REVIEW OF CENTRAL PENINSULA HOSPITAL CERTIFICATE OF NEED APPLICATION CONSTRUCTION OF A SPECIALTY CLINICS BUILDING

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BACKGROUND

The applicant for this Certificate of Need (CON) is Central Peninsula Hospital (CPH). CPH is a 49-bed acute care hospital that was opened in 1971. See *CON Application* at 19. It is owned by the Kenai Peninsula Borough and operated by Central Peninsula General Hospital, Inc. a 501 (c)(3) non-profit. *Id*.

CPH's primary service area consists of 9,126 square miles of the 25,600 square-mile Kenai Peninsula Borough. *Id.* at 17. As of 2012, the primary service area had an estimated population of approximately 36,700 residents. *Id.* at 30. CPH is the only hospital in the primary service area and is the largest hospital on the Kenai Peninsula. *Id.* at 41. CPH's services include "a 60-bed skilled nursing facility and numerous other key service lines . . . (e.g., primary care, emergency, obstetrics, pediatrics, psychiatry, ENT, urology, surgical pediatric dentistry, residential substance abuse treatment, medical/surgical unit, intensive care unit, wound care, cardiac rehabilitation, and many community wellness programs)." *Id.*

CPH submitted an application for CON in July 2013 for a three-story Specialty Clinics Building (SCB) in Soldotna in the Kenai Borough of Alaska. No other entity has submitted a letter of intent or CON application for concurrent review to construct a specialty clinics building in the Kenai Borough.

PROJECT DESCRIPTION

CPH's proposed project consists of a three-story building with 73,120 gross square feet of new construction. See *CON Application* at 6. This building will connect to the existing radiation oncology facility and the hospital, and will predominately house specialty clinics. *Id*. This plan affects the following services:

MRI	adds a new MRI 3.0 Tesla
PET/CT	adds new PET/CT machine
Endoscopy	adds two endoscopy rooms with two general anesthesia machines, platform scopes, and a C-arm
Oncology	adds 6 new infusion stations, replaces 6 existing infusion stations
Specialty Clinics	replaces[1] 6 existing clinics: spine, pain management, neurology, orthopedics, podiatry, general surgery
Clinical Space	adds 3 clinic spaces[2], some of which will be leased space

[1] Note: pg. 6 of the CON Application specifies that there is a replacement of 6 existing clinics, but pg. 12 of the application indicates that CPH is proposing the "relocation/*expansion*" of the 6 existing clinics (emphasis added).

[2] Note: pg. 6 and 12 of the CON Application specify that there is an addition of 3 clinic spaces, some of which will be leased space. However, pg. 12 and 13 indicate that the 2nd floor of the building will include 1 leased space and the 3rd floor will include 4 additional, undetermined clinic spaces that will include leased space. Therefore, the number of spaces being added for clinics is unclear.

Rehab. Space replaces space for supporting physical therapy and occupational therapy

CPH states that no services are being replaced with a different service (i.e. eliminated) or reduced. *Id*. However, it should be noted that at a minimum, with the ambiguity associated with the proposed space for clinics (i.e. See *CON Application* at 13: "four additional, undetermined clinics . . . will likely be a combination of leased and hospital-owned clinics"), there will likely be an addition or expansion of other services.

The estimated total project cost is $39,463,363:	$26,665,674	general construction
	$7,857,380	equipment
	$4,940,309	other costs, i.e. administrative costs, consultants, permit fees

If granted a CON, CPH plans for the SCB to be completed in December 2015, and operational in January 2016. *Id*. at 64.

REVIEW

Per its application, CPH states that there are services provided by this project that do not require a CON. See *CON Application* at 16. This references the fact that imaging services within the project (i.e. the proposed MRI and PET/CT) are the only services that have service-specific review standards under the "Alaska Certificate of Need Review Standards and Methodologies", which is adopted by reference in 7 AAC 07.025(a)(3).

CPH is a licensed health care facility under AS 18.07.111(8), and the proposed project consists of an "expenditure" that is over the $1.45 million threshold for "construction" of a health care facility.[3] Although the proposed imaging services within the project are the only services with service-specific review standards, given that the project as a whole is the "expenditure" that exceeds $1.45 million, and given that CPH is applying for a CON for the project as a whole, the project must be reviewed in its entirety, not just by the proposed imaging services that have service-specific review standards.

To perform this review, the entire project will first be subject to the General Review Standards. Then, "[a]fter determining whether an applicant has met the general review standards in Section I of this document, the department will apply the . . . service specific review standards in its evaluation of an application for a certificate of need for magnetic resonance imaging [and for Positron Emission Tomography]." *Alaska Certificate of Need Review Standards and Methodologies* at 23-24.

In order to perform the analysis of the project under some of the General Review Standards, it may be necessary to evaluate each individual service that is incorporated into the project.

[3] Per AS 18.07.111(6), "construction" includes the extension or modification of a health care facility.

General Review Standards

General Review Standard #1- Documented Need:

The applicant documents need for the project by the population served, or to be served, including, but not limited to, the needs of rural populations in areas having distinct or unique geographic, socioeconomic, cultural, transportation, and other barriers to care.

This first general review standard requires an analysis to determine whether the applicant "documents need for the project by the population served, or to be served[.]" In order to determine whether there is a documented need for this project, it is necessary to evaluate each service that is incorporated into the project. The following service areas will be reviewed: MRI, PET/CT, endoscopy, oncology, specialty clinics (general clinical space), specialty clinics (consolidation of existing clinics), and rehabilitation space.

MRI

Per its application, CPH is proposing the addition of a second MRI that would be housed in the SCB. The proposed MRI is a Siemens Magnetom Skyra 3T Open Bore MR with Tim 4G + DOT system. Per the CON application, "This 3T MRI will provide a convenient service to patients by complementing adjacent service lines[.]" *CON Application* at 11.

Although a new MRI of this caliber will purportedly improve image quality, reduce scan times, and enhance patient experiences, the issue proposed under the first general review standard is whether there is a documented need for the project by the population served. The application does not directly address the concept of need in this context. Rather, it mainly focuses on the benefits of adding new technology. For example, CPH contends that the "entire project is predicated on the belief that whenever possible, high quality care should be offered as close to home as possible." *Id*. at 37. While this mission is absolutely commendable, it fails to address whether there is an actual, documented need for the project by the population served, or to be served.

CPH does make some arguments concerning documented need. For example, CPH points out that "there is another MRI in the area, but it is obviously limited to outpatient care only and with weekday daytime hours." *Id*. at 40. CPH further asserts that this "project significantly lowers the cost of receiving such services [i.e. MRI providing 3T resolution] for the consumer, as patients will not be required to travel to Anchorage for such services." *Id*. at 42.

Again, while these positions are persuasive in many respects, they are not predicated on a strong documentation of need. This is especially apparent when CPH addresses the excess capacity in imaging services that will result from the proposed MRI. In its section on "Context of proposed project in long range planning," CPH essentially attempts to established need for the proposed MRI using uncertain predictions: "Additional MRI and other imaging services *will likely be required*, as the population demands increase over time"; "*Future* projects that will act as a *catalyst* for increased capacity . . . ." *Id*. at 16 (emphasis added).

Recommendation: The proposed project, as it relates to the proposed MRI, does not meet General Review Standard #1.

PET/CT

Per its application, CPH is proposing the addition of a new Positron Emission Tomography (PET)/CT machine. The proposed equipment is a Siemens Biograph MCT 20 Excel. See *CON Application* at 6.

Similar to the analysis above concerning the proposed MRI, the application appears to not directly address the concept of need. CPH specifies that "its motivation stems from [its] mission as a community hospital and a desire for ill patients to receive care closer to home." *Id.* at 24. Again, this is a very commendable mission. However, the issue under review concerns documented need, not motivation or interest, and CPH seems to miss this with respect to the proposed PET/CT machine: "we recognize that there may be logistical or business reasons for ultimately not deciding to install PET . . . ." *Id.*

Again, CPH provides strong support for why new technology and services could benefit its service area: "With the completion of the Radiation Oncology Center in July of 2013, the medically served population is in need of a PET/CT unit, which will enhance the services provided for those receiving cancer treatments." *Id*. at 16. However, this support does not demonstrate a documented need for the PET/CT services.

CPH does assert that there is a documented need by virtue of the fact that there is no PET/CT machine on the Kenai Peninsula. It supports this with the position that the proposed PET/CT machine will reduce the cost of receiving these services by eliminating significant travel costs. However, absence of a service in this context is not enough to demonstrate a documented need for that service, especially when the only barrier to access is the need to travel to Anchorage.

CPH proposes an alternative request in the event that its application for a PET/CT machine is denied. Specifically, if there is a denial, CPH "will seek to expand our existing CT service by adding a second CT scanner." *Id*. at 24. This alternative is supported by a purported need that arises from the fact that although there is another CT in the area, access is currently limited by hours of operation and service to outpatient populations only. *Id* at 40.

Again, while there may be a purported need for a PET/CT machine or a second CT machine to supplement CPH's newly built cancer center, and while CPH offers some persuasive positions, the positions are not predicated on a strong documentation of need for the project by the population served or to be served.

Recommendation: The proposed project, as it relates to the proposed PET/CT and/or CT, does not meet General Review Standard #1.

Endoscopy

Per its application, CPH currently operates one general procedure room that is used for endoscopy, pain management, and other noninvasive procedures. It is proposing the addition of a two more "endoscopy or procedure suites." *CON Application* at 11. "The endoscopy/procedure suites will be utilized for such procedures . . . and other simple minor procedures requiring conscious sedation." *Id*. at 12.

In its description of this component of the project, CPH asserts that the two additional endoscopy or procedure suites will reduce pressure on the preoperative and recovery space for existing operating rooms. See *Id*. at 6. More specifically, these suites will be "*enhancing* CPH's capacity for meeting current and future endoscopy suite procedure demands." *Id*. at 12 (emphasis added).

"Enhancing" the ability to meet demand is not an adequate demonstration of a documented need for the project, and the application does not go much further in offering support for this expansion. It should be noted that the proposal specifically calls for two anesthesia machines in this component of the project. The need for these types of machines in this context does not appear to make sense for two reasons. First, the application references procedures that will be provided in these suites. In listing the procedures that will be provided, the application qualifies these procedures in the same category as other "simple minor procedures" that require "conscious sedation." *Id*. at 12.

Second, a basic web search on endoscopy procedures through WebMD yielded the following results: "For most examinations with an endoscope, a sedative is provided . . . General anesthesia (puts you totally asleep for a period of time) is given in *only very special circumstances*." *WebMD*[4] (emphasis added). Given that that the application specifically references conscious sedation and given that a mainstream authority identifies the rarity of using general anesthesia in these types of procedures, calling for two anesthesia machines for "two endoscopy suites" does not support CPH's attempt at documenting need.

It should also be noted that some of the public comments were directed at this component of the application and the two anesthesia machines. Some commenters asserted that approving the expansion of two endoscopy or procedure suites with two anesthesia machines will actually result in the conversion of these spaces into ambulatory surgery suites without CON approval.

<u>Recommendation: The proposed project, as it relates to the proposed addition of two endoscopy or procedure suites does not meet General Review Standard #1.</u>

Oncology

Per its application, CPH is proposing to include a 7,287 square foot oncology/ infusion center. See *CON Application* at 12. The center will include 12 infusion stations, 3 private rooms, a procedure room, and a centralized pharmacy workroom. *Id*. This specifically entails replacing 6 infusion stations and adding 6 new infusion stations. *Id.* at 6.

[4] http://www.webmd.com/digestive-disorders/digestive-diseases-endoscopy

The application indicates that a "major driving force of this project is to combine all cancer related services into a single location, making navigation through the system easier and less stressful." *Id*. at 12. This is a result of CPH's "evidence based planning" that uses community health needs assessments (CHNA). *Id*. at 59. "Cancer Care has consistently been the number one identified need in the last three CHNA surveys conducted. In the most recent CHNA, 71% of respondents placed cancer care as the number one need in the community. The proposed project (*sic*) will address this need." *Id.* at 20.

Given that there is documentation of the served public's perception that more cancer services are needed in the community, and given that the project further develops existing oncology services at CPH, CPH has adequately demonstrated a documented need for this component of the project for the population that is served or to be served.

Recommendation: The proposed project, as it relates to the proposed oncology services, does meet General Review Standard #1.

Existing Specialty Clinics

Per its application, CPH is proposing the "relocation/expansion" of six existing clinics. The clinics are pain management, neurology, orthopedics, podiatry, general surgery, and spine. See *CON Application* at 12. It is unclear as to whether this is a pure relocation of services for purposes of consolidating service delivery into a single location or whether it is a relocation with an expansion of services. The summary on page 6 of the application indicates that the proposal is to "Replace existing 6 clinics", but page 12 indicates that "CPH is proposing the *relocation/expansion* of five existing clinics owned or being developed by the hospital . . . and one existing leased clinic[.]" (emphasis added).

The application indicates that "CPH has transitioned to more of a regional medical center setting where services are and specialties have expanded." *Id*. at 38. This appears to be in response to "increased pressure to avoid costly inpatient care and replace it with lower cost outpatient and preventative care." *Id*. at 53. Accordingly, the proposed project "shifts CPH's focus from an inpatient/surgical facility to having a 73,000 square foot building solely dedicated to outpatient care." *Id*.

Currently, CPH uses office space that is both adjacent to its campus and off campus. *Id*. at 38. CPH indicates that these spaces are at 100% capacity and that additional acquisitions "would further fragment hospital operations and result in poorly coordinated patient care and ongoing operational inefficiencies." *Id*. at 39.

Given that the actual need for these services has already been addressed in some fashion since they currently exist and CPH wishes to continue forward with them, and given that this project "will address the decade old space issues" for the facility, CPH has adequately demonstrated a documented need for this component of the project for the population that is served or to be served. *Id*. at 39.

Recommendation: The proposed project, as it relates to the 6 existing specialty clinics, does meet General Review Standard #1.

Undesignated Clinical Space

Per its application, CPH is proposing the addition of space for at least 3 more clinics, some of which will be space for lease. See *CON Application* at 12. As explained in an earlier footnote, it is unclear as to exactly how many additional clinics will fill the proposed space. Some parts of the application indicate 3 undesignated clinical spaces, while other parts indicate "four additional, undetermined clinics." *Id*. at 13.

This portion of the project contains several unknowns. The application indicates that the undetermined clinics will likely be "a combination of leased and hospital-owned clinics." *Id*. It also provides some insight on possible and anticipated future clinics.

Since this portion of the project concerns clinics, the documented need draws from the rationale in the analysis above on the existing clinics. If a CON is approved and the project proceeds, it would be unreasonable to not consider the need of other clinical services in the future and the space that would be required to house those services. Without additional, undesignated space, if CPH were to "address the unmet needs of local residents" in the future, it would be forced to acquire outside space, which would result in fragmented services that could result in poorly coordinated patient care. *Id*. at 15.

Given the documented need for the existing clinics, there is a natural documented need for additional, undesignated space for future clinics.

Recommendation: The proposed project, as it relates to the undesignated clinical space, does meet General Review Standard #1.

Rehabilitation Space

Per its application, CPH is proposing the replacement of the facility's rehabilitation space. See *CON Application* at 6. CPH is specifically proposing space for physical and occupational therapy, which will include a 621 square foot gym and 5 treatment rooms. *Id*. at 13.

The application indicates that "[d]emands placed on rehabilitation services are projected to increase." *Id*. at 13. It also indicates that CPH anticipates an increased emphasis on rehabilitation services. Given that the actual need for these services has already been addressed in some fashion since they currently exist and CPH wishes to continue forward with them, and given the projected increase in demand, CPH has adequately demonstrated a documented need for this component of the project.

Recommendation: The proposed project, as it relates to the rehabilitation space, does meet General Review Standard #1.

General Review Standard #2 – Relationship to Applicable Plans:

The applicant demonstrates that the project, including the applicant's long-range development plans, augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery. A demonstration under this standard should show that the applicant has checked with the department regarding any relevant state plan, with appropriate federal agencies for relevant federal plans, and with appropriate communities regarding community or regional plans.

Per its CON application, CPH has demonstrated that it performed due diligence on and considered planning at the local, state, and federal levels. At the local level, the "proposed project was spawned from a comprehensive process which included community health needs assessments, strategic planning, an open community process, and master site planning." *CON Application* at 59.

Additionally, CPH reviewed relevant state plans and is active at the federal level. *Id.* "The proposed project is not at variance with any known state, regional or local plans or guidelines[.]" *Id.*

Recommendation: The proposed project does meet General Review Standard #2.

General Review Standard #3 – Stakeholder Participation:

The applicant demonstrates evidence of stakeholder participation in planning for the project and in the design and execution of services.

Per its CON application, CPH has demonstrated evidence of stakeholder participation in planning for the project and in the design and execution of services. There appears to have been extensive stakeholder participation for the proposed project. Examples of such participation include involvement from the Hospital Nonprofit Operating Board, members of the medical staff, the elected Hospital Service Area Board, and the Kenai Peninsula Borough Mayor. See *CON Application* at 59-60. Perhaps most importantly, "The plans to move forward were unanimously approved by multiple boards, work groups, committees and ultimately the local Kenai Peninsula Borough (KPB) Assembly." *Id.* at 21.

Recommendation: The proposed project does meet General Review Standard #3.

General Review Standard #4 – Alternatives Considered:

The applicant demonstrates that CPH have assessed alternative methods of providing the proposed services and demonstrates that the proposed services are the most suitable approach.

Per its CON application, CPH has demonstrated that it assessed alternative methods of providing the proposed services and that it is pursuing the most suitable approach. CPH specifically assessed methods that range from "doing nothing" to "acquiring and leasing properties in multiple locations." *CON Application* at 60. CPH asserts that its current model for service delivery is somewhat fragmented. Therefore, "doing nothing" as an alternative will adversely affect delivery of some of the proposed services. "Collaboration under the current scenario is difficult at best and inefficient at worst." *Id.* at 60. Similarly, acquiring more leases in off-campus locations would further fragment the current service delivery system. "The alternative

result of CPH acquiring and facilities leasing space has led to an inefficient and muddled delivery system for both patients and specialty physicians." *Id.*

Given the consequences identified by CPH under the alternative methods, its proposal to consolidate its service delivery system appears to be the most suitable approach.

Recommendation: The proposed project does meet General Review Standard #4.

General Review Standard #5 – Impact on the Existing System:

The applicant briefly describes 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.

Per its CON application, CPH did not adequately describe the anticipated impact of its proposed project as a whole. For instance, it adequately described the impact of some of the services that are part of the project, but failed to do so with others.

CPH's impact assessment for the proposed PET/CT machine is adequate because there are no "scanners located in the primary or secondary service area for CPH and therefore there is no anticipated impact to existing facilities." *CON Application* at 61. However, CPH provides little to no detail in its impact assessment for an additional MRI or CT machine. More specifically, it acknowledges that there is an independent diagnostic testing facility (IDTF) offering these services a mile away, but it simply states that it is unable to properly determine impact since it "has no direct knowledge or information regarding this facility other than services advertised." *Id.*

CPH also provides no detail as to the anticipated impact of the "relocation/*expansion*" of its specialty clinics. *Id*. at 12 (emphasis added). Rather, it states that "there are no anticipated impacts on existing local health care facilities as defined in AS 18.07.111 (8)." *Id.* at 61. While AS 18.07.111(8) defines the meaning of "health care facility" in the context of a CON, the specialty clinic services are part of a project that, in its entirety, is subject to CON requirements. Therefore, a more thorough impact analysis should have been performed to assess how the relocation/expansion of the specialty clinics will affect existing health care systems within CPH's service area.

Recommendation: The proposed project does not meet General Review Standard #5.

General Review Standard #6 – Access:

The applicant demonstrates that the project's location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services. This includes the relocation of existing services or facilities.

Per its CON application, CPH has demonstrated that the project's location is accessible. For example, all facilities at CPH are in compliance with the American's with Disabilities Act. See *CON Application* at 62. Moreover, "access for all patients will be improved due to the collocation of existing services and clinics onto the campus. This will provide patients the ability address there clinical and ancillary needs in one location." *Id.*

Recommendation: The proposed project does meet General Review Standard #6.

Service-Specific Review Standards: Diagnostic Imaging Services

After determining whether a project has met the general review standards, the department must apply service-specific review standards for services designated in the *Alaska Certificate of Need Review Standards and Methodologies*. For purposes of this CPH's application, only the proposed MRI, PET/CT, and CT services require this additional review.

Magnetic Resonance Imaging (MRI)

Per its application, CPH is proposing the addition of a second MRI that would be housed in the SCB. The proposed MRI is a Siemens Magnetom Skyra 3T Open Bore MR with Tim 4G + DOT system. "This 3T MRI will provide a convenient service to patients by complementing adjacent service lines[.]" *CON Application* at 11. MRI services are subject to 3 review standards, as applicable.

1. Except as provided in Review Standard 2, an applicant who seeks to establish an MRI service demonstrates the ability to provide a minimum of 3,000 MRI scans per year by the end of the third operational year, dating from the initiation of the service.

CPH asserts that both this review standard and the next review standard do not apply because they "pertain to applicants who 'seek to establish an MRI service.' These two standards do not apply, as CPH has an existing MRI service." *CON Application* at 23. While CPH is correct that it has an existing MRI service, its assertion that this standard does not apply is incorrect because it is in fact seeking to establish an MRI service through a proposed second MRI. Since CPH is seeking to establish an MRI service through the proposed MRI, and since it did not demonstrate the ability to provide a minimum of 3,000 MRI scans per year by the end of the third operational year of the proposed MRI, it has not met this review standard.

Recommendation: The proposed project, as it relates to the MRI, does not meet this service-specific review standard.

2. An applicant who seeks to establish an MRI service in a community with a population of 10,000 or less demonstrates the ability to provide a minimum of 1,000 MRI scans per year by the end of the third year, dating from the initiation of the service. (Based on the estimate of a minimum of 2,500 scans/70,000 people, it is estimated that the minimum service area population for an MRI service to provide a minimum of 1,000 MRI scans per year would be 28,000 people.)

CPH is not seeking to establish the proposed MRI service in a community with a population of 10,000 or less. Therefore, this service-specific review standard is not applicable.

Recommendation: Since this is not applicable, this service-specific review standard should be waived under 7 AAC 07.025.

3. No MRI service will be approved at a location that is less than 30 minutes access time of an existing MRI service performing fewer than 3,000 scans per year, or of a CON-approved, but not yet operational, MRI service.

CPH indicates that its current MRI exceeds the 3000 scan threshold. However, it also recognizes the fact that there is a local independent diagnostic testing facility (IDTF) (owned by Providence Imaging Center) that is less than 30 minutes away with an upgraded 1.5T MRI machine. See *CON Application* at 23.

CPH presumes that that the scan volume at the IDTF is not near the 3000 threshold. Its presumption is correct. Given this presumption, CPH requests a waiver to this service-specific review standard according to 7 AAC 07.025(b)(1), which states: "The department will recommend to the commissioner that a review standard be waived if the applicant documents to the department's satisfaction that meeting the standard would cause a reduction in the availability, quality, or accessibility of services to the consumer in the service area[.]"

CPH asserts that meeting this standard would cause a reduction in the availability, quality, or accessibility of services to the consumer in the service area for three reasons. These reasons can be paraphrased as follows: first, this project makes available technology that does not currently exist on the Kenai Peninsula; second, this MRI machine can accommodate a larger range of patients; and third, unlike the nearby IDTF, as an acute care hospital, CPH must provide access to all patients with medical need. See *Id.* at 23.

Based on the reasons put forth by CPH, the department cannot recommend to the Commissioner that this standard be waived per 7 AAC 07.025(b)(1). The regulation is clear that there must be a satisfactory showing that meeting the standard would "cause a reduction" in the availability, quality, or accessibility of services. CPH's application indicates that the proposed MRI is a new technology that does not exist on the Kenai Peninsula. Also, the application does not state or imply that failure to approve the CON will change the way in which CPH currently delivers its imaging services. Therefore, denying a non-existent service should not "cause a reduction" in the availability, quality, or accessibility of current services.

Recommendation: The proposed project, as it relates to the MRI, does not meet this service-specific review standard. Additionally, this service-specific review standard should not be waived.

Positron Emission Tomography (PET/PET-CT)

Per its application, CPH is proposing the addition of a new Positron Emission Tomography (PET)/CT machine. The proposed equipment is a Siemens Biograph mCT 20 Excel.

1. An applicant who seeks to establish a new PET service demonstrates the ability to provide a minimum of 750 PET scans per year by the end of the third operational year, dating from the initiation of the service.

CPH anticipates that it will only perform approximately one third of the 750 annual PET scans required by the end of the third operational year. See *CON Application* at 24. Given the projected shortfall, CPH requests a waiver to this service-specific review standard. Unlike the waiver request to the MRI service-specific review standard #3, the request here does not offer any purported justification for a waiver. The application essentially stands on the following statement: "Because the existing Radiation Oncology Center already requires treatment planning CTs, CPH believes it is appropriate to request a PET/CT to address long-term needs." *Id*.

CPH has not documented, to the department's satisfaction, any showings under 7 AAC 07.025(b) that support a waiver of this review standard.

Recommendation: The proposed project, as it relates to the PET/CT, does not meet this service-specific review standard. Additionally, this service-specific review standard should not be waived.

2. No new PET scanner will be approved at a location that is less than one hour travel time of an existing PET scanner performing fewer than 750 scans per year, or of a CON-approved, but not yet operational, PET scanner.

The proposed PET/CT machine will not be at a location that is less than one hour travel time of an existing PET scanner performing fewer than 750 scans per year, or of a CON-approved PET scanner. Therefore, this service-specific review standard is not applicable.

Recommendation: Since this is not applicable, this service-specific review standard should be waived under 7 AAC 07.025.

3. In a community that produces isotopes locally, no new PET scanner will be approved in the service area unless average use of each existing PET scanner exceeds 1,300 scans per year.

The proposed PET/CT machine will not be in a community that produces isotopes locally. Additionally, there are no existing PET scanners located in the community or service area at issue. Therefore, this service-specific review standard is not applicable.

Recommendation: Since this is not applicable, this service-specific review standard should be waived under 7 AAC 07.025.

4. In a community that is dependent upon shipped isotopes, no new PET scanner will be approved in the service area unless average use of each existing PET scanner exceeds 1,000 scans per year.

There are no existing PET scanners located in the community or service area at issue. Therefore, this service-specific review standard is not applicable.

Recommendation: Since this is not applicable, this service-specific review standard should be waived under 7 AAC 07.025.

5. An applicant who seeks to expand a PET service demonstrates an average service volume of at least 1,300 PET scans annually for each PET scanner at the service site.

CPH is not seeking to expand a PET service. Therefore, this service-specific review standard is not applicable.

Recommendation: Since this is not applicable, this service-specific review standard should be waived under 7 AAC 07.025.

6. PET services must be located in the same community as, or co-located with, facilities offering comprehensive oncology, cardiovascular, and neurology services.

CPH requests a waiver to this service-specific review standard. Unlike the waiver request to the MRI service-specific review standard #3, the request here does not offer any purported justification for a waiver. Therefore, CPH has not documented, to the department's satisfaction, any showings under 7 AAC 07.025(b) that support a waiver of this review standard.

Recommendation: The proposed project, as it relates to the PET/CT, does not meet this service-specific review standard. Additionally, this service-specific review standard should not be waived.

Computed Tomography (CT)

CPH proposes an alternative request in the event that its application for a PET/CT machine is denied. Specifically, if there is a denial, CPH "will seek to expand our existing CT service by adding a second CT scanner." *CON Application* at 24.

1. An applicant who seeks to establish a new CT service in an urban area (population of 70,000 or more) demonstrates the ability to provide a minimum of 3,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

CPH asserts that of the four service-specific review standards, only standard #4 applies because the first three "relate to applicants seeking to establish a new service." *Id*. While CPH is correct that it has an existing CT service, its assertion that this standard, and standards #2 and #3, do not apply is incorrect because it is in fact seeking to establish a new CT service in an area through the addition of a new, second CT.

However, since CPH is seeking to establish a new CT service in a service area that consists of "an estimated population of approximately 36,700 residents for 2012," this service-specific review standard is not applicable. *Id.* at 30.

Recommendation: Since this is not applicable, this service-specific review standard should be waived under 7 AAC 07.025.

2. An applicant who seeks to establish a new CT service in a rural area demonstrates the ability to provide a minimum of 1,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

Since CPH is seeking to establish a new CT service in a service area with a population that is less than 70,000, and since it did not demonstrate the ability to provide a minimum of 1,000 CT scans per year by the end of the third operational year of the proposed additional CT, it has not met this review standard.

Recommendation: The proposed project, as it relates to the CT, does not meet this service-specific review standard.

3. No new CT service will be approved in a service area or at a location that is less than 30 minutes travel time of an existing CT service performing fewer than 3,000 scans per year, or of a CON-approved but not yet operational, CT service.

Per the analysis under CT service-specific review standard #1, the department believes that contrary to CPH's position, this review standard does apply to CPH since it is seeking to establish a new CT service in the service area through the addition of a CT machine. There is a local independent diagnostic testing facility (IDTF) (owned by Providence Imaging Center) that is less than 30 minutes away and that provides CT services. See *CON Application* at 23. Per the utilization data collected by the department, the IDTF is performing far fewer than 3,000 scans per year. Specifically, it performed 31 scans in 2011 and 116 scans in 2012. Accordingly, CPH has not met this review standard.

Recommendation: The proposed project, as it relates to the CT, does not meet this service-specific review standard.

4. An applicant who seeks to expand an existing CT service must demonstrate an average service volume of at least 4,000 CT scans annually for each existing CT scanner at the service site.

While CPH is proposing to establish a new CT service in an area with a new machine, this establishment of a new service in a service area also constitutes an expansion of CPH's internal, existing capacity. Therefore, this review standard requires a utilization analysis of CPH's existing CT machine to ensure that there is not excess capacity internally.

Through its application, CPH does demonstrate an average service volume of at least 4,000 CT scans annually for its existing CT scanner. "CPH crossed this threshold eight years ago, with 4,141 CT scans in FY05. This volume continued to increase, with FY12 volumes of 6,464 in our last full year completed." *Id*.

Recommendation: The proposed project, as it relates to the CT, does meet this service-specific review standard.

FINANCIAL FEASABILITY

Per its application, CPH indicates that the proposed project will be funded entirely through revenue bonds obtained from the Alaska Bond Bank and approved by the Kenai Borough Assembly. See *CON Application* at 43. The total project cost is $39,463,363. Actual operations will be funded from revenues generated by the project. CPH indicates that the revenues will also be enough to cover all interest payments required from the revenue bonds. *Id*. "CPH will be able to make bond payments without Borough tax revenue support." *Id*.

Construction Costs

a. Site acquisition	$N/A
b. Estimated general construction**	$26,665,674
c. Fixed equipment, not included in a**	$4,511,708
d. Total construction costs (sum of items a, b, and c)**	**$31,177,382**
e. Major movable equipment**	$3,345,672
f. Other cost:**	
(1) Administration expense	$380,122
(2) Site survey, soils investigation, and materials testing	$35,140
(3) Architects and engineering fees	$2,314,348
(4) Other consultation fees (preparation of application included)	$207,449
(5) Legal fees	$0
(6) Land development and landscaping	$682,500
(7) Building permits and utility assessments (including water, sewer, electrical, phones, etc.)	$740,000
(8) Additional inspection fees (clerk of the works)	$580,750
(9) Insurance (required during construction period)	$0
g. **Total project cost (sum of items d, e, f)**	**$39,463,363**
h. Amount to be financed	$39,463,363
i. Difference between 2.g and 2.h (list, as Schedule 1, available resources to be used, e.g., available cash, investments, grants funds, community contributions, etc.)	$0
j. Anticipated long-term interest rate	4.9%
k. Anticipated interim (construction) interest rate	4.9%
l. Anticipated long-term interest amount	$19,525,287
m. Anticipated interim interest amount	$3,808,309
n. **Total items g, l, and m**	**$23,333,595**
o. Estimated annual debt service requirement	$3,139,848
p. Construction cost per sq. ft.	$426
q. Construction cost per bed	$N/A
r. Project cost per sq. ft.	$540
s. Project cost per bed (if applicable)	$NA

** Items must be certified estimates from an architect or other professional. Major medical equipment may be documented by bid quotes from suppliers.

Projected Operational Budget

Projected Line Item Operational Budget FY2016-FY2020	FY16	FY17	FY18	FY19	FY20
OPERATING REVENUE					
MRI Revenue	$ 7,657,344	$ 8,076,354	$ 8,518,292	$ 8,984,413	$ 9,476,040
CT Revenue	$ 5,643,288	$ 5,986,964	$ 6,351,570	$ 6,738,381	$ 7,148,748
P.E.T./CT Revenue	$ 2,191,200	$ 2,311,102	$ 2,437,566	$ 2,570,950	$ 2,711,632
X-Ray Revenue	$ 3,300,633	$ 3,481,243	$ 3,671,737	$ 3,872,654	$ 4,084,566
Infusion Oncology Revenue	$ 1,398,068	$ 1,517,519	$ 1,647,176	$ 1,787,910	$ 1,940,670
CP-Surgical Services Clinic Revenue	$ 2,373,596	$ 2,503,479	$ 2,640,469	$ 2,784,956	$ 2,937,349
CP - Orthopedic Clinic Revenue	$ 4,008,199	$ 4,227,527	$ 4,415,314	$ 4,579,608	$ 4,733,506
CP- Neurology Clinic Revenue	$ 1,385,723	$ 1,461,550	$ 1,541,526	$ 1,625,878	$ 1,714,846
CP - Womens Health Clinic Revenue	$ 836,480	$ 882,252	$ 930,529	$ 981,448	$ 1,035,152
Physical Therapy Revenue	$ 1,567,440	$ 1,701,362	$ 1,846,726	$ 2,004,511	$ 2,175,776
Speech Therapy Revenue	$ 539,576	$ 585,677	$ 635,717	$ 690,033	$ 748,989
Endoscopy Suite Revenue	$ 6,491,871	$ 6,881,383	$ 7,294,266	$ 7,731,922	$ 8,195,838
Occupational Therapy Revenue	$ 367,637	$ 399,048	$ 433,143	$ 470,150	$ 510,320
Pharmacy	$ 8,022,561	$ 8,503,914	$ 9,014,149	$ 9,554,998	$ 10,128,298
Gross Patient Revenue	**$ 45,783,615**	**$ 48,519,376**	**$ 51,378,181**	**$ 54,377,812**	**$ 57,541,730**
ALLOWANCES & DEDUCTIONS FROM REVENUE					
Allowances & Deductions	$ 20,086,649	$ 21,282,398	$ 22,530,433	$ 23,838,697	$ 25,217,754
Charity Care	$ 1,648,210	$ 1,746,698	$ 1,849,615	$ 1,957,601	$ 2,071,502
Total Allowances & Deductions From Revenue	**$ 21,734,859**	**$ 23,029,095**	**$ 24,380,047**	**$ 25,796,299**	**$ 27,289,257**
NET PATIENT REVENUE	**$ 24,048,756**	**$ 25,490,281**	**$ 26,998,134**	**$ 28,581,514**	**$ 30,252,473**
OTHER OPERATING REVENUE					
Rent Income	$ 419,328	$ 419,328	$ 419,328	$ 419,328	$ 419,328
Cafeteria Sales	$ 332,273	$ 352,209	$ 373,342	$ 395,742	$ 419,487
Total Other Operating Revenue	**$ 751,601**	**$ 771,537**	**$ 792,670**	**$ 815,070**	**$ 838,815**
NET OPERATING REVENUE	**$ 24,800,357**	**$ 26,261,818**	**$ 27,790,804**	**$ 29,396,584**	**$ 31,091,288**
OPERATING EXPENSE					
Salaries	$ 3,289,304	$ 3,387,983	$ 3,489,622	$ 3,594,311	$ 3,702,140
Provider Salaries	$ 2,640,063	$ 2,719,265	$ 2,800,843	$ 2,884,868	$ 2,971,414
Employee Benefits	$ 1,277,198	$ 1,315,514	$ 1,354,979	$ 1,395,629	$ 1,437,498
Contract Labor	$ 91,710	$ 94,920	$ 98,242	$ 101,681	$ 105,239
Other Professional Fees	$ 20,468	$ 21,184	$ 21,926	$ 22,693	$ 23,488
Drugs & IV Solutions	$ 2,147,642	$ 2,222,809	$ 2,300,608	$ 2,381,129	$ 2,464,469
Other Supplies	$ 409,735	$ 424,076	$ 438,919	$ 454,281	$ 470,181
Utilities	$ 551,043	$ 570,330	$ 590,291	$ 610,951	$ 632,335
Repairs & Maintenance	$ 127,041	$ 131,487	$ 136,089	$ 140,852	$ 145,782
Leases & Rentals	$ 6,779	$ 7,016	$ 7,262	$ 7,516	$ 7,779
Insurance	$ 803	$ 831	$ 860	$ 890	$ 921
Interest	$ 1,745,393	$ 1,682,769	$ 1,617,078	$ 1,548,167	$ 1,475,880
Provision for Bad Debt	$ 2,147,252	$ 2,275,559	$ 2,409,637	$ 2,550,319	$ 2,698,707
Other	$ 57,908	$ 59,935	$ 62,032	$ 64,204	$ 66,451
Total Operating Expense	**$ 14,512,338**	**$ 14,913,678**	**$ 15,328,388**	**$ 15,757,491**	**$ 16,202,283**
OPERATING INCOME (LOSS)	**$ 10,288,019**	**$ 11,348,140**	**$ 12,462,416**	**$ 13,639,093**	**$ 14,889,005**
NON-OPERATING REV/EXP/DEPRECIATION					
Non-Operating Revenue & Expenses					
Non-Cash Expense - Depreciation	$ (2,822,127)	$ (2,822,127)	$ (2,822,127)	$ (2,822,127)	$ (2,822,127)
Total Non-Operating Rev/Exp/Depreciation	**$ (2,822,127)**	**$ (2,822,127)**	**$ (2,822,127)**	**$ (2,822,127)**	**$ (2,822,127)**
NET INCOME (LOSS)	**$ 7,465,892**	**$ 8,526,013**	**$ 9,640,289**	**$ 10,816,966**	**$ 12,066,878**

PUBLIC COMMENT SUMMARY

A public meeting was held in Soldotna August 16, 2013. Approximately eighteen individuals attended the meeting in person, with five providing comments. Of those in attendance, there were three private citizens, ten CPH employees, one Providence employee, one from Heritage Place, and two who did not indicate any affiliations.

Three people spoke in opposition based on their perception that the project would be creating an increase in ambulatory surgical capacity at CPH. In contrast, two people spoke in favor of the project.

A written public comment period was open from July 31, 2013 to August 30, 2013.

Thirty-three letters were received in support of the application. Eighteen of these letters were from employees of CPH and fifteen were from private citizens.

Five letters were received in opposition to the application. The letters in opposition were individually prepared (i.e. not form letters) and outlined opposition for several reasons: no need for general anesthesia machines in the proposed endoscopy rooms; unused capacity at the Providence Imaging Center for MRI and CT in Soldotna; the proposed projects will cause financial harm to the Kenai/Soldotna landlords currently renting to CPH; and, the building might result in increased taxes as a consequence of the revenue bonds used to finance the project.

Ten letters were not considered because they were received after the public comment deadline.

RECOMMENDATIONS

Overall Recommendation

The CON Program recommends that the Commissioner approve in part and deny in part CPH's application for a CON concerning its Specialty Clinics Building Project.

Approval in Part

The CON should be approved for the following project components:

- Oncology
- Specialty Clinics
- Additional, undetermined Clinical Space
- Rehabilitation Space

Rationale: These project components satisfy General Review Standards 1, 2, 3, 4, 6.

Denial in Part

The CON should be denied for the following project components:

- MRI
- PET/CT
- CT
- Endoscopy Suites

Rationale: These project components do not satisfy General Review Standards 1, 5. Additionally, the first three project components failed to satisfy nearly all of the service-specific review standards for Diagnostic Imaging Services.

Recommended Conditions

Approval of the Certificate of Need for this project as it relates to the recommended project components is conditioned on CPH submitting and the Commissioner approving a revised budget for the project.

Rationale: If CPH chooses to proceed with this project based on the limited approval, it will likely need to revise its project plans. Therefore, a revised budget will be necessary for review and approval.

APPENDIX A

I. General Review Standards Applicable to all Certificate of Need Applications

Review Standards

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:

1. The applicant documents need for the project by the population served, or to be served, including, but not limited to, the needs of rural populations in areas having distinct or unique geographic, socioeconomic, cultural, transportation, and other barriers to care.

2. The applicant demonstrates that the project, including the applicant's long-range development plans, augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery. A demonstration under this standard should show that the applicant has checked with the department regarding any relevant state plan, with appropriate federal agencies for relevant federal plans, and with appropriate communities regarding community or regional plans.

3. The applicant demonstrates evidence of stakeholder participation in planning for the project and in the design and execution of services.

4. The applicant demonstrates that CPH have assessed alternative methods of providing the proposed services and demonstrates that the proposed services are the most suitable approach.

5. The applicant briefly describes 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.

6. The applicant demonstrates that the project's location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services. This includes the relocation of existing services or facilities.

APPENDIX B

VII. Diagnostic Imaging Services: Review Standards and Methodology

The department will develop and maintain data sources for measuring utilization rates and will identify regional and national norms to use in assessing the reasonableness of applicant assertions about projected levels of service.

A. Magnetic Resonance Imaging

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards, as applicable, in its evaluation of an application for a certificate of need for magnetic resonance imaging:

1. Except as provided in Review Standard 2, an applicant who seeks to establish an MRI service demonstrates the ability to provide a minimum of 3,000 MRI scans per year by the end of the third operational year, dating from the initiation of the service.

2. An applicant who seeks to establish an MRI service in a community with a population of 10,000 or less demonstrates the ability to provide a minimum of 1,000 MRI scans per year by the end of the third year, dating from the initiation of the service. (Based on the estimate of a minimum of 2,500 scans/70,000 people, it is estimated that the minimum service area population for an MRI service to provide a minimum of 1,000 MRI scans per year would be 28,000 people.)

3. No MRI service will be approved at a location that is less than 30 minutes access time of an existing MRI service performing fewer than 3,000 scans per year, or of a CON-approved, but not yet operational, MRI service.

B. Positron Emission Tomography (including PET/PET-CT)

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for Positron Emission Tomography:

1. An applicant who seeks to establish a new PET service demonstrates the ability to provide a minimum of 750 PET scans per year by the end of the third operational year, dating from the initiation of the service.

2. No new PET scanner will be approved at a location that is less than one hour travel time of an existing PET scanner performing fewer than 750 scans per year, or of a CON-approved, but not yet operational, PET scanner.

3. In a community that produces isotopes locally, no new PET scanner will be approved in the service area unless average use of each existing PET scanner exceeds 1,300 scans per year.

4. In a community that is dependent upon shipped isotopes, no new PET scanner will be approved in the service area unless average use of each existing PET scanner exceeds 1,000 scans per year.

5. An applicant who seeks to expand a PET service demonstrates an average service volume of at least 1,300 PET scans annually for each PET scanner at the service site.

6. PET services must be located in the same community as, or co-located with, facilities offering comprehensive oncology, cardiovascular, and neurology services.

C. Computed Tomography

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for computed tomography (CT) services:

1. An applicant who seeks to establish a new CT service in an urban area (population of 70,000 or more) demonstrates the ability to provide a minimum of 3,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

2. An applicant who seeks to establish a new CT service in a rural area demonstrates the ability to provide a minimum of 1,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

3. No new CT service will be approved in a service area or at a location that is less than 30 minutes travel time of an existing CT service performing fewer than 3,000 scans per year, or of a CON-approved but not yet operational, CT service.

4. An applicant who seeks to expand an existing CT service must demonstrate an average service volume of at least 4,000 CT scans annually for each existing CT scanner at the service site.

APPENDIX C

Estimated Impact to Medicaid

THE STATE of ALASKA
GOVERNOR SEAN PARNELL

Department of Health and Social Services

OFFICE OF RATE REVIEW

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MEMORANDUM

To: Kevin Perron, CON Coordinator

From: Jared Kosin, Executive Director
Office of Rate Review

Date: September 27, 2013

Subject: Certificate of Need Review for Central Peninsula Hospital Specialty Clinics Building

Central Peninsula Hospital would like to build a new three-story (basement included) Specialty Clinics Building located adjacent to the existing hospital. This project is Phase V of Central Peninsula Hospital's master plan to expand and upgrade the facility and to accommodate cancer treatment. The building will be 73,120 gross square feet of new construction and will connect to the existing radiation oncology facility and the hospital. Expanded services include: MRI, endoscopy, oncology infusion, additional space for specialty clinics, and rehabilitation space. PET/CT will be a newly added service. There are no services that are being replaced with a different service (i.e., eliminated) or reduced. The estimated completion date is December 2015. The estimated total cost of the project is $39,463,363. The proposed project will be funded through revenue bonds sold by the Kenai Peninsula Borough.

Approval of this certificate of need would generate a Certificate of Need (CON) add-on to the Central Peninsula Hospital Medicaid inpatient per-diem rate. This add-on would be for the facility's FYs 2015-2016. Ultimately, the total cost of the project would be integrated into the FY 2015 base year for inclusion in the FY 2017 Medicaid rates. There would also be increased charges to the program for the newly available outpatient services, which would generate increased Medicaid payments. However, there would not be a change to the overall Medicaid outpatient reimbursement rate for the 2015-2016 rate years.

Although the CON add-on and future Medicaid rates cannot be determined at this time, the chart below estimates the added cost to Medicaid over the next three years. Over the life of the project, the total capital cost to Medicaid is estimated to be $5,524,871.

Estimated Medicaid Cost (*using information available in CON*)

	2015	2016	2017
Inpatient Capital	$82,971	165,941	$165,941
Inpatient Operating	-	-	$326,211
Outpatient Capital	-	-	$229,157
Outpatient Operating	-	-	$450,482
Outpatient Payments (Charges) Increase **	$647,681	$1,720,113	0
New Additional Total Cost to Medicaid (est. with CON available information)	$730,652	$1,886,054	$1,171,791

**These amounts include Capital and Operating paid through increased charges for outpatient services.

Please note, all calculations in this memorandum are estimates only and are based on the assumptions set forth in the CON application. The Department is not bound by these estimates or assumptions. Also, please note 7 AAC 07.070(i):

> ***Approval of a certificate of need does not imply any guarantee of federal, state, or private money, including Medicaid payments or grant awards, and does not imply any guarantee of profitability.***

Should you have any questions please contact Christine Goetz at 334-2476 or me at 334-2447.