

Administrative Hearings and the Administrative Law Judge (ALJ) issued a proposed decision on December 5, 2012 finding that Appellant had “failed to meet its burden of dislodging the need calculation that was the fundamental basis” for the agency’s decision and the “denial of Kahtnu’s application should remain undisturbed.” On January 4, 2013 the Commissioner of HSS adopted the ALJ’s decision as final and appealable to the Superior Court. Kahtnu filed an appeal with this court on January 18, 2013 and oral argument was held February 10, 2014.

Relevant Law

Pursuant to A.S. § 44.62.560 judicial review by the Superior Court is limited to review of a final administrative order. When reviewing an agency decision the court will apply four principal standards of review: 1) the substantial evidence test for questions of fact; 2) the reasonable basis test for questions of law involving agency expertise; 3) the substitution of judgment test for questions of law where no expertise is involved; and 4) the reasonable and not arbitrary test for review of administrative regulations.¹

The issuance of Certificates of Need is governed by regulations established by HSS pursuant to its statutory obligation under AS § 18.07.041 to determine if “the availability and quality of existing health care resources or the accessibility to those resources is less than the current or projected requirement for health services required to maintain the good health of the citizens of the

¹ *State, Dept. of Health & Social Services v. North Star Hosp.*, 280 P.3d 575, 579 (Alaska 2012).

state.” HSS has adopted standards and methodologies under which need is calculated by comparing the sufficiency of current health care facilities in a particular area with the projected need for that area. When a CON applicant is seeking to build general surgery facilities a formula is used to determine the rate of usage of surgery services in the proposed service area over the last three years, as well as the capacity of the currently existing facilities in that area, which is then projected forward to the population anticipated in the fifth year after the project is completed. The expected demand is compared to the current capacity of existing operating rooms to see if there is a residual unmet need. If the existing facilities are insufficient to meet the projected need a CON may be granted. Pursuant to 7 AAC 07.025 this methodology must be used to determine whether need exists and cannot be waived. Without a CON a party cannot build a medical facility which would cost more than a million dollars.²

Kahtnu’s Current Appeal

Kahtnu’s application was initially denied for three reasons. The CON staff found that Kahtnu 1) did not clearly outline the cost and size of the project; 2) did not define a service area; and 3) failed to show need for additional surgical capacity in the Kenai Peninsula Borough. After the administrative appeal hearing the ALJ determined that the first basis was unfounded but the second and third were sufficiently valid to uphold the denial. In upholding the initial denial the Commissioner adopted the ALJ’s findings that: 1) Kahtnu’s application failed to

² AS § 18.07.031.

analyze and define a service area and target population other than the whole Kenai Peninsula Borough; and 2) using the entire Kenai Peninsula Borough as the proposed service area, the need calculation under the general surgery services review methodology is too low to support granting a CON for Kahtnu's project. It is this determination which the court must review.

The HSS Commissioner's finding of fact that Kahtnu's proposed service area was the entire Kenai Peninsula Borough was supported by substantial evidence.

Kahtnu believes it defined the "proposed service area" in its application as the Northern Kenai Peninsula. The Commissioner upheld the CON staff's factual determination that the only service area for which the application provided sufficient information to determine whether a need existed was the entire Kenai Peninsula Borough. Thus, whether a need existed was calculated by the CON staff using the entire Kenai Peninsula Borough as the proposed service area.

Questions of fact are reviewed for substantial evidence.³ Where there is conflicting evidence on the record we generally defer to the judgment of the agency.⁴

In order for HSS to perform the necessary calculation and determine whether a need exists population data for a proposed service area must be provided. Question four of the CON application requires the applicant to "identify the target population to be served" by the proposed project. It defines

³ *North Star Hosp.*, 280 P.3d at 579.

⁴ *Morris v. State, Dept. of Admin., Div. of Motor Vehicles*, 186 P.3d 575, 577 (Alaska 2008).

target population as “the population that is or may reasonably be expected to be served by a specific service at a particular site.” In answering this question applicants are instructed to “explain whether this is a local program, or a program that serves a population outside of the proposed service area” and to “use the most recent Alaska Department of Labor and Workforce Development statistics for population data and projections.” Applicants are given four examples of ways in which population may be defined and allows population to be “defined in one or more ways.” If the proposed population varies from the population projected by the Department of Labor (DOL), the applicant must “explain and document any variances from [the DOL] projections.” In response to this question Kahtnu submitted population statistics from the DOL for the entire Kenai Peninsula Borough, as well as 2010 Census information for the Kenai Peninsula Borough and several cities on the peninsula.⁵ No explanation or narrative regarding these documents was provided.

In response to question six on the application Kahtnu performed a need calculation using the population projections for the entire peninsula, which contains two hospitals with surgical facilities, but only the surgery rooms located at Central Peninsula Hospital. This created an inflated estimation of the anticipated need for additional surgical facilities and was not consistent with HSS’s mandatory calculation methodology. Although at certain points in its application Kahtnu identified the Central Peninsula Hospital as the “only

⁵ Kenai City, Soldotna City, Kalifornsky CDP, Nikiski CDP, Sterling CDP, and Salamatof CDP.

hospital in the proposed service area,” suggesting a service area smaller than the entire peninsula,⁶ in other places it referenced the Kenai Peninsula as a whole. Because the only complete population statistics which were provided were for the entire peninsula but the only data regarding available facilities was limited to those at Central Peninsula Hospital, when HSS performed its own need calculation it had to rely on the usage data it collected under its mandatory reporting regulations to determine how many surgery rooms already existed and their current rate of usage.

Kahtnu argues that HSS’s application and regulations prevented it from providing any data other than DOL data for the entire peninsula, since the DOL does not provide population information for a smaller area, such as the Northern Kenai Peninsula. However, question four on the application invites explanation for any variance from the DOL data. It was Kahtnu’s decision not to provide any additional explanation regarding its proposed service area and the population in that area.

There was substantial evidence to support the determination that the appropriate service area for calculating whether need exists for Kahtnu’s proposed surgery center was the entire Kenai Peninsula Borough. Upon reviewing Kahtnu’s application, the CON staff found that the application failed to sufficiently identify and analyze *any* proposed service area. The only area for which sufficient population data was provided to perform the necessary need

⁶ South Peninsula Hospital contains two operating rooms and is located in Homer.

calculation was for the entire Kenai Peninsula Borough. After holding an administrative review hearing and reviewing the evidence before the CON staff when they made their recommendation, the ALJ found that the staff was correct in using the entire Kenai Peninsula Borough to perform its need calculation. Where, as here, there is conflicting evidence as to what the proposed service area was intended to be, we will defer to the agencies' determination of this factual issue.

It was reasonable and not arbitrary for HSS to not use its regulatory ability to get additional information from an applicant during the application process to obtain the necessary data to determine what Kahtnu's "proposed service area" was.

Kahtnu also argues HSS should have used its ability to get additional information from an applicant to obtain additional data directly from Kahtnu before it made the factual determination as to what the "proposed service area" was.

There are two regulations which permit HSS to reach out to an applicant during the Certificate of Need process if they need additional information: 7 AAC 07.050(b) and (c) and 7 AAC 07.067(b). 7 AAC 07.050 requires the agency to review a Certificate of Need application for completeness and, if additional information is necessary for the department to complete its review, the agency must inform the applicant and the applicant must submit the additional information or their application will be summarily denied. 7 AAC 07.067

prohibits an applicant (or any other third parties) from contacting the agency regarding an application after it has been closed for public comment. Section (b) of this regulation allows the department to contact the applicant "if necessary to obtain clarification, data, or expert information" even after the applicant can no longer reach out to the agency. In this instance, the agency did not request additional information regarding the proposed service area at either stage.

Questions of the application of an agency's own regulations are reviewed to determine whether they were reasonable and not arbitrary.⁷

Completeness is not defined in the regulations. However, it is reasonable to assume an application is complete once all of the required questions have been answered and any necessary documentation has been provided. When the CON staff deemed Kahtnu's application complete, all of the questions had been answered. Nothing more is required under 7 AAC 07.050.⁸

Under 7 AAC 07.042 HSS is required to post public notices once an application is received and then again after the application is determined to be complete. In these notices, which are issued before final review of the application by the agency, the CON staff defined Kahtnu's proposed service area as the Northern Kenai Peninsula. However, once the staff performed a final review of Kahtnu's application, they determined that it was unclear what the proposed service area was based upon the information provided in the

⁷ *North Star Hosp.*, 280 P.3d at 579.

⁸ If an application were denied because a question had been left blank and the applicant were not given an opportunity to rectify the situation before the denial were issued this would violate 7 AAC 07.050.

application and that the only area for which sufficient information had been provided to perform a need calculation was the entire Kenai Peninsula Borough. Because the information provided in Kahtnu's application was inconsistent, the staff had to review information outside of the application to determine whether a need existed for the proposed facility. Whether this information came from the applicant or from other sources available to HSS was within the discretion of the agency.

Although the 7 AAC 07.067 permits CON staff to gather additional information from an applicant, it does not require them to do so. Nor is it unreasonable for the CON staff to rely on HSS's own data regarding existing facilities, rather than demand further information and explanation from an applicant when the relevant information is within the agency's control.

While it is somewhat concerning that an applicant may never receive notice as to deficiencies in the information it provided in its application before that application is denied, ultimately the burden is on the applicant to provide sufficient information illustrating a need using the mandatory methodology. The only burden on HSS is to uphold its statutory obligation under AS § 18.07.041 to determine whether a need exists.

7 AAC 07.025(c), which precludes HSS from waiving its methodology in determining whether to issue a Certificate of Need, is consistent with and reasonably necessary to implement the authorizing statutes under which CONs are issued (AS § 18.07.041 and AS § 18.07.101).

Finally, Kahtnu argues that the methodology used by HSS to determine need is not the best available methodology and may result in denial of CON applications where actual need is demonstrated through other methodologies. It believes the regulation banning waiver of the established methodologies is contrary to HSS's statutory obligation to determine if need exists.

The question of whether a regulation is consistent with a statute is a question of law to which we apply our independent judgment.⁹ The question of whether the regulation is necessary to implement the statute is a policy decision to which we apply rational basis review.¹⁰ When there is no contention that an administrative agency failed to comply with the Administrative Procedure Act in promulgating a challenged regulation we presume that the regulation is valid and place the burden of proving otherwise on the challenging party.¹¹ We will uphold the regulation as long as it is "consistent with and reasonably necessary to implement the statute authorizing its adoption."¹²

AS § 18.07.041 directs HSS to determine if "the availability and quality of existing health care resources or the accessibility to those resources is less than the current or projected requirement for health services required to maintain the good health of the citizens of the state." Under AS § 18.07.101 the Commissioner of HSS is directed to adopt regulations establishing procedures governing the CON process. 7 AAC 07.025 adopts standard and methodologies which must be

⁹ *Grunert v. State*, 109 P.3d 924, 928-29 (Alaska 2005).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

complied with by the CON staff in determining whether a need exists. Methodologies are specific mathematical formulas for calculating whether a projected need exists, whereas standards pertain to the information and showings an applicant must include in its application. Although an applicant may request a waiver of a standard, under 7 AAC 07.025(c) methodologies may not be waived.

In its initial application and throughout its appeal Kahtnu has sought a waiver of the methodology used to determine whether an additional surgery center is necessary. It asserts that trend analysis more accurately portrays the need that will exist in the Northern Kenai Peninsula five years after its proposed project has been completed. The argument that trend analysis is better in this particular case was waived when the parties stipulated to review upon the record in front of the ALJ. The only question still before the court is whether HSS's determination, as illustrated through the adoption of 7 AAC 07.025, that consistently applying the same method to determine need rather than individually analyzing each application based upon varying calculation methods is consistent with HSS's statutory directive to adopt regulations which are intended to determine whether need exists.

The proper formula for predicting future need is a policy determination which, so long as not arbitrary and unnecessary, is within the agency's discretion. The regulation prohibiting waiver of methodology was implemented expressly to prevent arbitrary determinations regarding whether need exists.

Although there may be factual instances in which HSS's adopted methodologies fail to predict Alaska's health care needs, this is not that case. The value of consistency and predictability in determining need is clear. The regulations adopted by HSS establishing its need calculation methodologies and refusing to waive them are rational and consistent with HSS's statutory directive to determine need.

Conclusion

HSS's denial of Kahtnu's Certificate of Need is AFFIRMED.

DATED at Anchorage, Alaska this 18th day of June, 2014.



Paul E. Olson
Superior Court Judge

I certify that on 6/19/14 a copy
of the above document is being sent following at
their addresses of record (for names not on agency)

S. Rose, K. Vogel

[Redacted Name]
Administrative Assistant