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

In the Matter of:	)	
	)	
KAHTNU VENTURES, LLC	)	OAH No. 12-0123-DHS
	)	

DECISION

Kahtnu Ventures, LLC applied for a Certificate of Need (CON) to build a single-suite Ambulatory Surgery Center at a site on Main Street Loop in Kenai, Alaska. The staff of the CON program in the Department of Health and Social Services recommended denial of the certificate, and on April 4, 2012, the Commissioner of Health and Social Services accepted the recommendation and denied Kahtnu's application.

Department regulations allow a denied applicant to challenge the denial in an evidentiary hearing, and Kahtnu has availed itself of that opportunity. The final decision on the record developed at the hearing returns to the Commissioner. This decision concludes that, while not all bases for the initial denial were valid, the record does not support overturning the overall result. The application should remain denied.

I. Application and Initial Denial

Kahtnu Ventures is an entity made up of seven or eight physicians who live and practice in the Kenai Peninsula Borough.[1] Kahtnu first applied for a Certificate of Need in September of 2011.[2] That application lapsed.[3]

On November 18, 2011, Kahtnu filed a second application,[4] the one at issue in this case. The second application proposed to build an 8365-square-foot facility at a cost of about $9 million.[5] The facility would house one general surgery operating room, as well as one procedure room primarily devoted to administering nerve blocks associated with surgery.[6]

In the course of filing multiple copies of the second application, or in the course of the staff's review, someone may have mixed up pages of that application with the predecessor

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1 Ex. 1 at 4 (seven); CON 0119 (eight).
2 *See* Ex. 42 and authenticating affidavit of Sharon Anderson.
3 Ex. 16 at 1.
4 *Id.*
5 Ex. 1 at 6.
6 *Id.*

application.[7] Some confusion seems to have resulted, which may explain one of the subsequent errors in the staff's analysis that is explored below.

Kahtnu's application set out to document need for the project under the *Alaska Certificate of Need Review Standards and Methodologies* of December 9, 2005 ("*Standards and Methodologies*"), which have been adopted by regulation.[8] These include a standard and associated methodology specific to general surgery services, which together present a formula for calculating future need for operating rooms.[9] Although the CON regulations permit an applicant to "request that a review standard . . . be waived,"[10] Kahtnu did not request that any of the standards be waived.

The Certificate of Need staff reviewed the application for completeness as required by 7 AAC 07.050, and determined it to be complete on December 21, 2012.[11] Kahtnu presented the application at a public hearing in Kenai the following month.[12] The application received substantial public comment, both pro and con. Central Peninsula Hospital submitted a detailed written comment opposing the application, arguing that Kahtnu had failed to meet the CON review standards.[13]

On February 21, 2012, the CON staff issued an 11-page review of the Kahtnu application, recommending that the Commissioner deny the requested certificate.[14] Within the time limit set by regulation, the Commissioner took action on the recommendation, finding that

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[7] The staff posted what Kahtnu asserts was the true second application on its website, and that version (used, at Kahtnu's request, as the sole application for purposes of this decision) is Kahtnu Exhibit 1. It is certainly one of the application documents Kahtnu filed in November, and perhaps the only one. Some of the information is presented in odd places, and it is missing pages 52 and 53.

The version of the November 18 application that appears in the Record compiled by the staff for this appeal is a slightly different version of the same document, with pages in a different order, pages 52 and 53 included, and at least one page substituted from another document (CON 0087, which does not match the version of the same page the staff posted on the web, Ex. 1, page 87). This suggests that the staff was working with an imperfect copy of Kahtnu's official November 18 application.

Although Kahtnu makes much of this discrepancy as an illustration of staff incompetence, it is not clear where the fault lies. Since the version of the application Kahtnu regards as the official one is not perfect either—it is missing at least two numbered pages—and since Kahtnu submitted multiple copies of its November application, one cannot rule out an error by Kahtnu as the source of the problem. It is also quite possible that the staff got pages mixed up between the September and November applications. The two versions of the application were very similar and the error seems to have had a bearing on only one issue, discussed later in this decision.

[8] *See* 7 AAC 07.025(a)(3).

[9] *Standards and Methodologies*, Part VIII-A.

[10] 7 AAC 07.025(b). Waivers are not wholly discretionary; they must meet one of the criteria set out in the regulation.

[11] CON 0248.

[12] CON 0118-0140.

[13] Ex. 36.

[14] The review and attachments are found at Ex. 5.

"the application has not met the applicable criteria."[15] Kahtnu initiated this administrative appeal on May 3, 2012.

II. Permissible Scope of Kahtnu's Appeal

Administrative appeals of initial denials of Certificates of Need are decided by the Commissioner of Health and Social Services.[16] The applicant has the burden of persuasion to show that the initial decision ought to be changed.[17] If he is so persuaded, there are no restrictions on the Commissioner's ability to modify the decision as appropriate under the law, or to vacate the decision so as to seek additional information.[18] The Commissioner is not required to defer to his own prior decision or to his staff's recommendation.[19]

Although the Commissioner's freedom to correct errors in his prior decision is broad, the scope of what may be considered in an appeal hearing is quite narrowly constrained by the Certificate of Need regulations. The constraints relevant to this case are discussed below.

A. Alternative Methodologies

As its title implies, the *Standards and Methodologies* document adopted by regulation contains both standards that must be met to receive a Certificate of Need, and—for some standards—particular methodologies for determining if a standard is met. In the case of applications to build general surgery facilities, there is a special standard providing that the applicant must "demonstrate[] need in accordance with the following review methodology."[20] Only one "Review Methodology" is provided. It is a simple formula to determine the rate of usage of surgery services in the population over the last three years, which is then projected forward to the population anticipated in the fifth year after the project is completed. The resulting expected demand is compared to the rated capacity (as set by the same methodology) of existing and approved operating rooms, to see if there is a residual unmet need.

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15 The Commissioner's denial letter is in the record as an exhibit to the first pleading, Kahtnu's appeal letter.

16 7 AAC 07.080(e).

17 2 AAC 64.290(e), made applicable through 7 AAC 07.080(g) and AS 44.64.020(a)(11).

18 Among the permissible remedies would be to vacate the decision and require submission of additional information under 7 AAC 07.070(c).

19 *See, e.g., 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.* (Alaska Commissioner of Administration, May 26, 1998), at 4 ("the Commissioner is not obligated to defer to . . . [the Division of General Services]").

20 *Standards and Methodologies*, Part VIII-A.

Ever since the *Standards and Methodologies* were first adopted, it has been permissible to seek a waiver or exception to any *standard*.[21] At one time, however, it was controversial whether a *methodology* could be waived.[22] In 2010, the Department added a provision to 7 AAC 07.025, the regulation adopting the *Standards and Methodologies*, specifically providing that "The department will not waive a methodology adopted by reference under . . . this section."[23]

In the present appeal, Kahtnu has not sought a waiver of any standard, but has contended that the methodology for determining need under the General Surgery Services standard should be rejected in favor of a different methodology. 7 AAC 07.025 prohibits the Department from entertaining that aspect of Kahtnu's appeal.

Kahtnu argues that the prohibition on waiving a methodology is inconsistent with the ruling of Superior Court Judge Fred Torrisi in *South Anchorage Ambulatory Surgery Center v. State, Department of Health and Social Services*,[24] a decision that declined to follow the prior version of 7 AAC 07.025. Judge Torrisi perceived a potential conflict between the Certificate of Need statute and that regulation, which, like the current one, was being interpreted to preclude examination of alternative methodologies to evaluate need. There are at least two reasons that Kahtnu's argument is unpersuasive. First, and most fundamentally, the Department adopted the current version of 7 AAC 07.025 after—and with full knowledge of—Judge Torrisi's ruling. Insofar as there is tension between Judge Torrisi's reasoning and the new regulation, the Department has elected not to follow the Superior Court ruling outside the four corners of the case in which it was rendered. Because Superior Court decisions are non-precedential, this is permissible.[25] Second, while Judge Torrisi declined to follow the prior version of 7 AAC 07.025 (or at least the Department's interpretation of that regulation as of the time he made his ruling), he did so in the context of a case where "the uncontested facts" showed the result of the standard methodology to be counterfactual—showing excess capacity where there was actually a proven need for new capacity that was acknowledged by the Department's Commissioner.[26]

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[21] Former 7 AAC 07.025(b) (Reg. 177); current 7 AAC 07.025(b).

[22] *See In re South Anchorage Ambulatory Surgery Center Joint Venture*, OAH No. 06-0152-DHS, [Proposed] Decision and Order (recommended May 24, 2007, not adopted by Commissioner), at 16, published at http://aws.state.ak.us/officeofadminhearings/Documents/DHS/DHS060152.pdf.

[23] 7 AAC 07.025(c).

[24] No. 3AN-07-10738 CI (2008), published at http://aws.state.ak.us/officeofadminhearings/Documents/DHS/DHS060152.pdf.

[25] *Cf. Alaska Public Interest Research Group v. State*, 167 P.3d 27, 45 (Alaska 2007).

[26] Decision at 7-8. The Department had "adopted all of the findings" to this effect. *Id*. at 10.

There is no such concession in this case. In the present circumstances, the Department must follow its own regulation, which now explicitly prohibits alternative methodologies.[27]

B. Other Limitations on Scope of Hearing

In 2010, the Department rewrote its regulation governing appeals of Certificate of Need denials, placing the following restrictions on such appeals:

> (c) A hearing . . . must be based solely upon the record that existed at the time of the department's decision.
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> (d) At the hearing the applicant may
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> (1) call or cross-examine witnesses;
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> (2) present expert testimony to refute the department's decision, including the department's calculation of need;
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> (3) present additional evidence that was not part of the agency record if that evidence
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> (A) was available to the department during the application and decision process, but was not properly considered; or
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> (B) was unknown to the applicant or the department at the time of the decision, but is available at the time a request for hearing is made . . . .[28]

It must be noted at the outset that (c) and (d) could be read to contradict each other, with (c) prohibiting any evidence beyond the record assembled by the staff during their review, and (d) proceeding to allow exactly that kind of evidence. The parties to this case agreed that (c) should be read as the general rule and (d) as a limited exception to that rule.

Another feature of the above regulatory language is that it makes no provision at all for the staff to offer evidence. The Department has decided that the Commissioner's initial decision and the associated staff review must speak for themselves, and additional testimony or documentation to shore them up is not allowed, except perhaps to respond to *new* evidence from the applicant.

The applicant is given considerable latitude to explore and critique the reasoning behind the staff review, as long as the critique is not based on underlying factual information that could have been presented prior to the initial decision, but was not. Thus, for example, an applicant's expert can explain errors in the staff's application of its review methodology, including flaws in

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[27] *See Stosh's I/M v. Fairbanks North Star Borough*, 12 P.3d 1180, 1185 (Alaska 2000).

[28] 7 AAC 07.080. This is the first appeal heard under the new regulation.

the data the staff drew upon. Likewise, a critique of the staff's reasoning and data can be pursued through cross-examination of staff personnel.

III. Evidence Taken

Prior to the hearing, the administrative law judge (ALJ) ruled on evidentiary motions from both sides. Two notable types of proof were excluded.

One category of excluded evidence was testimony from a pair of Central Peninsula Hospital employees, which the staff wanted to offer to verify, explain, or add context to data the staff had relied on in its review. The ALJ ruled that 7 AAC 07.080 prohibits the staff from augmenting its analysis in this way. The ruling did not preclude Kahtnu from offering evidence to call the reliability of the staff's data into question, nor preclude the staff presenting evidence (including testimony from the Central Peninsula Hospital witnesses) to rebut any such showing that Kahtnu tried to make, but the staff was not allowed to shore up its analysis on its own initiative.[29]

The second significant category of excluded evidence was testimony of an expert witness, together with his illustrative exhibit, which Kahtnu wanted to offer to show that "the 'standard methodology' is useless" and to propose a different methodology, called trend analysis, for projecting future general surgery usage.[30] The ALJ excluded this evidence on the basis that the single methodology that has been adopted by regulation must be followed without exception.[31] Now that the issue in this case regarding target population has been resolved (Part IV-B below), one can perceive that the expert's testimony would not have been helpful even if it were permissible, since the trend analysis was done without using case counts from South Peninsula Hospital.[32]

After receiving the rulings excluding these items, the parties stipulated to try the case on the written record. That record would consist of the 2055-page numbered agency record that the CON staff had compiled, supplemented by Kahtnu Exhibits 1, 2, 5, 6, 11, 14-17, and 36-39.[33] Some of the exhibits were portions of the same numbered record; others were materials from state websites (such as the version of Kahtnu's application as posted on the CON website), or correspondence between the parties, that both sides felt were acceptable or necessary additions to

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29 Ruling on Remaining Issues in Motions in Limine (Aug. 3, 2012), at 2.
30 Kahtnu Ventures, LLC's Offer of Proof Regarding Frank Cohen and Exhibit 41 (Aug. 7, 2012).
31 Ruling on Remaining Issues in Motions in Limine (Aug. 3, 2012), at 1.
32 *See* excluded Ex. 41.
33 *See* Order on Hearing Procedures (Aug. 6, 2012).

the documents the agency had collected. The parties presented their arguments in simultaneous post-hearing briefs.

Along with its final brief, Kahtnu moved over objection to further supplement the record. This resulted in the admission of Exhibit 42 (filing fee checks to show application handling history) and of some deposition testimony of Karen Lawfer on procedural history.[34] The staff was given an opportunity to comment on the additional evidence, which did not exercise. The record closed on October 9, 2012.

IV. Evaluation of the Reasons for Denial

The staff recommendation urged denial of Kahtnu's application for several reasons. In making his initial denial of the application prior to this appeal, the Commissioner accepted all of the staff's reasons. The fact that all of the reasons were accepted is apparent because a program regulation requires the Commissioner to include a written statement of reasons if he differs with the staff's analysis,[35] and the Commissioner did not include any such statement with his denial letter.[36] For simplicity, this decision will simply refer directly to the staff's reasoning.

The staff had three reasons for denial, set out in the final "Recommendation" section of its review document.[37] These were:

1. "[T]he applicant did not clearly outline the cost and size of project;"
2. "[T]he applicant . . . did not define a service area;" and
3. "[T]he applicant . . . failed to show need for additional surgical capacity, through the general surgery standards and methodology, in the Kenai Peninsula Borough."

There were, in fact, two other potential reasons for denial in the staff's review document, but they do not appear in the final "Recommendation." One was failure to meet General Review Standard 5 – Impact on the Existing System.[38] The second was failure to meet General Review Standard 6 – Access.[39] It is not clear why, after expressly finding these standards to be unmet, the staff did not address or allude to them in the final "Recommendation." Neither party has

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[34] Ruling on "Motion to Supplement Record for Post-Hearing Brief" (Sept. 26, 2012). A chart showing the limited portions of the Lawfer deposition that may be used is found on page 2 of that ruling. Four rulings in the September 26 order, as reflected in that table, are hereby reconsidered and amended: Transcript passages 99:2-5, 61:12-15, 66:15-21, and 24:17 - 30:11 will be admitted. Though of no importance, this testimony was permissible if elicited *by Kahtnu*, and hence should not have been excluded.

[35] 7 AAC 07.070(d).

[36] The Commissioner's denial letter is in the record as an exhibit to Kahtnu's May 3, 2012 appeal letter.

[37] Ex. 5 at CON 0229.

[38] *Id*. at CON 0229.

[39] *Id*. at CON 0224.

addressed these standards in briefing, and no attempt will be made here to determine whether they could or could not supply an alternative rationale for denial of the application.

The three recommended bases for denying the Kahtnu application are addressed below. The first basis will turn out to be unfounded, but the second and third issues are sufficiently valid, when evaluated on the present record, that the application still ought to be denied.

A. Alleged Failure to Clearly Outline Cost and Size of Project

1. Cost of Project

The need to estimate the cost of the project arises from 7 AAC 07.040(a)(1), which requires an applicant to "submit all of the information required by the department's *Certificate of Need Application Packet*, dated December 9, 2005." The application packet asks for this information on pages 5, 42, and 54; it is used to calculate the fee that should accompany the application.

The staff asserted in its Review that Kahtnu gave three different costs in its application: $8,020,000 on page 42; $9,076,834 on page 5; and $9,176,834 on an attached estimate from Pfeffer Development.[40] The staff therefore concluded that the "costs are unable to be determined."[41]

The staff's assertion—that the application gives three different cost figures—is wrong. Pages 5, 42, and 54 of the application under review all provide exactly the same figure, a cost of $9,076,834, and the application fee was tendered on that basis.[42] The $8,020,000 figure does not appear in the application under review at all[43] (the staff may have been looking at a page from a prior, superseded application, which seems to have made its way into the record for this application[44]). The staff's third purported cost figure, $9,176,834, does not appear in the application either, and its appearance in the developer's estimate is clearly and concisely explained on page 5 of the application: the developer rounded one figure in a situation where the application does not call for rounding, resulting in a $100,000 difference in totals.[45]

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40 *Id.* at 0219.

41 *Id.*

42 Compare Ex. 1, pages 6, 87, and 108.

43 Page 42 of the application under review, which was posted on the department's website, is found at Ex. 1, p. 87. It lists a cost of $9,076,834. The staff's representation that a figure of $8,020,000 appears on page 42 is therefore mistaken.

44 *See* CON 0087 and footnote 7, *supra*.

45 Ex. 1 at 6.

In determining that the "costs are unable to be determined," the staff made a regrettable error. In any event, if the staff overlooked the explanation on page 5 and was confused by an apparent one-digit, one percent discrepancy in cost figures between $9,076,834 in the application and $9,176,834 in an attached document, it had two other solutions available to it. One would be to find the application incomplete in its completeness review under 7 AAC 07.050, on the basis that a required piece of information was not made sufficiently clear and/or that the proper fee had (possibly) been underpaid by one percent. The second would be to contact the applicant "to obtain clarification," as expressly permitted by the department's regulation at 7 AAC 07.067(b). The staff should not, however, have taken the application all the way through review without resolving its confusion on this easily explained matter, and then advised the Commissioner to deny the application on this basis.

2. Size of Project

The need to estimate the size of the project likewise arises from 7 AAC 07.040(a)(1)'s requirement for an applicant to "submit all of the information required by the department's *Certificate of Need Application Packet*, dated December 9, 2005." Page 5 of the packet asks for the "number of square feet of construction/renovation," and page 11 asks for "Total square footage of proposed facility/project." Although not directly connected to any review standard, these questions may be asked to define the scope of what the department would be authorizing if a certificate were granted.

Kahtnu's application listed 8365 square feet in both locations where the square footage was requested.[46] In keeping with these answers, the staff's public notices announced the proposed square footage of the project as 8365,[47] and the Office of Rate Review, in evaluating the application, likewise understood the size to be 8365 square feet.[48] Nonetheless, the staff asserted in its review that the "size of the facility is . . . in question."

The first basis for the staff's assertion is Kahtnu's answer to two other questions on page 11. Under "Area per bed, service unit, or surgery suite," Kahtnu listed "4183 SF per operating room and procedure room." Under "Percentage of total floor area used for direct service (non-bed activity)," Kahtnu entered "5,027.36 SF patient area 60.1%." The staff does not explain why these answers are problematic. The 4183-square-foot figure is exactly half of the 8365-square-

[46] *Id.* at 6, 12.
[47] *E.g.*, Ex. 6.
[48] Ex. 5 at 28.

foot total, reflecting the amount of square footage "per service unit" for the two service units mentioned in the answer. The 5027.36-square-foot figure presumably gives the portion of the 8365-square-foot total "facility/project" that is for direct service. Neither answer appears to be inconsistent with the 8365 total square footage listed elsewhere.

The second basis for the staff's assertion is the submission of a drawing in response to a request on page 39 of the application for "Schematic floor plan drawings (or conceptual drawings) of proposed functional use of various rooms."[49] Although the request for this drawing does not require any information about square footage, Kahtnu submitted a drawing of the layout of a single floor that included a legend reading:

FIRST LEVEL	8,365 SF.
SECOND LEVEL	4,951 SF.
THIRD LEVEL	4,951 SF.
TOTAL BUILDING	18,267 SF.

There is no question that the inclusion of this legend was confusing, since it seemed to contradict not only the square footage mentioned several other places in the application, but also the application's statements in two locations that the ASC would be a "single story" or "one-story" facility (although the floorplans of the other stories would then have been missing).[50] The error was made more puzzling by the fact that the floorplan was plainly incomplete, showing only a procedure room and omitting any representation of an operating room for the ASC. Kahtnu corrected the latter confusion on January 20, 2012, submitting a complete floorplan of a one-floor ASC with both an operating room and a procedure room and listing no square footages on the plan itself,[51] along with a cover e-mail referring to this as "the 8,365 square foot plan."[52] But the January 20 submission also included a marked-up version of the original floorplan, with the above-quoted legend and its reference to "18,267 SF" left uncorrected.[53]

Although Kahtnu must bear some blame for this confusion, the confusion would likely have been quite easy to resolve. It may well be, for example, that the legend on some drawings referring to a three-level facility is simply an artifact of an earlier plan. Certainly, whenever asked directly, Kahtnu has been completely consistent in framing the project as being for a one-

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[49] Ex. 1, p. 80.

[50] Ex. 1 at 6, 12. At least one public commenter was confused by this error by Kahtnu. CON 1535.

[51] Ex. 5 at CON 0242.

[52] *Id.* at CON 0239. The staff's review claimed this drawing shows a facility larger than 8365 square feet if it is "to scale" (CON 0220), but there is simply no basis in the record for that assertion by the staff. It is entirely plausible that the drawing at CON 0242 depicts a proposed building of 8365 square feet.

[53] *Id.* at CON 0241.

level ASC of 8365 square feet. If the staff believed the legend on one of the plans referring to 18,267 square feet and three floors might be the true scope of the project, it would follow that the application was incomplete, because it failed to include plans for the second and third floors. For this reason, and also for the reason that the square footage is not relevant to any standard of review and thus not central to the handling of the application, the problem ought to have been addressed in the completeness review under 7 AAC 07.050 or through a clarification request under 7 AAC 07.067(b). It should not have been raised for the first time in the final review and used as a reason to deny the certificate.

B. Alleged Failure to Define a Service Area

The staff review identifies failure to "define a service area" as one of the main reasons to deny Kahtnu's application. This appears to be a shorthand for the closely related concept of failing to define a population to be served by the proposed facility, and both parties have treated the question in that manner in their arguments. The target population for a facility may be the residents of a geographic area, but the CON application does permit applicants to justify the use of a target population that is not defined in a wholly geographic way.[54]

Except in wholly isolated medical markets,[55] defining the population available to a proposed facility plays a central role in the Certificate of Need evaluation. One must understand the population being served in order to evaluate what facilities are already available to that population, and to determine whether there will be a shortfall in the capacity of those facilities going forward.

At the same time, the service area/population served matter is far from a simple one. Geographic areas are not walled off from one another, and patient preferences may be complex. Part IV-B of the CON application contains a detailed question on this topic:

> 4. Identify the target population to be served by this project. The "target population" is the population that is or may reasonably be expected to be served by a specific service at a particular site. Explain whether this is a local program, or a program that serves a population outside of the proposed service area. Use the most recent Alaska Department of Labor and Workforce Development statistics for population data and projections. Explain and document any

[54] For example, Section IV, question B-4 of the application allows applicants to explain that a proposed project "serves a population outside of the proposed service area." *See* Ex. 1 at 15.

[55] *Cf. In re Alaska Medical Development-Fairbanks, LLC*, OAH No. 06-0744-DHS (Comm'r of Health & Soc. Serv. 2007), main Decision & Order at 39-41 (selection of the appropriate target population was mathematically unimportant in case where supply of existing operating suites was agreed by all to be exactly six) (http://aws.state.ak.us/officeofadminhearings/Documents/DHS/DHS060744.pdf).

variances from those projections. The population may be defined in one or more ways:

a. Document the service area by means of a patient origin analysis.

b. Justify the customary geographical area served by the facility using trade and travel pattern information. Indicate the number and location of individuals using services who live out of the primary service area.

c. Use Alaska Department of Labor and Workforce Development information, including current census data on cities, municipalities, census areas, or census sub-areas, to describe trends, age/sex breakdowns, and other characteristics pertinent to the determination of need.

d. The population to be served can be defined according to the unique needs of patients requiring specialized or tertiary care (e.g. heart, cancer, kidney, alcoholism, etc.) or the needs of under-served groups.

Given the way need is calculated in the CON process, this may be the single most important question in the entire application.

Remarkably, Kahtnu provided no narrative at all, and no analysis at all, in answer to this question. Instead, Kahtnu attached 10 pages of population and demographic data relating to the Kenai Peninsula Borough in general,[56] and five pages each relating to Kenai (city), Soldotna, Kalifornsky, Nikiski, Sterling, and Salamatof.[57] All of this was apparently printed directly from state web pages, with no effort to highlight or isolate the data that might be particularly relevant to the application. Kenai, Soldotna, Kalifornsky, Nikiski, Sterling, and Salamatof are *some* of the Census Designated Places (CDPs) used as statistical units for population in the Kenai Peninsula. There are a number of others that might have been candidates for inclusion: Ridgeway, Funny River, Cohoe, Point Possession, Cooper Landing, etc.[58] Indeed, Ridgeway is right next to the proposed ASC, whereas Nikiski and much of Sterling are considerably farther away. At any rate, Kahtnu made no effort to explain why data for any individual CDPs had been provided, nor to explain the rationale for including some and not others.

Kahtnu now contends that the staff should have defined the "target population" as whatever population is served by Central Peninsula Hospital, and implies that this target population would exclude the population served by the South Peninsula Hospital in Homer. Perhaps there is a case to be made for defining the service area this way. One might demonstrate—if true—that the Central and South Peninsula Hospitals do not draw significantly

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[56] Ex. 1 at 17-24, 55-56.

[57] *Id*. at 25-54.

[58] For a map of CDPs in the area, *see* http://labor.alaska.gov/research/census/borcamaps/2_12_0map.pdf.

from the same populations. One might identify geographic populations whose absolute size or growth rate has been projected by the Department of Labor and Workforce Development, and lay out an analysis of why those geographic populations or their growth rate could serve as a proxy in need calculations for the nongeographic target population Kahtnu feels the staff should have identified.

What is significant for purposes of this case is that Kahtnu did none of this in its application. Instead, the application referred broadly to "Surgical volumes in the Kenai Peninsula Borough."[59] When asked to define "the number of persons from the target population who are currently using these services and who are expected to continue to use the service," Kahtnu gave "58,562" and "64,077", which are projected populations for the entire Kenai Peninsula Borough, including Homer.[60] And when asked the detailed question, quoted above, about defining the target population, Kahtnu responded with an unexplained set of copied statistical data from the borough as a whole, along with materials from a scattered assortment of about half the communities in the northwest part of the borough.

It is difficult to see how the staff, presented with such an application, could have run need calculations for anything other than the whole Kenai Peninsula Borough. If Kahtnu intended another result, its application, and particularly its response to question IV-B-4, was prepared with insufficient diligence.

Failing to analyze and define a service area and target population other than the whole Kenai Peninsula Borough likely is not a basis to deny an application in this context. It does, however, have consequences for the calculation of need.

C. Alleged Failure to Show Need for Additional Surgical Capacity

In order to support a Certificate of Need, the information developed through the application process must demonstrate a need for the proposed project under the general surgery review methodology. This methodology focuses on projected demand for general surgery in the fifth year following implementation of the project. If the projected number of general surgeries in that year exceeds the capacity of the existing and CON-approved operating rooms available to the target population, need has been shown under the General Surgery Services Review Standard. For the type of operating rooms available at existing facilities on the Kenai Peninsula,

[59] Ex. 1 at 8.
[60] Compare *id.* at 57 with *id.* at 17.

the capacity of the existing and CON-approved operating rooms is determined by applying a fixed "target use rate" of 900 surgeries per operating room per year.[61]

Kahtnu's application ran a need calculation under this methodology, showing an unmet need in 2019 in the neighborhood of one full operating room.[62] There were two controversial aspects to the data Kahtnu fed into the calculation, however. This section will resolve those controversies and then walk through the need methodology using the correct inputs.

1. Exclusion of South Peninsula Hospital General Surgery Suites

First, Kahtnu needed to feed into the calculation the number of existing operating rooms serving the target population. Although, as explained above, Kahtnu had used the population of the entire Kenai Peninsula Borough as the target population, Kahtnu counted only the three operating rooms at Central Peninsula Hospital (CPH) in Soldotna; it left out the two operating rooms at South Peninsula Hospital (SPH) in Homer. There is absolutely no explanation, analysis, or data in the application to support this choice. Since the SPH operating rooms plainly serve a portion of the target population, the staff correctly added them to the supply side of the calculation, raising the total number of current operating rooms to five.

2. CPH Surgery Count Data Used in Calculation

Second, in developing a general surgery use rate for the target population, Kahtnu needed to count surgeries occurring in the existing operating rooms. In counting surgeries at CPH, Kahtnu seems to have used figures drawn primarily from a CPH report titled "Surgical Cases by Physician Specialty," which counted surgical cases by July-to-June fiscal year.[63] It is notable, however, that the application Kahtnu filed did not indicate where these figures came from or provide any context or documentation for them.[64] The staff ran the calculation using two different sets of numbers for CPH, both of them lower than Kahtnu's:

1) A calendar-year case count using "data submitted to CON program in yearly surveys;"[65] and

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[61] *See Standards and Methodologies*, Part VIII-A. The parties seem to agree that the operating rooms in the borough are all "operating rooms serving both inpatients and outpatients" under this standard.

[62] Ex. 1 at 60.

[63] Ex. 11. For "2009" and "2010" (actually FY 2010 and 2011), the numbers in this report match those in Kahtnu's need calculation, found in Ex. 1 at 60. For "2008," the numbers do not correspond to one another, for reasons Kahtnu has not explained, but the discrepancy is small.

[64] *See* Ex. 1 at 60. The source documents appear among prints of a PowerPoint presentation that was apparently given at a public hearing on January 19, 2012, and one may surmise that they were turned over to the staff at that time. *See* CON 0178-0182; Ex. 5 at 10 (indicating data was "presented at public meeting 1/19/2012"). They were also sent in on January 23, 2012 with a cover e-mail. CON 354-359.

[65] Ex. 5 at 9.

2) A fiscal-year case count using Kahtnu's numbers as a starting point, but subtracting endoscopies and Caesarian sections.[66]

The staff's two case counts were similar, and they each yielded approximately the same "use rate" in the need calculation. The question whether the Kahtnu count or one of the staff's lower counts should be used is a determinative issue in this case.[67] Kahtnu has criticized the staff's election to use the alternative figures in lieu of Kahtnu's figures. The next few paragraphs explore the choice between the competing case count numbers. In evaluating the staff's approaches, it will be easiest to start with the first, "yearly surveys" case count.

Kahtnu has failed to prove out its critique of the staff's use of the yearly survey data. On the face of it, it is hardly surprising that the staff would rely on and use the data submitted to it—for exactly this purpose—by health facilities pursuant to the program's own data-gathering regulation, 7 AAC 07.105. Kahtnu prefers its own data, pointing out that "Kahtnu's data [was] . . . provided by CPH itself."[68] The same is true of the survey data collected under 7 AAC 07.105. Kahtnu objects that the yearly survey data was "inconsistent and ambiguous," with "two different forms provided by CPH for the same reporting period, showing different numbers."[69] This is not so. The staff used numbers from just one form, the one that provides a count specifically associated with the exactly three general surgery operating rooms that all agree are present at CPH.[70] The other form in the record, which Kahtnu alleges is inconsistent, is a compilation of data from multiple facilities that, for CPH, has a case count for "5" inpatient/outpatient surgery suites at the hospital; the case count is higher, but it plainly includes "surgeries"—perhaps C-sections, for example—not performed in the three general surgery operating rooms. If there is true inconsistency between these documents, or if there is something about the manner in which they were compiled that makes them unreliable, it was Kahtnu's burden to bring that out through evidence offered at the hearing.

Kahtnu's final and potentially most significant objection to the CPH survey data is a contention that the staff has improperly excluded endoscopies from the total number of surgeries.[71] In Kahtnu's view, the staff had no regulatory basis to exclude endoscopies from the

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66 Ex. 5 at 10.
67 Footnote 86, below, shows why it is determinative.
68 Post Hearing Brief of Kahtnu Ventures, LLC at 53.
69 *Id.*
70 CON 2010.
71 Post Hearing Brief of Kahtnu Ventures, LLC at 53-54.

general surgery count. Kahtnu observes that the General Surgery Services review standard says that it does

> not apply to (1) open-heart surgery subject to the standards in B of this section; (2) surgery suites dedicated to C-sections and other birth-related surgeries; or (3) surgery suites dedicated to LASIK or other eye surgery.

Kahtnu points out that endoscopies are not among the excluded items.

This argument confuses a scope-of-coverage issue with a definitional issue. The above exclusion simply establishes that the need for open-heart surgery *programs*,[72] for *facilities* for birth-related surgeries, or for *facilities* for eye surgeries will not be determined by reference to the General Surgery Services need formula. It does not establish what general surgery is or what "general surgery cases" means in the context of the CON Review Methodology. Kahtnu reads the passage as though it said "general surgery cases means all surgery cases except open-heart surgery, birth-related surgery, or eye surgery," but it does not say that.

"General surgery cases" is undefined in the Certificate of Need regulations and in the incorporated standards and methodologies. The interpretation of this phrase, and the associated handling of minor surgeries and relatively simple endoscopies that potentially may occur in doctor's offices or minimally equipped procedure rooms, has vexed the department in the past.[73] In this case, the department seems to have set out to count, as a general surgery, each instance of patient treatment that occurred in one of CPH's three, or SPH's two, general-purpose operating rooms. For SPH, it used the patient count reported for the two SPH suites.[74] For CPH, it used the patient count reported for the three general-purpose CPH operating rooms.

The "endoscopies" whose exclusion Kahtnu protests were listed separately in the CPH data in a line for a fourth suite; they were not mixed in with the count for the three general surgery suites.[75] The staff did not categorically exclude all endoscopies, but rather excluded procedures (there is support in the record for believing they were, indeed, endoscopies[76]) that evidently did not require an operating room because they did not occur in one. There is some inherent logic in this approach. The staff was evaluating a certificate of need for a general-purpose operating suite, and it needed to develop a use rate for the existing facilities of that type

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72 *See* Review Standard VIII-B ("Open-Heart Surgery").

73 *See, e.g., In re Alaska Medical Development-Fairbanks, supra*, main Decision & Order at 43 n.204 (approach has not always been consistent).

74 CON 2049.

75 This is made clear by CON 2010.

76 *See* Ex. 36 at 13 (CPH characterizing totals from the fourth suite as being for endoscopies).

available to the target population. It makes sense to determine the use rate by counting only procedures that took place in the type of facility whose use rate is being studied. In any event, if the roughly 800 procedures per year that took place in CPH's fourth suite need to be counted as general surgeries, it would seem to follow that the fourth suite should also be counted as a general surgery operating room, which would increase current capacity available to the target population from five to six—an alteration that would be fatal to Kahtnu's application.[77]

The hearing provided Kahtnu with an opportunity to show either that the staff's approach was flawed or that the staff's data was flawed. Kahtnu did neither. With regard to the overall approach, Kahtnu might have brought expert testimony to explain why excluding procedures that took place in the fourth suite was illogical or somehow inconsistent with medical reality. With regard to the data, it could have used witnesses, from CPH or elsewhere, to show that the CPH survey numbers are falsely reported or otherwise unworthy of reliance. It did not attempt these things. Its only significant effort in this direction was to argue that CPH's reports contradict one another:

> The record reflects that CPH reported data to the CON Staff on three separate annual reports in which CPH indicated that the endoscopies were *included* within the figures for surgeries performed in the surgical suites. [Footnote: ROA 2023, 2030, 2040] The only reasonable explanation is that endoscopies were performed in the surgical suites along with other types of surgeries.[78]

The factual premise of this argument is wrong. Going to the three record pages cited by Kahtnu in the above quotation, one finds, on each occasion, that the higher surgery totals are on lines that attribute them, not just to the three surgical suites, but to "3" surgery suites and "1" procedure room. So, for example, CON 2040 gives a total of 3114 surgeries for 2008, occurring in the four venues collectively. The report the staff relied on, CON 2010, shows a similar number of surgeries overall (there is a very slight variance), but breaks them down, showing that 786 of them occurred in the fourth suite. There is no contradiction.

In short, Kahtnu did not show that the staff was wrong to rely on the usage data it had collected under the mandatory Certificate of Need reporting regulation. As noted above, the staff review also ran a second need calculation, endeavoring to use Kahtnu's CPH usage figures but correcting them for overinclusiveness. Kahtnu has criticized these corrections.

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[77] *See* footnote 86 below, showing that the maximum "need," even using Kahtnu's case count numbers, is between 5.04 and 5.15 suites in 2019. If there are already six suites, that need is already fully covered.

[78] Post Hearing Brief of Kahtnu Ventures, LLC at 48.

Kahtnu faults the staff for subtracting C-sections from the surgery totals Kahtnu provided for CPH. Kahtnu admits that C-sections ought not to be counted toward the general surgery case count, but contends that they had already been subtracted from the Kahtnu figures. Kahtnu characterizes this as a "blatant error."[79]

In fact, the handling of C-sections is as indicative of sloppiness on Kahtnu's side as of carelessness on the part of the staff. Kahtnu's only proof that C-sections had already been excluded is an asterisked footnote from the data used to support the "2008" (FY 2009) case count in its application. The footnote says: "C-Sections not included in FY09 case totals."[80] The presence of this footnote on one year's data, and not on the data for the other years, actually suggests that C-sections had *not* been excluded from two of the three years of case counts Kahtnu supplied. The staff's error, in overlooking the footnote, relates to one year, while Kahtnu erred regarding two years by incorporating C-sections in its totals for those years. The staff's error will be corrected in the need calculation later in this decision.

Kahtnu also contends that the staff improperly subtracted 2373 endoscopies from the surgery figures Kahtnu supplied for CPH. When the staff endeavored to use Kahtnu's fiscal year figures as a starting point but tried to correct them, the staff subtracted from Kahtnu's CPH totals the number of surgical procedures CPH had reported annually from the fourth suite: 786 for 2008, 761 for 2009, and 826 for 2010.[81] As discussed above, Kahtnu has not proved that there was anything wrong with the basic logic of excluding procedures that took place in another venue from the calculation of a "use rate" for the general surgery operating rooms. Although Kahtnu does not point it out, there is some inaccuracy in what the staff did: the staff was subtracting calendar year figures for usage of the procedure room from fiscal year figures for overall surgical procedures. However, since usage of the procedure room has apparently been fairly constant at about 800 events per year during the period in question, the disconnect between the figures should not make much difference.

The staff's corrections to Kahtnu's usage figures are therefore apparently supportable, except for the erroneous subtraction of 92 C-sections from the "2008" (FY 2009) total. Adjusting for this error but making the other needed corrections, the Kahtnu data yields an average yearly number of general surgeries at CPH of 2313 cases.[82] The staff's own data

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79 Post Hearing Brief of Kahtnu Ventures, LLC at 52.

80 Ex. 11 at 3.

81 Compare CON 2010 with Ex. 5 at 10.

82 [(2860 – 786) + (3148 – 761 – 113) + (3527 – 826 – 111)] ÷ 3.

generated from surveys yields an average yearly number of general surgeries at CPH of 2245 cases.[83] These figures vary by only three percent.

3. Need Calculation

In addition to complying with statutory and regulatory standards and meeting the general review standards, a CON application for general surgery services must show need under the single review methodology that has been adopted for that kind of project. As explained above, the staff ran this calculation using two sets of data, one drawing from its own survey data and one drawing from a CPH case count supplied by Kahtnu. Kahtnu has shown no errors in the data inputs used for the former calculation, and a minor error in the latter.

The staff's first calculation used a case count (CPH and SPH combined) of 9966 surgeries from 2008 through 2010, or an average of 3322 per year. Following the prescribed methodology, one divides this figure by the 2009 population of the Kenai Peninsula Borough (agreed by both sides to be 53,578), which yields a use rate of 62.00 per thousand. The next step is to multiply this rate by the projected population in the fifth year following completion of the proposed ASC (agreed by both sides to be 58,562). This yields a projected caseload of 3631 surgeries in that year. Using the rated capacity of the existing operating rooms (900 cases each, according to the methodology), such a caseload would require 4.03 operating rooms. There are already five general surgery operating rooms, and hence the methodology shows no need for any new ones.[84]

The staff's second calculation used a case count (CPH and SPH combined) of 10,076 surgeries from 2008 through 2010. As noted above, this number was understated because of the double-removal of 92 C-sections in the first year. The corrected number would be 92 higher, or 10,168, which translates to 3389 surgeries per year. Dividing this figure by the 2009 population of the Kenai Peninsula Borough (53,578) yields a use rate of 63.26 per thousand.[85] Multiplying this rate by the projected 2019 population gives a projected caseload of 3705 surgeries. At the rated capacity of the existing operating rooms, such a caseload would require 4.12 operating

[83] [2235 + 2107 + 2394] ÷ 3.

[84] *See* Ex. 5 at 9-10. The staff did these calculations correctly.

[85] Here there is a small, built-in, uncorrectable error in Kahtnu's favor because the CPH case numbers Kahtnu supplied were from July 2008 through June 2011, whereas the population being used is for July 1, 2009 (CON 0017), six months before the midpoint of Kahtnu's sample period. Since the population is growing, a population before the midpoint is a little too low and yields a slightly overstated use rate per thousand.

rooms. The calculation is still far short of showing a need for 5.01 or more operating rooms, which is what would be needed to justify new construction.[86]

Using both of the competing data sets, the need calculation under the general surgery services review methodology is too low to support granting a Certificate of Need for Kahtnu's project.

V. Conclusion

Although Kahtnu Ventures has shown that a portion of the staff reasoning behind the Commissioner's initial decision on its Certificate of Need application was flawed, it has failed to meet its burden of dislodging the need calculation that was the fundamental basis for that decision. The denial of Kahtnu's application should remain undisturbed.

DATED this 5th day of December, 2012.

By: *Signed*
Christopher Kennedy
Administrative Law Judge

[86] If Kahtnu's surgery numbers from CPH were used with no modifications at all, the outcome of the need calculation in Section IV-C-3 below would have been different. The need calculation would have gone as follows: (1) 3-year total surgeries at CPH plus SPH = 12,710; (2) average number of surgeries per year in target population = 4237; (3) use rate = 79.08 per 1000; (4) projected caseload in year 5 = 79.08 x 58.562 = 4631; (5) number of ORs needed at target use rate for existing capacity = 5.15.

If Kahtnu's figures were used with a single plainly required correction—elimination of C-sections from FY 2010 and FY 2011 figures, as discussed previously—the calculations would go as follows: (1) 3-year total surgeries at CPH plus SPH = 12,486; (2) average number of surgeries per year in target population = 4162; (3) use rate = 77.68 per 1000; (4) projected caseload in year 5 = 79.08 x 58.562 = 4549; (5) number of ORs needed at target use rate for existing capacity = 5.05.

Note that in both scenarios the additional 0.15 or 0.05 operating rooms beyond the existing capacity of 5.00 rooms is slightly overstated. Since the sixth room—the one proposed by Kahtnu—would be an outpatient-only room, its rated capacity would be 1200 surgeries and its projected usage if the existing rooms were all used at full rated capacity would be 131/1200, or 0.11 (11 percent of capacity) under the first scenario, and 49/1200 or 0.04 (4 percent) under the second. Thus the "need" using Kahtnu's surgery numbers as presented is arguably 5.11 rather than 5.15, and the need using Kahtnu's numbers with two years of C-sections removed is arguably just 5.04.

In any of these scenarios, however, there would be a fractional need for an additional suite beyond the five already available. In the past, the department has rounded need upward; that is, a fractional need is a need for one full suite. *See In re Alaska Medical Development-Fairbanks*, *supra*, main Decision & Order at 47 (need calculated at 1.26 suites is need for two suites).

As pointed out in footnote 77, none of these alternative calculations would show any need if there are already six countable operating rooms serving the target population.

Adoption

The undersigned adopts this decision as final under the authority of AS 44.64.060(e)(1). Judicial review of this decision may be obtained by filing an appeal in the Alaska Superior Court in accordance with AS 44.62.560 and Alaska R. App. P. 602(a)(2) within 30 days after the date of this decision.

DATED this 4th day of January, 2013.

By: *Signed*
Signature
William J. Streur
Name
Commissioner
Title

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