, in one context or another, advocated an application of the regulatory methodology that can best be described as creative. One party would class an OR housing a mix of inpatient and outpatient surgeries as an operating room "dedicated to outpatient surgery," even though there is a separate category in the regulation for "operating rooms serving both inpatients and outpatients." Others would include minor surgery procedures done in physicians' offices among "general surgery cases," even though the methodology indicates that "cases" must entail "a . . . visit to the operating room." Another party has found a "requisite adjustment" in the methodology that translates a projected unmet caseload of 1,514 cases into a "need" for four 1200-case suites with a collective capacity of 4800 surgeries, even though there is no text in the methodology regarding this adjustment.

The approach taken below has been to apply the methodology according to a conventional reading, whereby it is a largely mechanical formula producing a standard result.[158] The special circumstances the parties wish to bring to the table can, in many cases, be examined in the context of the 025(b) exception.

[156] *State v. A.L.I.V.E. Voluntary,* 606 P.2d 769, 777 (Alaska 1980) ("regulations are laws in every meaningful sense").
[157] *Wilson v. State Dep't of Corrections,* 127 P.3d 826, 829 (Alaska 2006).
[158] Should the department find through experience that a conventional application of the regulations as written produces undesirable results, it can propose amendments to the regulations, allowing these to be vetted through the public process.

3. Existing Supply

a. *For purposes of measuring capacity in the certificate of need process, there are six operating rooms in Fairbanks*

Fairbanks Memorial has seven licensed operating rooms.[159] Six are suitable for major surgery and one, OR1, for minor surgery. The staff, AMD-F and Kobuk argue that only the six suites suitable for major surgery should be counted as supply in the certificate of need analysis. FMH contends that all seven rooms should be counted.

The basic argument in favor of counting OR1 is simple. The Review Standards for General Surgery Services require that the projected need for capacity be compared against the "number of existing and CON-approved operating rooms."[160] The reference to CON-approved rooms relates to approved but yet-unbuilt capacity, of which there is none in Fairbanks; hence, the relevant capacity number is the "number of existing . . . operating rooms." The only explicit exclusions in the Review Standards are for "surgery suites dedicated to C-sections and other birth-related surgeries" and "surgery suites dedicated to LASIK and other eye surgery."[161] OR1 is an existing facility, it is licensed as an operating room, and it fits in neither of these excluded categories.

The staff's original reasons for electing to exclude OR1 cannot be sustained. First, the staff observed without investigation that the low number of surgeries in the room in its first months of operation "suggests" that it "may not" be available for general surgery. The surmise that OR1 "may not" be available for general surgery proved, at the hearing, to have been mistaken, in that the evidence showed that the room is available for additional general surgery within its limitations as a Class A suite.[162] The second basis for the staff's exclusion of OR1 was David Pierce's understanding that it was not a licensed operating room. In this belief he was simply misinformed.

In its post-hearing brief, the staff (joined by Kobuk) advances two new reasons for excluding OR1 from the count. One of the new reasons to exclude OR1 is that FMH chief executive Mike Powers, who was a particularly plain-spoken witness, frankly stated that he converted OR1 from a procedure room to an operating room with an eye toward DHSS's

[159] There are additional operating rooms used only for Caesarian sections and other birth-related surgeries. All parties agree that under the Review Standards and Methodologies these rooms are not to be counted as part of general surgery supply, and hence they are ignored throughout this discussion.

[160] Standards and Methodologies at 31.

[161] *Id*. at 30.

[162] *E.g.*, FMH cross-exam of Teslow (OR1 "used to be" overcrowded, but he now uses his Monday block time only lightly).

certificate of need regulations. He testified that when the new regulations effectively reduced the rated capacity of the six Class C suites, he decided to upgrade OR1, where surgeries were already occurring, from a procedure room to an operating room so as to demonstrate that the hospital had the capacity to do what it was already doing. The staff characterizes this as "manipulation of the Methodology." There is some irony in this characterization, since it was the staff itself that invited FMH to perform just such an upgrade: it had rejected FMH's 1999 application on the basis (in part) that OR1 could readily be converted to an operating room, perhaps obviating potential need for new construction of surgery capacity at FMH. In any event, there is no basis to apply the regulations differently simply because a party's behavior has been influenced by knowledge of the regulations.

The staff's second newly-identified basis to exclude OR1 is more telling. The staff contends that "[e]very surgeon to testify at the hearing—including those surgeons testifying on behalf of FMH—unequivocally, and without hesitation, testified that there were 6—and only 6—operating rooms at FMH."[163] This is essentially true of the surgeons who testified to a particular number of rooms (most, but not all, did), and it illustrates an important point. OR1, as a Class A suite, is far smaller and more limited in scope than the six centrally-located major surgery suites. It apparently is not suitable for most surgeries for which an operating room is mandatory: it appears that virtually every surgery that presently takes place in OR1 could be performed, albeit perhaps less comfortably, in a procedure room.[164] Even though it is licensed as an operating room, the surgeons do not think of it as one; they think of it as a procedure room.

This leads to the central question in assessing existing capacity in Fairbanks under the regulations: whether the phrase "existing . . . operating rooms" in the general surgery methodology ought to be interpreted to encompass operating rooms that are as limited in scope as Class A suites such as OR1. The general surgery certificate of need process, while designed to limit excessive investment, is also intended to assure that there is *enough* capacity to perform all types of surgery other that birth and eye procedures. Counting Class A suites could lead to anomalous results in this regard. To take a simple example, if a community has a projected caseload of 1000 major and 2000 minor surgeries a year and has four operating rooms, all of them Class A, an interpretation of the methodology that counts Class A suites would lead to a

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[163] Staff's post-hearing brief at 7.

[164] OR1 was a procedure room until the end of 2005. The testimony of Mr. Powers suggests that it was already accommodating the same surgery caseload before licensing that it accommodated after licensing in the early part of 2006.

conclusion that the community has ample capacity and needs no new surgical facilities—even though the community has 1000 surgical procedures each year (all of the major surgeries) that cannot be accommodated at all.[165] Such a result would be inconsistent with the certificate of need statute, which requires that the department "shall grant" a certificate if current or projected availability of services "is less than the current or projected requirement."[166]

Because of this anomaly, applying the methodology while counting Class A suites can mask serious capacity issues with respect to major surgery. One might argue that it does just that in the case of Fairbanks Memorial, where many surgeon complaints about difficulty in scheduling surgery relate to major surgeries, not to the minor surgeries that can be performed in OR1. Moreover, since most or all surgeries that presently take place in OR1 could be performed in a procedure room, one can infer that even when there are capacity issues relating to minor surgeries, they are less critical than those relating to major surgeries because of the feasibility of housing spillover procedures in facilities other than licensed operating rooms.

As has been noted before, the general surgery review standards are a regulation. They contain a regulatory phrase—"[the] number of existing . . . operating rooms"—that is undefined. Although the department staff has expressed views about the interpretation of this phrase,[167] it has never been elucidated in a final, formal decision at the commissioner level. This means that the commissioner, in this decision, is writing on a clean slate and is constrained by no prior interpretation.[168]

Where regulatory language is susceptible to more than one plausible interpretation, the commissioner has discretion to interpret it in a manner that furthers the regulation's overall intent, particularly when related to a matter within the agency's specialized knowledge and experience. So long as the interpretation is not "plainly erroneous or inconsistent with the regulation," it will ordinarily be given effect by the courts.[169] Principles of statutory

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[165] The methodology would assign the community a capacity of at least 3600 surgeries (900 per operating room).

[166] AS 18.07.041.

[167] In an Anchorage case (*In re Providence Health System Alaska,* OAH No. 06-0152-DHS), the staff has contended that all licensed operating rooms are part of the count; in this proceeding, it has taken multiple positions during the course of the hearing but ultimately settled on the view that some licensed ORs should not be counted.

[168] *See, e.g., United States v. Farley,* 11 F.3d 1385, 1390 (7th Cir. 1993) ("unpublished opinions of agency staff" not relevant to subsequent interpretation of agency's statute*); Chevron, U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837, 863 (1984) ("[a]n initial agency interpretation is not instantly carved in stone").

[169] *Lake and Peninsula Borough v. Local Boundary Commission*, 885 P.2d 1059, 1062 n.11 (Alaska 1994); *see also Northern Timber Corp. v. State,* 927 P.2d 1281, 1284 & n.10 (Alaska 1996) (suggesting that the broad deference recognized in Lake and Peninsula may only apply where the agency is interpreting regulations within its expertise).

construction carry over to the interpretation of regulations.[170] One such principle is that the interpretation of legal provisions should be guided by the "purpose, equity, or spirit" of the law as a whole.[171]

Because of the potential masking of capacity issues if the regulation is interpreted otherwise, the interpretation of "[the] number of existing . . . operating rooms" that is most in keeping with the overall goals of the certificate of need program, as expressed in its enabling statute, is one that focuses not on the technical issue of whether a room is licensed as an operating room, but rather on its capabilities. It is unnecessary for this decision to determine exactly what the threshold of capabilities should be to justify inclusion in the count; all that is necessary is to recognize that OR1, whose capabilities have not been shown to differ significantly from ordinary procedure rooms, falls below that threshold.

This is an interpretation of the phrase "operating rooms" that accords with its usage in common parlance by surgeons themselves. The evidence taken in this proceeding shows that surgeons do not ordinarily refer to rooms such as OR1 as "operating rooms."[172] Similarly, the veteran surgical nurse who testified extensively for FMH at the hearing repeatedly forgot to include OR1 when relating information about the hospital's operating rooms, betraying that she likewise does not think of it as such.[173]

Further, the methodology at one point (in the definition of GORR) refers to the operating rooms it seeks to count as "general operating rooms,"[174] thus using that phrase interchangeably with the term "operating rooms." Even FMH management does not view Class A rooms as "general operating rooms." This can be gleaned from a close reading of Agency Record 1387—part of FMH's own surge capacity application—where FMH declares that an existing 300-square-foot suite "does not meet current AIA general operating room space standards." A 300-square-foot suite easily meets Class A space standards. Hence, FMH management must believe that meeting Class A standards is not the same as meeting the standards for a "general operating room."

The fact that OR1 does not meet the common understanding of the terms "operating room" or "general operating room" used by professionals in the field confirms that it is

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170 *State Dep't of Highways v. Green,* 586 P.2d 595, 603 n.24 (Alaska 1978).

171 2B Sutherland Stat Constr § 56.02 at 306 (5th ed. 1992); *see also Van Beeck v. Sabine Towing Co.*, 300 U.S. 342, 351 (1937) (seek "consistency and unity with a legislative policy which is itself a source of law").

172 *See supra* text accompanying note 35.

173 Direct exam of Wood; AMD-F cross-exam of Wood in rebuttal.

174 Standards and Methodologies at 31.

reasonable for the terms to be construed in regulations to encompass only rooms more sophisticated than OR1. Since this reasonable construction is also the one that best furthers the purpose and spirit of the certificate of need law as a whole, it is the one that should be adopted.

b. The six operating rooms must be assigned a capacity of 900 surgeries each

i. Actual experience at FMH

Fairbanks Memorial showed at the hearing that it has, for a number of years, succeeded in accommodating an average caseload in its six Class C ORs of between 1000 and 1100 surgeries per suite per year.[175] Moreover, there are many indications that the six suites are not operating at their maximum capacity.

One key measure of excess capacity is availability of operating rooms at peak times. Among surgeons, the most popular time for scheduled surgeries is the "first case of the day," usually at 7:30 or 8:00 a.m., because the first case of the day does not risk delay owing to a time overrun by a prior surgery. At FMH, about 15 percent of "first case of the day" times go unused, and on the majority of weekdays (between 52 and 56 percent) there is at least one Class C operating room vacant at that time.[176]

Because FMH provides emergency surgeries, scheduled operations are sometimes bumped. It has, however, been many months since the hospital has had a single instance of a bumped surgery that it could not reschedule on the same day. On more frequent occasions, surgeons are offered a later time for the surgery but elect to reschedule a bumped surgery on a later day.[177] FMH is also able to offer surgeons block time—a dedicated period in a particular OR where that surgeon has exclusive scheduling rights, subject to certain rules—and waiting times to receive block time are not long.[178]

Surgeons' perceptions about whether the FMH caseload is straining its capacity varied widely. Ear-nose-throat surgeon Richard Raugust testified that although he hears complaints in the doctors' lounge, he thinks it is "hogwash" that surgeons cannot get reasonable access to

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175 These are average figures. The number of surgeries in individual ORs in any given year has ranged between 573 and 1,437. Agency Record at 1367-8 (FMH CON application).

The total number of surgeries at FMH reached the neighborhood of 6500 in 2002 and 2003, and has shown a modest decline since that peak. *E.g.*, FMH Ex. 17. The exact figures vary in different tabulations, but never by more than a few percent.

176 Direct exam of Wood.

177 Direct exam of McLane.

178 *Id.*; direct exam of Dr. Witham (obtained block time almost immediately upon starting practice); FMH cross-exam of Teslow (block time not the problem); FMH cross-exam of Cobden (has all the block time he has applied for).

operating rooms. Orthopedic surgeon David Witham is happy with his ability to schedule cases and finds it superior to his experience at Highline Community Hospital in Burien, Washington, where no one could have block time. OB-GYN Richard Hess finds OR availability for his specialty to be entirely satisfactory, in contrast to three-week wait times he has encountered at Seattle hospitals. On the other hand, general and thoracic surgeon Timothy Teslow testified quite convincingly that the volume handled in the FMH suites creates difficulties in his practice, which often involves fitting in surgeries that come up suddenly, entail relieving a patient's pain, but are not true emergencies. These must often wait until very late in the day. Orthopedists Richard Cobden and Mark Wade likewise have genuine scheduling constraints that seem, to a significant extent, to grow out of the fact that they often do types of orthopedic surgery calling for bulky equipment that will fit into only two of the FMH suites, greatly reducing the scheduling choices.[179]

The overall sense of the testimony was that FMH accommodates its present surgery volume fairly comfortably in most respects, but that utilization is heavy enough that some surgeries that have to be scheduled at the last minute must be scheduled at inconvenient times. In addition, the fact that four of the six Class C suites at FMH are too small for some orthopedic procedures creates heightened capacity issues in that specialty.

ii. The methodology's capacity ratings

The General Surgery Services methodology defines a target use rate, or "TU," for operating rooms of "900 surgical cases per operating room for operating rooms serving both inpatients and outpatients and 1,200 surgical cases for operating rooms dedicated to outpatient surgery use." As used in the formula, the "target use rate" is actually a capacity rating that is assigned to the two types of operating rooms mentioned.

An operating room in an ASC will obviously be dedicated to outpatients only. A hospital has a choice to dedicate a room to outpatients alone or to allow mixed use. At the hearing, however, there was broad agreement that the best management practice at a hospital is generally to allow mixed use, because it can be inefficient to force a surgeon who has just finished operating on an inpatient to move to a different room and staff for a follow-on operation on an outpatient, or vice versa.[180]

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179 Both Cobden and Wade also described scheduling issues arising from resource limitations other than physical OR space. These will be addressed in Part III-C below.

180 *E.g.*, Kobuk cross-exam of Wood.

FMH expert Dean Montgomery suggests that a hospital OR that serves both inpatients and outpatients should be given a rated capacity that is a "blended rate" between 900 and 1200.[181] In support of this view, he contends that the Maryland and North Carolina CON programs have regulations closely parallel to Alaska's, and they have interpreted those regulations to permit blending between the "mixed use" and "dedicated" depending on the *degree* to which a mixed use suite is dedicated to outpatient surgery.

What Mr. Montgomery advocates is an interpretation of the Alaska regulation that is directly counter to its language. He treats the regulation as though its two benchmarks were dedicated inpatient suites and dedicated outpatient suites, so that a blended number might need to be developed for mixed-use suites. But Alaska has specifically defined the capacity to be assigned to mixed-use suites. It is not necessary to do additional blending to arrive at that number, and to do so would ignore the word "outpatients" in the phrase "serving both inpatients and outpatients" that appears in the regulation.

The Maryland and North Carolina examples do not support Mr. Montgomery's position. Maryland does indeed assign "optimal capacity" numbers to "dedicated outpatient" and "mixed-use" rooms (1152 and 576 cases per year, respectively),[182] but it uses these numbers in a different structure from Alaska's: in Maryland, the need question is approached from another angle, with applicants required to show that they are using their existing suites up to the optimal level and that new suites will reach the optimal level in the second year of operation.[183] The first question has no parallel in Alaska methodology, and the second is somewhat different from any question asked in Alaska. Moreover, the three staff recommendations from Maryland that Mr. Montgomery has provided indicate, on close reading, that Maryland does not blend its two optimal capacity numbers, although it does convert them to minutes and allow applicants to meet the *fixed* targets through a showing that their OR minutes reach the target as converted. North Carolina has a methodology even more distinct from Alaska's, and there is likewise no evidence that it blends capacity ratings assigned to mixed-use and outpatient-only ORs to achieve a second-order mixed-use figure that supersedes the one printed in the regulations.[184]

FMH alternatively suggests that there should be a practical threshold before an OR would lose its status as "dedicated" to outpatient surgery and become a mixed use room: the hospital

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[181] Direct exam of Montgomery; FMH Ex. 35.
[182] FMH Ex. 35 at COMAR 10.24.11.05(A)(3).
[183] FMH Ex. 35 at COMAR 10.24.11.06(B)(4) and (7).
[184] *See* FMH Ex. 35, 2006 State Medical Facilities Plan (North Carolina).

observes that it seems absurd to reduce a suite's rated capacity from 1200 to 900 simply because one inpatient surgery was performed there on the last day of the year.[185] This argument for a *de minimis* threshold would have some appeal if one of the ORs at issue in this case genuinely had only one or a tiny handful of inpatient surgeries. That is not the case at FMH, where the mixed-use operating room that has the highest percentage of outpatient use, OR C, still accommodated an average of 173 inpatient surgeries per year in the 2003-2005 period.[186] This is not insubstantial or *de minimis* inpatient usage. The question of whether minimal inpatient usage should be disregarded can be left for another case.

For these reasons, FMH's alternative readings of the definition of "TU" are rejected. Operating rooms that serve a mix of inpatients and outpatients will, in this case, be assigned a rated capacity of 900 surgeries per year, and those that serve outpatients only a capacity of 1200 surgeries per year. These assigned capacities are conservative.[187] There are good reasons to use conservative capacity ratings. First, an operating room that is filled to its full maximum capacity will present scheduling difficulties, and there seems to be wide acknowledgement that it is not ideal to run ORs at their true "full" capacity.[188] Second, Alaska communities are generally small and widely dispersed, so that if a community were operating on the brink of its maximum capacity there might not be nearby facilities to absorb occasional overflows.

c. By regulation, current capacity is 5400 surgeries

All six Class C suites at Fairbanks Memorial serve a mix of inpatients and outpatients.[189] Accordingly, the current rated capacity of the existing supply of operating rooms in Fairbanks is six times 900, or 5400 surgeries per year.

4. Projected Demand

a. Understanding the formula for calculating projected demand

To calculate the projected caseload "C" five years hence, the methodology requires multiplication of the projected population "P" by the general surgery use rate "GSUR." The

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185 FMH Final Argument at 7.
186 Agency Record at 1368 (FMH CON application).
187 Note, however, that they are not as conservative as Maryland's.
188 E.g., FMH Ex. 35, *In re Good Samaritan Hosp*., Staff Recommendation at 25 (80% is target); Agency Record at 1715-7 (no adverse comment from FMH administrator on selection of low capacity numbers)
189 AMD-F cross-exam of McLane and Wood; Agency Record at 1368 (FMH CON application at 7).

general surgery use rate is itself a population-driven figure: it is a three-year historical average of the quotient of the number of surgeries delivered divided by the service area population.[190]

There is a choice to be made in selecting the population projection to insert for "P." The staff and the parties perceive this choice to be a selection of the population served by the project, which is largely (but not entirely) a matter of defining the project's service area. With respect to Fairbanks, participants in the hearing advocated service areas varying in size from as small as the Fairbanks North Star Borough alone (the staff's original choice) to as large as all of northern Alaska. One should note, however, that the definition of "P" in the methodology does not literally call for a service area population; instead, it simply refers to "the official state projected population in the fifth year." One literal reading of this phrase would be to insert the population of the whole state, as projected for the fifth year. And, as will be seen in the next paragraphs, even this broadest of all possible readings would not be irrational, nor would it lead to results appreciably different from an approach using a more limited "service area" population—provided the same population base is used throughout the calculation.[191]

This leads to one of the most important concepts in understanding the demand formula: under ordinary circumstances, it does not matter what service area is chosen for "P." Let us imagine, for purposes of illustration, a generic community of Anytown in which 1000 surgeries have been performed in each of the last three years. Anytown has a core service area A1 with an average population of 10,000 over the last three years. Anytown's facilities also serve—to a diminishing extent as one travels farther from the center—a larger geographic region A2 with an average population of 20,000 over the last three years. Both A1 and A2 have a growth rate, typical for most of Alaska, of 1% as projected by state demographers.

Selecting A1 as the appropriate service area, the calculation of caseload "C" would proceed as follows:

> C = P x GSUR
>
> C = (10,000 x 1.01^5) x (1000 ÷ 10,000)
>
> [Note: (10,000 x 1.01^5) is the population of A1 in year 5 after applying a 1% compounded growth rate, which is P in the formula. (1000 ÷ 10,000) is the per capita use rate for A1, which is GSUR in the formula.[192]]
>
> C = (10,000 x 1.051) x (0.10)

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[190] The methodology is imprecise in describing this quotient, but its intended meaning is clear enough. The imprecision has been discussed above in footnote 106.

[191] This reading would entail counting the whole state population *as users for the existing six operating rooms in Fairbanks*. This is not the same as a statewide use rate.

[192] For further discussion of GSUR, *see* note 106 *supra*.

$C = 10{,}510 \times 0.10$

$C = 1{,}051$

Selecting A2 as the appropriate service area, the calculation of caseload "C" would proceed as follows:

$C = P \times GSUR$

$C = (20{,}000 \times 1.01^5) \times (1000 \div 20{,}000)$

[Note: $(20{,}000 \times 1.01^5)$ is the population of A2 in year 5 after applying a 1% compounded growth rate, which is P in the formula. $(1000 \div 20{,}000)$ is the per capita use rate for A2, which is GSUR in the formula.[193]]

$C = (20{,}000 \times 1.051) \times (0.05)$

$C = 21{,}020 \times 0.05$

$C = 1{,}051$

Even though A2 has twice the population of A1, the projected caseload "C" in the formula is exactly the same regardless of which service area is selected. Mathematically, this is because the base population figures in "P" and "GSUR" cancel out. "C," the projected caseload in year 5, is ordinarily a function of the existing caseload and the growth *rate* that state demographers have projected for the base population.

Dean Montgomery, who with Thomas R. Piper was the principal author of the MacQuest study that included the initial draft of Alaska's latest CON Standards and Methodologies,[194] confirmed in testimony that, if the same population base is used throughout, it usually does not matter much to the outcome how broadly one draws the boundaries of the service area or defines the demography of the population.[195] Montgomery himself favors a relatively inclusive base population. He would not exclude Natives and military, noting that both groups receive surgeries at FMH with some regularity and thus account for some of the surgeries that are being counted. A more inclusive population base results in a lower use rate but a higher multiplier for that use rate in the final formula.

There are only two circumstances under which it matters what population one chooses for "P": (1) if a more restricted service area has a dramatically different short-term population growth rate from a larger or statewide service area; or (2) if the population used in "P" is not from the same area as the population used in "GSUR." Item (1) is not an issue in this case;

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193 For further discussion of GSUR, *see id.*

194 Agency Record at 1755.

195 Direct exam, ALJ exam, and staff cross-exam of Montgomery (first appearance). Robert Stetson testified likewise on direct exam.

variations in the growth rates of the proposed service areas were negligible. Item (2) is one of the central issues in this case.

b. The regulations do not allow importation of an outside surgery use rate

Step one of the General Surgery Services methodology requires the generation of a use rate consisting of the "cases provided over the preceding three years per 1,000 (persons)" [parentheses in original]. At bottom, the principal dispute in this case over application of the methodology turns on what is meant by "persons" in this definition. The decision under appeal used persons located in Anchorage, not Fairbanks. If "persons" refers to persons in the service area population—the same population base used in "P"—the calculation of caseload "C" is essentially a mechanical process; all of the population and caseload inputs are objectively determinable within a narrow range, and differences of opinion over the precise boundaries of the service area normally have no practical significance. If, on the other hand, "persons" can mean persons from any population the regulator happens to choose, the selection of those "persons" in juxtaposition to the selection of a different population "P" becomes by far the most important regulatory judgment to be made in the entire certificate of need process.[196]

As a matter of regulatory construction, it is a stretch to choose the latter interpretation of the word "persons." The Standards and Methodologies were adopted as a regulation after an extensive study followed by a public comment process in which some of Alaska's foremost health administration experts participated. If any of the participants had had an inkling that selecting the "persons" to be counted in GSUR was a discretionary choice unconnected to the identification of a service area population, it is unlikely that the subject would have received no discussion. And yet it received none.

On the contrary, there are indications in the regulatory history that all involved saw "use rate" as a presumptively local matter unless identified otherwise. With respect to the open heart surgery methodology, for example, the department initially proposed a formula using a use rate "UR" parallel in definition to the one at issue in this case, but with a special note that the department would use national rates for pediatric open-heart surgery.[197] There was a colloquy in the comment process between Providence administrator Susan Humphrey-Barnett and the staff in which Ms. Humphrey-Barnett assumed that, as the draft was then set up, the local use rate

[196] There is a parallel issue of what is meant by "cases" in the definition—whether this means cases in the service area, or cases anyplace. All agree that the "cases" have to be from the same area as the "persons."

[197] Agency Record at 1720.

would be used for other (non-pediatric) open-heart surgeries.[198] The staff seems to have agreed, because it inserted new language into the special note specifying that regional and national use rates would also be used for the non-pediatric surgeries.[199] The reason for both elements of the special note was the volume of open-heart surgery currently going outside Alaska. What is significant about the handling of the issue in the open-heart surgery context is that all concerned felt a special notation was needed to permit an escape from the local use rate (which, in the context of open-heart surgery, was an escape both the commenter and the staff felt was needed). With general surgery, there is no special notation at all, and readers such as Ms. Humphrey-Barnett could be expected to understand the language just as she understood the initial draft language for non-pediatric open-heart surgery: unless specified otherwise, the use rate is the local use rate.

As Dean Montgomery explained at the hearing in uncontroverted testimony, local use rates subsume myriad local demographic factors that would be virtually impossible to pick apart through analysis.[200] Fairbanks, for example, has special characteristics, such as a younger and disproportionately male population, that may well explain its lower surgery usage than Anchorage, and the benefit of a local use rate is that these demographics come through in the rate without the need to quantify each of them.[201] Most CON states spend large sums each year to maintain local use rate data precisely because of their unique value in the projection of future trends. The substitution of an outside use rate—indeed the highest use rate in the state—when a local rate is available is unheard of in national CON practice.[202] Moreover, longtime healthcare planner Robert Stetson observed that one would never make such a substitution in a business setting when trying to project demand.[203]

The staff currently advocates an open-ended interpretation of "persons" whereby any population may be chosen provided the regulator can articulate a reason for choosing it. This risks making the surgery methodology an unpredictable, easily manipulated statistical pretense. Private sector planners trying to predict whether a project would likely meet the presumptive CON standards would have no way of making that assessment, because all would depend on which of an almost infinite number of possible populations the department would light upon as

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[198] *Id.*
[199] The new language is footnote 5 to the final Standards and Methodologies document.
[200] Direct exam of Montgomery; direct exam of Stetson (first session).
[201] Direct exam of Montgomery.
[202] *Id.*; direct exam of Stetson.
[203] *Id.*

the one whose rate of usage it would apply. If the "persons" whose usage is assessed must be the persons in the service area, on the other hand, the published methodology involves little discretion and has predictable outcomes.

To interpret "persons" to mean persons in the service area does not leave the department without recourse should there be special, identifiable factors depressing the local use rate. The regulatory structure has carefully left an escape hatch—the 025(b) exception—for that kind of situation. The 025(b) exception (which will be explored at length below) comes only *after* the Standards and Methodologies have been applied as written, however, and it requires special findings.

For all of these reasons, this decision construes "persons" in the regulatory definition of GSUR to be the "persons" in the service area population. The detailed delineation of that population is the only matter within agency discretion; once it is defined, the population and the "persons" for whom the use rate must be determined are one and the same.

There is a further reason to reject using the Anchorage use rate at this time, even if substitution were justified at an earlier stage of the proceeding. When she originally selected the Anchorage use rate, the commissioner sought to substitute one urban rate for another on the theory that usage in Fairbanks would eventually mirror that of Alaska's other urban center. As will be seen below, however, the staff has now determined that the service area from which the population "P" in the formula will be taken is not limited to the urban Fairbanks North Star Borough, as it was when the commissioner made her initial decision, but instead encompasses a large area of rural environs. Rural use rates are much lower than urban use rates in Alaska. The change in defined service area makes the Anchorage use rate a gross mismatch, attaching a big-city use rate to regions such as the Yukon Koyukuk Census Area.[204]

c. The regulations do not allow counting of surgeries done in offices

AMD-F introduced evidence regarding surgical procedures presently done in offices and non-FMH procedure rooms in Fairbanks. By AMD-F's count, which may be overstated, there are 3,000 to 4,000 of these "surgeries."[205] According to the testimony, all are procedures that are

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[204] *See, e.g.*, 1/31/07 direct and re-direct exam of Dr. Scott Goldsmith (UAA professor of economics). Yet another reason not to use the Anchorage use rate is that it apparently was calculated by counting a large number of endoscopies as general surgeries. The department does not seem to have had a consistent approach with respect to endoscopies, so that use rates for different service areas may be wholly incomparable. *See, e.g.*, Rarig & Pierce depos.; direct exam of Stetson.

[205] AMD-F has used a figure of 3,900 at times, which Kobuk continues to use. Kobuk post-hearing brief at 4. AMD-F's most recent figure is 3,280, a number that included two or three hundred procedures not done in Fairbanks. AMD-F post-hearing brief at 12. For more sober estimates, *see* sections III-C-4 and 5 below.

being done with adequate safety outside an operating room setting, but for a portion of them there is arguably some medical desirability to move them to an OR of some kind.[206]

Both AMD-F and Kobuk, but not the staff, advocate adding the annual total of all of these procedures directly into the number of "general surgery cases provided over the preceding three years" that is used to calculate GSUR.[207] This is not possible. The text of Step One of the methodology states that the word "cases" in the phrase "general surgery cases" means "patients who may have one or more surgical procedures during a particular *visit to the operating room*" (italics added). A patient who does not visit the operating room is not a general surgery "case" for purposes of the methodology. The time for consideration of these non-OR surgeries is during evaluation for an 025(b) exception, not while applying the methodology.

d. The staff's most recent selection of a population base is reasonable

As noted above in the summary of the staff's original recommendation, the staff acknowledged during the appeal process that it had used inconsistent assumptions in selecting population figures for use in calculating projected demand. Accordingly, the staff substituted a different projected 2013 service area population at the hearing. The new population excludes Natives and military, in keeping with the exclusion of those segments from the historical populations used to calculate the statewide and Anchorage use rates the department applied in the same formula. At the same time, the staff has expanded the service area for Fairbanks surgery facilities. Instead of restricting the service area to the Fairbanks North Star Borough, it now favors an "Interior" service area that encompasses that borough, Denali Borough, Southeast Fairbanks Census Area and Yukon Koyukuk Census Area.[208]

FMH suggests that the staff's sudden interest in a larger service area—an interest that developed at precisely the moment when preparations for Ms. Rarig's deposition revealed the inconsistency in handling the Native and military populations[209]—is a demonstration that what really mattered to the staff was a preconceived outcome, not an objective process. By expanding the service area, the staff could return the population essentially to the same levels it originally achieved by mistakenly including Natives and military, and then argue that its prior error was immaterial. FMH's allegation is not wholly implausible, but it is irrelevant because this decision

[206] They are described in more detail in sections III-C-4 and 5 below.
[207] Kobuk post-hearing brief at 4 & n.4; AMD-F post-hearing brief at 12.
[208] FMH Ex. 1.
[209] FMH Ex. 29 and associated 2/1/07 oral stipulation; Rarig depo. at 71-72; Rarig 1/30/07 testimony; FMH re-direct and staff re-cross of Rarig on 1/31/07.

(unlike the staff's calculation) will use the same population base in "P" and "GSUR." The reasonableness of the population base will be judged on its merits rather than by its motive.

Fairbanks is a regional center to which people from a wide area travel for at least a portion of their surgical needs. No expert at the hearing testified that it was inaccurate to characterize the service area as the staff did, encompassing the Interior region as a whole.[210] Fairbanks Memorial itself sees the Interior region as part of its secondary service area for at least some services.[211]

Testimony was slightly more divided on exclusion of military and Native elements of the population, with Montgomery, as noted above, preferring to include these groups because they do receive some of the counted surgeries at FMH. Montgomery's position was not developed with detailed information about the excluded populations, however, and FMH has not argued that it be followed. It is always necessary when defining a service area population to draw distinctions that leave out some of the population served. Owing to tourism, for example, Fairbanks surgeons perform surgeries on people from other states and countries, and yet these populations will not be within any service area definition. There was general agreement that military and Native use of civilian surgery facilities in Fairbanks is quite low. In light of the limited evidence on the subject and the lack of any concerted argument from any party that it should be overturned, the staff's decision to exclude Natives and military from the count is an area where deference to their judgment is appropriate.

Since the staff's position regarding a geographically broader service area was not challenged by any expert testimony, and since its exclusion of the Native and military segments of the service area population is entitled to deference, the staff's figure for service area population "P" will not be disturbed.

e. By regulation, projected demand is 6914 surgeries in 2013

It is now possible to apply the formula for calculating projected demand.

For P, the population input will be the state-projected civilian non-Native Interior region population for 2013. That number is 86,647.[212]

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210 Goldsmith testified that there is some difference of opinion as to the appropriate surgical market boundaries for Fairbanks, but would not opine that the broader boundaries were inappropriate. 1/31/07 Goldsmith testimony, direct exam. Montgomery felt that either local or regional market definitions can be appropriate. 1/31/07 Montgomery testimony, direct exam.

211 Staff cross-exam of Powers; Powers depo. at 46.

212 FMH Ex. 1; attachment to staff's post-hearing brief.

GSUR will be calculated using the same population base. The methodology calls for developing a use rate based on an average of the "preceding three years." The "preceding three years" as of the filing of the applications and the inception of this appeal were 2003-2005, and that remains the last three-year period for which reliable population and case-count data were presented at the hearing. The calculation of GSUR is as follows:

2003 population	76,111	2003 case count	6,497
2004 population	79,913	2004 case count	6,284
2005 population	80,823	2005 case count	6,118
Average	78,949	Average	6,300

Per capita use rate = 6,300 ÷ 78,949 = .0798

Expressed as a use rate per thousand persons, this number is 79.8. The staff generated this same number in its last round of calculations, attached to its post-hearing brief, although the number is mislabeled "2002-2004 avg."[213]

The projected caseload "C" in the formula is the product of the projected 2013 population and the per capita use rate, or .0798 times 86,647. The result is a caseload of 6,914 surgeries.

5. Calculation of Need under the Regulatory Methodology

The number of cases that the methodology projects for 2013 exceeds, by 1,514, the rated capacity of the six general surgery suites presently available in Fairbanks. It would require two outpatient surgery suites, with their rated capacity of 1200 surgeries each, to cover this projected unmet demand. The precise need yielded by the methodology is 1.26 suites.

Under the methodology as printed, there are no further steps to the analysis: The "need" is two suites, unless one moves to an 025(b) exception taking the CON process outside the methodology. The staff, however, contended at the end of the hearing that there are two additional steps *under the methodology* (not resorting to 025(b)) that will convert the need of two to a need of four.

According to the staff, when there are two applicants any need must be apportioned between them.[214] The staff does not explain why this is so. Next, there is what the staff calls "the requisite adjustment for economic viability"[215] based on the uncontested fact that ASCs need to house two suites to operate efficiently. The result is that a need of one or two suites is automatically translated to a need of four suites under the methodology whenever there are two

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213 A use rate calculated from 2002-2004 inputs would be .0826 (82.6 per thousand).
214 Staff post-hearing brief at 9.
215 *Id*. at 10.

qualified applicants. Indeed, were there three qualified applicants, the staff's logic would translate the need to six.

The staff's reasoning runs afoul of the regulations at the very first step. When there are concurrent applications, the Standards and Methodologies do not provide for an automatic apportionment of any unmet need between them. Instead, there is an explicit requirement to "compare the extent" to which the applicants meet three concurrent review standards. The only purpose such a comparison could have would be to enable the staff to select which applicant is best qualified to meet the need, if there is not enough need for both. No comparison has ever been done in this case.

The automatic apportionment and the "requisite" adjustment to give each applicant a full facility is not part of the Standards and Methodologies. The Standards and Methodologies yield a need of two suites.

C. Availability of an Exception to the Methodology under 7 AAC 07.025(b)

1. Exceptions Are Allowed

As has been mentioned before, 7 AAC 07.025 sets up two tracks for approval of a certificate of need. To be approved by the commissioner, a CON application ordinarily "must . . . meet" the requirements of the Standards and Methodologies document that has been adopted by reference as a regulation.[216] Under section 07.025(b), however, the staff may recommend an exception to one or more of the standards when there is a demonstration "that the availability, quality, or accessibility of existing healthcare services creates an unreasonable barrier to services in the service area."[217] The commissioner may grant such an exception by authority that comes implicitly from section 07.025, because there would be no point for the regulation to authorize the recommendation if the commissioner could not accept it. Further, 7 AAC 07.070(b)(7) allows the commissioner to consider, in addition to the staff recommendation and various matters in the record, any "special or extraordinary circumstances" relating to community access to health care or to feasibility of the proposed activity. Section 07.070(b)(7) does not create a freestanding basis for the commissioner to override the Standards and Methodologies—section 07.025 being explicit that an application "must . . . meet" those requirements or qualify for an 025(b) exception—but it suggests circumstances relating to access and feasibility that may bear on an 025(b) finding. These provisions combine to create a second

[216] 7 AAC 07.025(a).
[217] 7 AAC 07.025(b).

track to approval of a certificate of need application whereby, if a threshold showing is made, one or more of the Standards and Methodologies can be overridden. By way of shorthand, the exceptional track has been referred to in this decision as the 025(b) exception.

All parties agree that 025(b) exceptions are available for the six "General Review" and three "Concurrent Review" standards found at the beginning of the Standards and Methodologies document. At final argument, there was a difference of opinion over whether there can be an 025(b) exception to the service-specific methodologies. The staff took the position that there cannot because these are "methodologies," not "standards," and section 07.025(b) refers only to "an exception to one or more of the standards." All three private parties disagreed with the staff on this point of interpretation.

The matter is easily resolved by a close reading of the Standards and Methodologies document. The document itself refers to the mathematical methodologies as "standards." It does so in the very first operative sentence of the document: "The department will apply the following general review standards, the applicable service-specific review standards set out in this document, the standards set out in AS 18.07.043, and the requirements of 7 AAC 07 in its evaluation of each certificate of need application."[218] This sentence does not separately refer to service-specific methodologies, instead subsuming them in the phrase "service-specific review standards." Similarly, the General Surgery Services section of the document provides that the one "service-specific review standard" for general surgery is: "The applicant demonstrates need in accordance with the following review methodology."[219] Plainly, an exception to this "standard" necessarily entails an exception from the "methodology" it refers to. The distinction between standards and methodologies is a distinction without a difference, and the General Surgery Services methodology is potentially subject to the 025(b) exception.

2. Need to Choose Between Applicants Not a Basis for an Exception

The staff has advocated that when the methodology identifies a need and there are two qualified applicants, the need must be apportioned among them and then, if the need is too small after apportionment to support viable projects, the need must be augmented to ensure that both can survive. This is not a basis for an 025(b) adjustment because, as explained above in section III-B-5, it ignores the explicit regulatory mandate to "compare" applicants so that a reasoned choice can be made between them. Moreover, the prerequisite for an 025(b) exception is that

[218] Alaska Certificate of Need Standards and Methodologies (Dec. 9, 2005) at 2.
[219] *Id*. at 30.

there be a demonstrated "unreasonable barrier to services" caused by "availability, quality, or accessibility of existing healthcare services." A desire to avoid the regulatory task of choosing between applicants is not such a barrier.[220]

3. Poor Management Not a Basis for an Exception

In final argument, Kobuk suggested that "the lack of block time for physicians" could be a basis for an 025(b) finding so as to depart from the need calculated under the methodology. The underlying basis for this argument is presumably that if existing capacity is inefficiently managed, that can be an "unreasonable barrier to services" justifying an exception to limitations imposed by the methodology.

As a factual matter there is no justification to make an exception on this ground in the present case. As explored above in section III-B-3-b-i, FMH successfully operates its surgery suites at an average of between ten and twenty percent above their rated capacity under the methodology. Moreover, block time is reasonably available to surgeons.[221] Management issues do not cause the existing surgery capacity in Fairbanks to perform below the capacity assigned to it by the methodology.

4. Artificial Suppression of Demand as a Basis for an Exception

AMD-F argues that the surgical case count at FMH is artificially depressed because FMH has chosen to enter into an unusual contractual arrangement that bars a significant group of surgeons from using its facilities, forcing them to conduct their surgeries elsewhere. If substantiated, such an arrangement could indeed affect the "availability . . . or accessibility of existing healthcare services" so as to "create[] an unreasonable barrier to services in the service area." It can therefore support an 025(b) exception.

Like most hospitals, FMH has for many years maintained an exclusive contractual relationship with an anesthesiology group, whereby in exchange for a commitment from the group to maintain coverage at all times the hospital agrees to grant privileges only to members of the group.[222] In June of 2005, the hospital took the relatively unusual step of extending this

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[220] There is a related question that need not be resolved in this decision because sufficient need (two suites) has been found to support a CON for one fully viable ASC. The related question is whether, if there were a need for only one suite but a new facility could not be viable unless two suites were authorized, the department should adjust upward to issue a CON for two suites. The regulations do not seem to provide for such an adjustment directly, but it is conceivable that if existing facilities in the service area were unable or unwilling to expand to cover the need for one additional suite, the department could rationally make a finding of "unreasonable barrier" under 025(b) that would support an upward departure from the methodology on this basis.

[221] *See supra* note 130.

[222] Direct exam of Powers.

exclusive arrangement to the area of pain management.[223] Thereafter, only members of Fairbanks Anesthesia Group could practice pain management medicine at FMH, apart from the minimal patient visits accorded under "courtesy privileges."[224] Fairbanks Anesthesia Group had one physician who was board-eligible (though not then board-certified) in pain management, Dr. Jiang.[225] Dr. Jiang has since maintained a relatively limited pain management practice at FMH, accounting for 26 surgical procedures last year.[226]

The decision to create an exclusive arrangement in pain management roughly coincided with an effort by AMD-F affiliate Alaska Medical Development to establish a pain management practice in Fairbanks. Alaska Medical Development president Lawrence Stinson had been on the FMH medical staff in the 1990s; he then left the state for fellowship training and returned to establish the Alaska Medical Development pain management clinics in Southcentral Alaska.[227] Alaska Medical Development became interested in expanding its practice to Fairbanks, and began constructing a medical office building there in May of 2005.[228] Stinson sought at first to center the practice at FMH, but after some initial interest the hospital took the position that the offered services were not needed.[229] After seeking privileges at FMH without success, Stinson was formally barred by the 2005 exclusivity agreement.[230] Alaska Medical Development has five board-certified pain management physicians, including two who live in Fairbanks and a third who regularly sees patients in Fairbanks.[231] Because of the exclusivity agreement, none of them was eligible for active privileges at FMH at any time between the inception of the ASC applications and the hearing.[232]

No evidence was presented that the refusal to accord privileges to Stinson or his colleagues grew out of a judgment that their practice does not meet FMH standards. On the contrary, the hospital has made at least one recent business overture to Dr. Stinson.[233] Though

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223 AMD-F cross-exam of Powers; direct exam and FMH re-cross of Stinson; Ex. 9 to Powers depo. Pain management medicine addresses pain issues that have defied treatment. There have been great advances in the field in recent years, particularly in the area of surgically-implanted spine stimulators. Relatively minor outpatient surgical procedures now play a large role in the field. Direct exam of Stinson.

224 *E.g.*, Powers depo. at 27-29. A physician with courtesy privileges can visit up to six patients a year at the hospital and can order labs or x-rays, but cannot admit patients or perform any surgeries there. AMD-F cross-exam and ALJ exam of Powers; direct exam of Stinson.

225 AMD-F cross-exam of Powers.

226 Re-direct exam of Powers.

227 Direct exam of Stinson; Joint Ex. 6.

228 Agency Record at 1452.

229 FMH re-cross of Stinson.

230 Direct exam of Stinson.

231 *Id.*

232 AMD-F cross-exam of Powers; Ex. 9 to Powers depo.

233 Powers depo. at 70.

not well explained at the hearing, the decision to bar the Alaska Medical Development physicians through an unusual exclusive arrangement with Dr. Jiang's group seems to have been a judgment related primarily to administrative concerns.[234]

It is undisputed that, by barring most pain management physicians from Fairbanks Memorial, the hospital has caused some diversion of surgeries from the existing surgery suites in Fairbanks to other venues.[235] This diversion consists of two components: surgeries performed in Anchorage, and surgical procedures performed in Fairbanks in the Alaska Medical Development procedure room.

The surgeries that go to Anchorage are the ones that "clearly need to be performed in an operating room setting."[236] Stinson himself takes a negligible number of surgeries to Anchorage,[237] but his two Fairbanks partners see a more substantial number of Fairbanks patients at Anchorage surgical facilities. Between the two of them, they apparently bring about 200 operating room surgeries to Anchorage annually.[238]

Apart from the 200 AMD-F surgeries, no significant movement of outpatient surgery of any kind from Fairbanks to Anchorage was demonstrated at the hearing.[239]

Alaska Medical Development also performs between 1200 and 1500 surgical procedures annually in its procedure room in Fairbanks.[240] These, however, are not the surgeries that "clearly need to be performed in an operating room setting." Instead, they are minor surgical procedures. Alaska Medical Development proposes to move "most if not all" to its ASC, where

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[234] *Id*. at 17-24. Shortly after the hearing in this case, FMH overcame any misgivings it may have had about granting privileges to other pain management providers and agreed with Fairbanks Anesthesia Group to rescind the exclusivity arrangement in that field. FMH Ex. 36, 37.

[235] *Id*. at 30-31.

[236] Direct exam of Stinson.

[237] The number seems to be one or two a month at most. Direct exam of Stinson; *see also* AMD-F Ex. H at 2 ("several" patients brought to Anchorage in first year).

[238] Direct exam of Dr. Nancy Cross (one of the Alaska Medical Development pain management physicians in Fairbanks). Dr. Cross's estimates for herself and her Fairbanks partner, which she gave off the top of her head without the benefit of any precise case count, should be regarded as maximum figures. In the same testimony, Dr. Cross estimated that Anchorage-based Dr. Stimson brought 30 to 50 surgeries to Anchorage per year, whereas the true number based on testimony from Stimson himself seems to have been substantially lower. Note that AMD-F had ready access to precise figures from its patient records, but offered none; this suggests that a true case count would not have improved upon Dr. Cross's rough estimate.

[239] *See, e.g.,* FMH cross-exam of AMD-F surgeon Teslow (lack of available ORs is not causing patients to leave Fairbanks). A 1999 study, done at a time when Fairbanks operating rooms were busier than they are now, showed only 1% of outpatient surgeries going to Anchorage. Direct exam of Powers; *cf* FMH Ex. 38.

[240] Direct and FMH cross-exam of Stinson. This estimate has been relied upon in preference to various higher estimates offered by AMD-F because (1) this is the estimate of Alaska Medical Development's president and (2) AMD-F has chosen not to document the caseload estimates with hard case-count figures that it could readily obtain. Even crediting Dr. Stinson's estimate is generous to AMD-F, since Dr. Stinson at one point testified that the total is "maybe less" than 1200 per year. Direct exam of Stinson (near end of testimony).

billing for them would be enhanced.[241] There was no testimony, however, that there is a medical "need" to perform all or even most of these procedures in a 504-square-foot Class C operating room rather than in a procedure room such as the one accommodating them today. There was also no testimony that any particular proportion of these surgeries would, in fact, be performed in an operating room in the ASC rather than in a procedure room there.[242] Alaska Medical Development's Dr. Cross did testify that some procedures, such as cervical epidural injections, can be done in a way that is more sophisticated or more comfortable for the patient in an ASC operating room than in an office procedure room. This testimony was convincing but it was not quantified: One cannot tell how *many* of the 1200 to 1500 procedures now being performed have a medical reason to be conducted in an OR.

At bottom, AMD-F has demonstrated an access issue creating an unreasonable barrier to pain management surgery in the service area. This supports an exception to the need methodology in the form of an upward adjustment of the calculated need. Recall that the need methodology indicated an unmet need of 1514 surgeries per year in 2013. The appropriate upward adjustment is at least 200 cases to account for the surgeries going to Anchorage to be performed in operating rooms there. The more difficult question is what further upward adjustment is appropriate with respect to the 1200-1500 procedure room surgeries.

In addressing this question, one must distinguish between the ability to fill ASC suites and "need." AMD-F can unquestionably fill its proposed suites with surgical procedures of some kind. The certificate of need process, however, is about the more subtle concept of "need." Indeed, a starting point for the CON regime is the recognition that "'supply generates demand'" in the health care field."[243] The mere fact that between 1200 and 1500 minor surgeries currently being performed in a procedure room can be conducted in state-of-the-art Class C operating rooms as well does not establish that those rooms need to be built. Certificate of need theory holds that the higher billings that will attend each of those 1200 to 1500 procedures, once they move to an ASC, could add unnecessary cost to the health care system.[244]

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[241] Direct exam of Stinson.

[242] It is unclear whether the AMD-F facility would be built with procedure rooms. The floor plan at Agency Record 1450 depicts none, but it covers only half the 22,516 square-foot facility.

Dr. Jiang, the pain management specialist at FMH, apparently conducts most of his surgical practice in either procedure rooms or in OR1. Note that OR1, a Class A suite, has not been counted as an operating room in this decision.

[243] FTC Report at ch. 8, p. 3 (quoting and paraphrasing Thomas R. Piper); *see also* Pierce depo. at 27-28 (need not same as demand; CON focuses on need).

[244] These higher billings were discussed in section III-A-4-b above.

The "need" in a certificate of need calculation is need "to maintain the good health of the citizens of this state."[245] It is thus medical need. Of the 1200-1500 procedures that, as a class, are being artificially excluded from FMH, we know that some, but not all, would for medical reasons be better conducted in an OR. Beyond that, AMD-F has left the record incomplete.

In this context it is AMD-F that must show the basis for an exception, because it is the "applicant" who must make the showing needed for an 025(b) exception.[246] AMD-F did not attempt that showing and did not receive an 025(b) exception in the initial CON determination, but it has attempted to do so at the formal hearing stage. As it turns out, the showing it must make is fairly substantial: The regular methodology yielded an unmet projected need of 1514 surgeries, sufficient to require two new operating rooms at the rated capacity of 1200 surgeries per year, but to expand the requirement to even one additional room one would need to raise the unmet medical need to 2400 surgeries. In other words, AMD-F must find nearly 900 additional surgeries *for which there is a medical need for an operating room* in order to establish an exception that alters the overall number of new suites needed. And more precisely, to be of significance in this exercise a surgical procedure would have to have a medical need to be performed in an OR of enough sophistication to meet the threshold for counting in a CON proceeding, as explored in section III-B-3 above.

This AMD-F has failed to do. It has firmly established a basis for an upward adjustment of only 200 cases. This leaves an adjusted unmet need of 1714 cases, 686 cases short of the 2400 that can be accommodated within the rated capacity of two ASC suites before a third might be required. Relying only on nebulous and generalized caseload testimony, AMD-F has not established by a preponderance of the evidence that at least 686 of the 1200-1500 procedures it presently conducts in Fairbanks need, for medical reasons, to be moved to general surgery operating rooms.

There is a second way of approaching the case-count suppression issue that is even less favorable in outcome to AMD-F. This approach would be to re-do the entire methodology with the diverted cases added in. The difficulty of this approach from AMD-F's point of view is that

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245 AS 18.07.041.

246 The issue of burden of going forward with evidence and burden of proof is potentially complex in this multi-sided appeal. This particular issue arises primarily in the context of FMH's appeal of AMD-F's certificate of need. In general, FMH has the initial burden within that appeal of coming forward with evidence that a particular aspect of the CON decision under review was deficient; otherwise, the original decision stands. FMH met that threshold with respect to the 7 AAC 07.025(a) decision under the presumptive methodology that led to issuance of a CON to AMD-F, and a reexamination of the methodology has resulted in some changes to the outcome. It remains clear that insofar as AMD-F needs to rely on 025(b) as a new, fallback basis to uphold its certificate, it needs to make the showing required in section 07.025(b).

the exclusivity arrangement came into being in late June of 2005, just six months before the 2003-2005 sample period for calculation of GSUR. Adding the diverted cases back into the case count therefore has relatively limited effect. Below is a recalculation showing the result even if one gives AMD-F the benefit of the doubt on all issues, using 1500 (Stinson's high figure) for surgical procedures in the Fairbanks procedure room and assuming that every one of these has a medical need for a sophisticated operating room. The case count for 2005 is augmented by half of 1500 (representing the maximum supposed additional case volume in Fairbanks, halved because exclusivity began only in late June of the sample year 2005) and by half of 200 (representing the surgeries done in Anchorage), for a total augmentation of 850.

The calculation of GSUR is as follows:

2003 population	76,111	2003 case count	6,497
2004 population	79,913	2004 case count	6,284
2005 population	80,823	2005 case count	6,968
Average	78,949	Average	6,583

Per capita use rate = 6,583 ÷ 78,949 = .0834 (83.4 per thousand)

The projected caseload "C" in the formula is the product of the projected 2013 population and the per capita use rate, or .0834 times 86,647. The result is a caseload of 7,226 surgeries. This exceeds the current rated capacity of 5,400 by 1,826 cases, resulting in a projected need of 1.52 outpatient surgery suites.

5. Voluntary Diversion of Cases Not a Basis for an Exception

AMD-F offered limited testimony from orthopedist Dr. Cobden to the effect that he chooses to perform a few minor surgeries in an office setting even though they would be marginally safer in an OR. The reasons for this can be financial benefit to the patient or the avoidance of a day or two's wait for convenient non-emergency operating room time.[247] Dr. Cobden estimated that between 100 and 150 procedures a year fall in this category.[248] By way of example, he mentioned abscess drainage and removal of pins.[249] Dr. Cobden's testimony seemed to imply that he would move all of these procedures to an operating room of some kind if one were next to his office. His testimony did not shed any light on whether the surgeries would require one of the state-of-the-art Class C suites in the ASC, or whether they might be performed

247 Direct exam of Cobden.
248 *Id.*
249 *Id.*

in some other setting in the ASC that would improve on the facilities in his office. Similarly, AMD-F general and thoracic surgeon Dr. Teslow presently does several hundred minor surgical procedures in his office for reasons of scheduling convenience, a significant portion of which he would move to an ASC if he could.[250] Dr. Teslow was more specific in his testimony than Dr. Cobden, explaining that the availability of I.V. sedation is what makes an operating room preferable for some of these procedures. This kind of sedation can be done only in a real operating room. He estimates that he would move "the preponderance" of his 217 anal/rectal procedures, about 50 skin procedures, and about 100 breast procedures from his office to an ASC, which suggests a total of about 275 surgical procedures.

The threshold question posed for an 025(b) exception is not whether about 400 of Dr. Cobden's and Dr. Teslow's surgeries would be placed in the ASC, but whether there is presently "an unreasonable barrier to services" with respect to operating room availability for these procedures. The limited testimony offered was not adequate to establish that these diversions result from "an unreasonable barrier to services" as opposed to routine physician-patient choices.

6. Public Desire for Competition Not a Basis for an Exception

There was some attention in the preliminary decision on these applications to the community's desire for alternatives and to optimization of competition.[251] While not relied upon in that decision to justify an 025(b) exception, nor advocated by any party at the hearing as a basis for such an exception, it may be appropriate to briefly address the potential role of these values in an 025(b) decision as such a suggestion may yet be made.

The Department of Health and Social Services has written 7 AAC 07.025(b) quite restrictively, limiting exceptions to the methodology to circumstances where there is an existing "barrier to services." If no barrier to services is found, a CON application, "[t]o be approved by the commissioner . . . *must* . . . meet the standards and use the methodologies set out in the department's document."[252] Hence, while the commissioner can consider benefits of competition in many contexts, a desire for competition could not be a basis to assess the fundamental issue of need other than through the published methodology. It is also noteworthy that a basic purpose of the certificate of need process is, in a sense, to limit competition, since

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250 Direct and FMH cross-exam of Teslow.

251 Agency Record at 1610.

252 7 AAC 07.025(a) (italics added).

unlimited competition is thought to be a poor or counterproductive cost-control mechanism in the health care field.[253]

7. The Degree of Departure from the Methodology that Has Been Justified

As has previously been noted, the General Surgery Services methodology produces a very conservative assessment of existing capacity. In this case, it assigns operating rooms that have been known to handle as many as 1,437 surgeries in a year a capacity of only 900 surgeries. At the same time, the methodology locks in an upward trend in projected surgery usage in any community showing normal population growth, even if real local trends are otherwise. Thus Fairbanks, which has a declining trend in operating room usage, is automatically projected to show growth in the future. The net effect is that the methodology is already structurally biased toward a comparatively generous assessment of medical need for new general surgery suites. The provision for exceptions to further increase projected need when there is an existing barrier to services is a wise one, but it should not be applied casually. A strong showing should be required before there is an upward departure from a methodology already designed to yield generous need projections.

In this case there was indeed a strong showing of an unreasonable barrier with respect to much of the pain management surgery for Fairbanks patients. An exception to the methodology would be appropriate to account for this excluded surgery. AMD-F did not follow through on its strong showing when it came to quantifying that surgery, however. It elected as a tactical matter to rely on the vaguest of case count numbers and exhibited a frustrating refusal to distinguish between "surgical procedures" and the kind of surgeries that have a genuine medical need for an operating room. The barrier was not shown to divert so many surgeries—the number needed was about 900—that the methodology's projection of a need for two ASC suites should be bumped to a higher number of suites.

E. Choice Between Kobuk and Alaska Medical Development

After applying the methodology and reviewing the potential bases for an exception, the number of additional outpatient surgical suites *for which there is a medical need* remains two. It is undisputed that the two suites need to be awarded together, since single-suite ASCs are not economically efficient. The Standards and Methodologies prescribe three special standards to assist in choosing between concurrent applicants for a single service. The department is required to "compare the extent to which each applicant, including any parent organization of the

253 *See supra* section I-B.

applicant" demonstrates the characteristics listed in these concurrent review standards. The concurrent review standards relate to quality of service and to care for low-income or uninsured patients.

Both Kobuk and AMD-F have presented attractive applications, and each of them made a brief pitch in closing argument that it is the preferable alternative if only one ASC is to be built. Kobuk points out that one of its two principal investors, Dr. James, has already built two ASCs in Anchorage and that its proposal is much lower in cost than AMD-Fs, factors that may bear on its ability to ensure high quality service and to serve those of limited means. AMD-F points to its broader array of participating physicians and to their particular qualifications (many are doubly or triply board-certified), factors that may likewise bear on quality of service.

A comparison of the two applicants and a reasoned choice between them is hampered at this stage by the fact that the staff has never attempted the comparison. The staff's expertise has not been brought to bear on the problem. Moreover, there may be important comparative data available to the staff that—because the comparison has never been attempted—is not now in the record. Under the circumstances, the appropriate course is the remand this matter to the staff for the limited purpose of making an expedited decision regarding which ASC applicant is entitled to a certificate of need in preference to the other.

It is not impossible that Kobuk and AMD-F, who cooperated well during the hearing, might fashion a joint venture and thus avoid the need for a choice that excludes one of them. The terms of the remand should be broad enough to permit such a solution.

IV. <u>Reevaluation of the FMH Surge Capacity Proposal</u>

Kobuk Ventures is the only party appealing the grant of a surge capacity certificate to FMH. Kobuk offered no specific evidence in support of its appeal during the course of the hearing. It offered no argument in its appeal letter,[254] nor in any of its written briefs during the appeal. The advocacy of the appeal was limited to brief oral comments of counsel to the effect that FMH did not demonstrate a need for the surge suite because it failed to evaluate the possibility of using OR1 for surge capacity instead of building a new room.

In fact, the FMH application contains a thoughtful discussion of alternatives as required under General Review Standard 4.[255] The application does not expressly discuss using OR1 for surge capacity as a freestanding alternative, but the reasons for not doing so are easy to identify.

[254] Agency Record at 1635.
[255] Agency Record at 1387-8.

First, FMH seeks to build a suite that meets "current AIA general operating room space standards," which, according to FMH, the present "very small" 300-square-foot surge room on the second floor does not meet.[256] This makes it clear that FMH is planning something more than a Class A suite, since a 300-square-foot operating room would neither be "very small" in that class nor below AIA Class A standards, even under the AIA's latest revision.[257] Hospital CEO Mike Powers confirmed in testimony that the objective is to upgrade the present Class A surge suite to Class C.[258] Hence, to use OR1 as a replacement for the present overflow suite on the second floor would not achieve the project's objectives. Second, OR1 is already in use for procedures and a few surgeries; to give it double duty as the surge capacity room while decommissioning the second-floor suite would entail an overall reduction in the hospital's capabilities.

To the extent that Kobuk has pursued its appeal at all, it has articulated only one alleged basis to overturn the grant of a certificate of need to FMH. That basis proves on analysis to be inadequate, and the appeal should be rejected.

V. <u>Conclusion</u>

No basis has been established to overturn certificate of need to Fairbanks Memorial Hospital for construction of a surge capacity suite. One of the two certificates of need issued to Kobuk Ventures, LLC and Alaska Medical Development – Fairbanks, LLC will need to be vacated. Pursuant to 7 AAC 07.070(c)(1) and (2), this matter is remanded to the Department of Health and Social Services certificate of need staff to conduct a comparison of the two ambulatory surgery center applicants as required by the Alaska Certificate of Need Review Standards and Methodologies, Additional Considerations for Concurrent Review of More than One Application. The staff shall make a recommendation on the basis of that comparison no later than fifteen days from the date of adoption of this decision and order, unless the commissioner in her discretion finds good cause to extend the date for submitting the recommendation.

Nothing herein shall preclude Kobuk Ventures, LLC and Alaska Medical Development – Fairbanks, LLC from amending their applications so as to propose a joint project for the

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[256] Agency Record at 1387.

[257] *See* J. Sprague (chairman for the AIA 2006 Guidelines for Design and Construction of Health Care Facilities), *Sneak preview: What changes are coming up in the revised design guidelines?,* HospitalConnect, Dec. 21, 2005.

[258] Direct exam of Powers.

construction of two ambulatory surgery suites. If such a joint proposal is submitted and is substantially similar to one of the applications already submitted, it will be reviewed as a submission under 7 AAC 07.070(c)(1)(C) and the commissioner, in consultation with her staff, will issue a final agency decision thereon.

DATED this 18th day of April, 2007.

By: *Signed*
Christopher Kennedy
Deputy Chief Administrative Law Judge

[This document has been modified to conform to technical standards for publication.]