

2025 Iowa Certificate of Need (CON) Application

Instructions: 1. Complete all the sections below. 2. Provide concise, evidence-based responses, with supporting documentation or data as needed. 3. Reference lowa Code 10A.714, as needed, to complete the application. 4. Upload additional documentation, as needed.

Primary Contact

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Facility Name

St. Anthony Regional Hospital and Nursing Home

Facility Address

311 S. Clark St, Carroll County, CARROLL, Iowa 51401

Project Title

St. Anthony Regional Hospital- Equipment Installation- Fixed PET/CT Scanner

1. Applicant and Facility Overview

a. Project Purpose and Objectives:

This project aims to enhance access to timely, high-quality diagnostic imaging services in West Central lowa through the acquisition and deployment of a PET/CT scanner. The primary objective is to improve early detection, diagnosis, and treatment planning for a range of conditions focusing on cancer care. In addition to expanding imaging capabilities, the PET/CT scanner will serve as a vital backup to the hospital's primary CT scanner, ensuring uninterrupted diagnostic services during periods of equipment service or repair.

The populations served by this project include rural residents, elderly individuals, people with disabilities, and medically underserved communities across the West Central lowa region. These populations often face significant barriers to care, including geographic isolation, limited transportation, and lower socioeconomic status. By bringing advanced imaging technology closer to where patients live, the project directly addresses these barriers and improves health equity across the region.

This initiative is aligned with documented community health needs, as identified through regional health assessments and provider feedback. West Central Iowa has been designated as a Health Professional Shortage Area (HPSA) and Medically Underserved Area (MUA), indicating persistent challenges in accessing comprehensive healthcare services. By enhancing local imaging capacity, this project supports earlier intervention, reduces the need for patients to travel long distances for critical diagnostics, and contributes to improved health outcomes for vulnerable and high-risk populations.

b. Relationship to Long-Range Development Plan:

The proposed PET/CT scanner aligns directly with St. Anthony Regional Hospital's long-range strategic plan, which is centered on becoming the trusted and preferred healthcare provider for the communities we serve. As part of our ongoing growth initiative, we are committed to expanding services that address the region's evolving healthcare needs—particularly in rural and underserved areas.

One of the strategic priorities outlined in our development plan is to set a path for long-term success and sustainability. The installation of a PET/CT scanner supports this objective by increasing access to advanced imaging services, especially for cancer patients in West Central Iowa. Timely access to PET/CT scans is critical for accurate diagnosis, staging, and treatment planning, and this project will significantly reduce wait times and eliminate the need for patients to travel long distances for these services.

The project also supports other key pillars of our strategic plan:

Establishing priorities and focus: By investing in essential diagnostic infrastructure, we are
prioritizing the services that have the most significant impact on patient outcomes and
community

health

- Organizational alignment: The implementation of the PET/CT scanner will cascade throughout the
 organization, aligning clinical operations, staff development, and care coordination efforts to
 maximize the unit's impact.
- Accountability and goal achievement: Clear performance metrics and leadership oversight will ensure that the project remains on track and delivers measurable improvements in service access.

efficiency, and patient care.

Overall, this project is a strategic investment in our facility's mission to meet the healthcare needs of our region while strengthening our long-term capacity to deliver high-quality, patient-centered care.

c. Description of Proposed Service/Program:

Service Type:

The proposed service is an equipment expansion project involving the installation of a PET/CT scanner at St. Anthony Regional Hospital. This advanced imaging technology will enhance our diagnostic capabilities, particularly in oncology.

Scope of the Program:

- Installation of a state-of-the-art PET/CT scanner.
- Integration into existing imaging and diagnostic workflows.
- Training for imaging and clinical staff to ensure high-quality operation and interpretation.
- Use of the PET/CT scanner as both a primary imaging modality and a backup for the existing CT scanner during downtime or service periods.

Intended Outcomes:

- Improve access to advanced imaging services for rural and medically underserved populations in West Central Iowa.
- Enable earlier and more accurate diagnosis, staging, and monitoring of cancer and other serious conditions.
- Reduce delays in care by providing local access to PET/CT services, decreasing the need for patients to travel to distant facilities.
- Increase operational efficiency and reduce service disruptions by providing critical CT backup capacity.

This service expansion supports better health outcomes by enhancing the hospital's ability to provide timely, accurate, and locally accessible diagnostic care.

d. Target Population: Specify geographic and demographic areas.

St. Anthony Regional Hospital serves as a vital healthcare provider in West Central Iowa, with a central location in Carroll County. The hospital's primary service area for cancer care extends beyond Carroll County to include 15 surrounding rural counties, forming a comprehensive regional hub for oncology and diagnostic imaging services.

Based on data from the Iowa Cancer Registry, St. Anthony provided cancer treatment to patients across this multi-county region between 2020 and 2022, reflecting established referral patterns and community reliance on the hospital's services. The estimated population within this catchment area is approximately 150,000 lives, representing a largely rural and aging demographic that faces significant barriers to timely access to advanced diagnostic services such as PET/CT imaging.

The attached Hospital Cancer Profile (January 22, 2025) provides further insight into patient origin data, cancer types treated, and service utilization, demonstrating both the reach and impact of St. Anthony's oncology services.

See attached:

By locating a permanent PET/CT scanner within this region, St. Anthony Regional Hospital is addressing a critical diagnostic gap—particularly for rural populations who would otherwise need to travel significant distances or face delays due to limited mobile unit availability. This investment directly supports faster diagnoses, more coordinated cancer care, and improved outcomes for thousands of lowans.

e. Relation to Existing Provider Network: Summarize relationship with other health care providers/services in the region.

St. Anthony Regional Cancer Center is the only provider of full-service cancer care in West Central Iowa, making it a central hub in the region's healthcare network. The center plays a critical role in coordinating care with a wide range of referring providers, including primary care physicians, specialists, and hospitals throughout the region.

The addition of a PET/CT scanner will strengthen these existing relationships by enhancing the diagnostic services available locally. Referring providers will benefit from faster access to advanced imaging, allowing for quicker diagnosis and treatment planning. This will support better continuity of care and reduce delays that often result from the need to refer patients to distant facilities for PET/CT imaging.

St. Anthony's care model emphasizes extensive coordination across services, including diagnosis, transportation, social services, nurse navigation, nutrition counseling, and spiritual support. The new imaging capabilities will integrate seamlessly into this model, improving patient outcomes and experiences by delivering comprehensive, collaborative care in one location.

By investing in this technology, St. Anthony Regional Hospital further solidifies its role as a regional healthcare leader and strengthens the collaborative provider network that supports rural and underserved populations across the area.

f. Funding Sources and Financial Resources: Identify and document sources of funding and financial viability.

St. Anthony Regional Hospital intends to support this initiative primarily through internally generated cash flow from operations. The hospital has maintained a strong financial position, enabling it to reinvest in strategic priorities that align with its mission of delivering high-quality, patient-centered care.

Funding for this initiative will be drawn from:

• Operational Cash Flow: As detailed in the attached Budget Summary, the hospital's ongoing operations generate sufficient revenue to support capital and programmatic investments without

jeopardizing financial stability.

• Potential Grants and Partnerships: While not the primary source of funding, the hospital will explore grant opportunities and public-private partnerships to supplement internal funding and enhance

long-

term viability.

• Community Fundraising: The hospital is committed to engaging the local community through targeted fundraising campaigns. These efforts not only raise financial support but also deepen community involvement and ownership in the hospital's mission.

These funding mechanisms collectively underscore the hospital's commitment to responsible financial stewardship and its ability to sustain this initiative over time.

Current # of Beds (if changing)

Current bed type (if changing)

Requested # of Beds (if changing)

Requested bed type (if changing)

Document Upload

2. Community Need and Service Gaps

a. Description of Need:

St. Anthony Regional Cancer Center continues to see increased referrals along with more chronically ill cancer patients. As our reach expands, so does the need to expand our comprehensive care options locally. Our target population will be those impacted in our 16 county geographic location. It will be those patients that are newly diagnosed with cancer, those currently being treated and those we are being followed into survivorship.

In the most recent Cancer in Iowa Report, Iowa continues to be the second highest in age-adjusted rate of new caners diagnosis and is one of only 2 states with rising age-adjusted rate of new cancers. We continue to see those increased rates being referred to our facility. The St. Anthony Regional Cancer Center directly supports these increased cancer care needs.

See Attached: https://shri.public-health.uiowa.edu/wp-content/uploads/2025/02/cancer-in-iowa-2025.pdf

b. Assessment of Existing Services and Gaps:

Currently, PET/CT imaging services in our region are provided exclusively through a mobile service, which significantly limits accessibility and availability. At St. Anthony Regional Hospital, this mobile unit is scheduled to be onsite only one day per week, with a maximum capacity of five scans per visit. The mobile truck though adequate, does not provide the environment and comfort of a fix in-house scanner.

As referrals for advanced imaging have grown—driven largely by an increasing incidence of cancer and greater demand for timely diagnostics—the current model is no longer sufficient to meet patient needs. Patients often face delays in scheduling, which can lead to postponed diagnoses and treatment plans, particularly for time-sensitive conditions like cancer.

The limited availability of PET/CT services also places strain on referring providers and care coordination efforts, as they work within tight scheduling constraints to secure appointments for their patients. Additionally, rural and medically underserved populations, who already face transportation and access challenges, are disproportionately affected by these service limitations.

This assessment highlights a clear gap in both capacity and accessibility of PET/CT services in the region. A permanent, in-house PET/CT unit at St. Anthony would address this gap by increasing availability,

reducing wait times, and improving continuity of care for patients throughout West Central Iowa.

c. Alternatives Analysis:

In evaluating how to expand PET/CT imaging services, several alternative approaches were considered. Each was assessed based on cost, feasibility, effectiveness, and ability to meet the growing needs of our patient population.

- 1. Continue Using Mobile PET/CT Services (Status Quo)
 - Cost: Lower upfront cost since services are contracted.
 - Limitations: Availability is restricted to one day per week with a maximum of five scans, creating delays in diagnosis and treatment. Growing patient volumes have exceeded this capacity, and scheduling bottlenecks limit provider flexibility and impact patient outcomes.
 - Conclusion: Not a viable long-term solution due to limited access and increasing demand.
- 2. Increase Frequency of Mobile Unit Visits
 - Cost: Slightly higher ongoing service cost without capital investment.
 - Limitations: Scheduling additional mobile visits is constrained by vendor availability and regional demand. This approach still lacks the consistency, reliability, and efficiency of an on-site,

dedicated

PET/CT unit.

- Conclusion: Temporarily helpful but not sustainable or scalable for meeting future needs.
- 3. Refer Patients to Distant Facilities
 - Cost: No capital investment required.
- Limitations: Patients face travel burdens, care delays, and fragmented care coordination. This
 approach disproportionately affects elderly, rural, and underserved populations and does not
 align

with our commitment to local, patient-centered care.

- Conclusion: Inconsistent with organizational mission and community health goals.
- 4. Acquire and Install a Permanent PET/CT Scanner (Selected Approach)
 - Cost: Higher upfront investment with long-term value and return.
 - Benefits: Increases access, improves scheduling flexibility, ensures timely diagnosis and treatment, and supports integrated, high-quality cancer care within the community. Also serves as a reliable backup for existing CT services.
 - Conclusion: Best aligns with organizational strategy, patient needs, and regional healthcare gaps.

Rationale for Selected Approach:

The installation of a permanent PET/CT unit at St. Anthony Regional Hospital represents the most effective, sustainable, and patient-centered solution to meet both current and anticipated diagnostic imaging needs. This investment enhances care coordination, reduces delays in diagnosis and treatment, and supports our mission to deliver accessible, high-quality healthcare—particularly for rural and medically underserved populations.

After a comprehensive evaluation of our long-term master campus plan and upcoming facility upgrades, it is clear that now is the optimal time to expand imaging services. Integrating a permanent PET/CT unit aligns with our strategic growth priorities and allows us to meet increasing demand while improving continuity of care.

d. Accessibility Considerations:

Access to advanced imaging services, particularly PET/CT imaging, is a significant challenge for residents of West Central Iowa and surrounding rural communities. The current reliance on a mobile PET/CT unit limits both convenience and capacity, with services only available one day per week and capped at five

scans. This limited availability often results in scheduling delays, which can be especially critical for patients requiring timely cancer diagnostics and treatment planning.

Distance and Transportation Barriers:

Many patients in our service area live 30 to 60 miles or more from the nearest alternative fixed PET/CT provider, typically located in metro areas such as Des Moines or Omaha. For elderly individuals, patients with disabilities, or those without access to reliable transportation, these distances pose a significant barrier to care. This is further complicated by the time and cost involved in arranging long-distance travel, often requiring patients to rely on family members or public transit options that are limited or unavailable in rural areas. The mobile truck does not allow patients that need a transfer lift to be accommodated and has limited space for a cart transfer.

Service Accessibility:

By installing a permanent PET/CT scanner at St. Anthony Regional Hospital, we can provide consistent, local access to this critical diagnostic service. This will:

- Eliminate long travel times for patients across West Central Iowa.
- Support same-day or next-day scheduling options.
- Ensure better continuity of care through local coordination between providers, specialists, and support services.
- Significantly reduce the care burden for medically underserved, rural, elderly, and mobility-challenged patients.

This project directly addresses the core accessibility challenges faced by the communities we serve and reinforces our commitment to equitable, high-quality care delivery across geographic and socioeconomic boundaries.

e. Community Input/Support:

Documentation attached includes:

- Letters of Support from local medical oncology providers- see attached
- Survey Data collected from patients, staff, and community members indicating strong support for cancer care initiatives in our Community Heath Needs Assessment.

https://www.stanthonyhospital.org/webres/File/legal/CHNA%20August%202022.pdf

This input has directly shaped the project's design, ensuring alignment with community priorities and increasing the likelihood of long-term success and sustainability.

Document Upload (if needed)

Letters of Support.pdf

f. Non-discriminatory Access:

St. Anthony Regional Hospital is committed to providing equitable, inclusive healthcare services to all individuals, regardless of race, ethnicity, gender, religion, age, disability, sexual orientation, insurance status, or ability to pay. The proposed PET/CT service will be fully accessible and available to all patients in need of diagnostic imaging, with no discrimination in how referrals are accepted or services delivered.

We uphold federal and state non-discrimination laws and maintain policies to ensure fair access to services for all populations, including those who are medically underserved, elderly, rural, or disabled. Interpretation services, mobility accommodations, and financial assistance programs are in place to further support equitable access.

Additionally, the PET/CT service will be available to all referring providers across the region, including both allopathic (MD), osteopathic (DO) and APP practices. St. Anthony values collaborative care and supports a

diverse provider network. Referrals from both types of practices will be accepted without preference, and we will continue to maintain open lines of communication to ensure all providers can access and coordinate imaging services for their patients.

This inclusive approach aligns with our organizational mission to improve the health of the communities we serve through compassionate, high-quality, and accessible care for all.

3. Impact on Existing Providers

a. Impact Assessment:

The addition of a permanent PET/CT scanner at St. Anthony Regional Hospital is designed to enhance—not duplicate—existing imaging services in West Central Iowa. Currently, PET/CT services are offered only through a mobile unit with extremely limited availability (one day per week, five scans) for our location and as needed at surrounding facilities. This model is inadequate for the growing demand, particularly due to the rise in cancer diagnoses and other conditions requiring advanced imaging.

Avoidance of Unnecessary Duplication

- There are no fixed-site PET/CT services currently located within St. Anthony's immediate service
 area
- Patients who cannot be scheduled through the mobile unit must be referred to facilities in metro areas such as Des Moines or Omaha, often traveling 60+ miles.
- By providing local, consistent access, this project fills a clear gap in service and does not displace or

overlap with existing services in nearby communities.

Positive Impact on Regional Provider Network

- The PET/CT scanner will support regional referring providers—including rural clinics and independent practitioners—by offering reliable, timely imaging close to their patients.
- It will improve diagnostic turnaround times and streamline care coordination, particularly for cancer patients who require multiple types of imaging and follow-up care.
- Collaboration with allopathic and osteopathic providers across the region will be maintained and strengthened.
- The addition of this unit will allow the expansion to provide PSMA PET scans for prostate cancer diagnosis. This is a new standard of care for prostate cancer staging and this patient population

is

of

our number 1 diagnosis for male patients.

No Negative Impact from Relocation

- This project does not involve relocating services from another provider or facility. Instead, it adds new permanent capacity to meet a documented and growing regional need.
- Mobile PET/CT service utilization will discontinue at St. Anthony once the fixed unit is operational, but this change will not negatively affect other facilities, as demand continues to exceed

available

capacity in the region.

Addressing Service Gaps

- This investment addresses critical access barriers for rural, elderly, and underserved populations.
- It enhances continuity of care by reducing the fragmentation that results from sending patients out

town for essential imaging services.

The installation of a fixed PET/CT scanner at St. Anthony Regional Hospital represents a strategic enhancement to the region's healthcare infrastructure. It addresses a service gap without duplicating

existing offerings, improves care coordination, and expands access without negatively impacting other providers or facilities.

b. Community and Economic Impact: Broader system effect and value-added to the community. The installation of a permanent PET/CT scanner at St. Anthony Regional Hospital will generate significant value for both the healthcare system and the broader West Central lowa community. The project goes beyond improving clinical capacity—it also contributes to economic stability, workforce development, and overall community well-being. By offering advanced imaging closer to home, patients can receive care and return to their home communities more timely.

Healthcare System Benefits

• Improved Patient Outcomes: Timely and local access to PET/CT imaging supports earlier diagnosis,

more accurate staging, and improved treatment planning, particularly for cancer patients. This can

lead to better outcomes and reduced healthcare costs over time.

 Enhanced Care Coordination: The availability of advanced imaging on-site streamlines communication between referring providers, specialists, and support services, improving efficiency

and patient experience.

 Reduced Outmigration: By offering advanced diagnostic services locally, the hospital can retain patients who might otherwise seek care in larger urban centers, helping maintain continuity of care

and trust in local providers.

Economic Impact

 Retention of Healthcare Dollars: Local access to PET/CT services means that patients and insurers

can keep healthcare spending within the community rather than transferring those dollars to urban

hospitals and providers.

• Support for Local Businesses: By reducing the need for travel to metro areas for imaging services.

patients and their families can remain in the community, supporting local businesses such as pharmacies, restaurants, gas stations, and lodging.

Community Value

• Increased Trust and Access: Community members gain confidence in their local healthcare system

when they can receive high-quality, comprehensive care close to home.

• Health Equity: By reducing access barriers for rural, elderly, and medically underserved populations,

the project supports fair and equitable care delivery throughout the region.

 Strategic Growth: This project strengthens St. Anthony's role as a regional healthcare hub, reinforcing long-term sustainability and supporting future service expansions.

The PET/CT project offers more than a clinical upgrade—it is a catalyst for broader community health and economic vitality. It supports patient-centered care, creates jobs, retains local spending, and strengthens the region's healthcare infrastructure for years to come.

c. Efficiency in Use of Resources: Shared/cooperative arrangements to maximize efficiency. St. Anthony Regional Hospital is committed to using healthcare resources efficiently through shared infrastructure, coordinated staffing, and collaborative provider engagement. The proposed PET/CT

scanner will be integrated into our existing diagnostic imaging department, allowing us to maximize operational efficiency while meeting a growing regional demand for advanced imaging.

Shared Infrastructure and Staff

- The PET/CT scanner will utilize shared clinical space, IT systems, and support services already in place within the hospital's imaging department.
- Existing radiology personnel, including technologists and radiologists, will be cross-trained to support

the new technology, and improving workforce flexibility.

 Administrative functions such as scheduling, billing, and reporting will be coordinated through current

systems, ensuring consistency and avoiding duplication.

Cooperative Use Across Providers

The PET/CT scanner will be accessible to a broad network of referring providers across the region, including both allopathic and osteopathic practices, rural clinics, and specialists. This shared access

promotes efficient utilization of the equipment and ensures a wider impact across the community.

 Coordination with the St. Anthony Regional Cancer Center allows for streamlined care planning and

imaging for oncology patients, reducing redundancy and unnecessary testing.

Strategic Backup Capability

 The PET/CT unit will also serve as a backup CT scanner when the hospital's primary CT unit is down for service or repair. This dual functionality ensures continuous imaging capacity and minimizes care disruptions without the need for costly third-party rentals or emergency transports.

By integrating the PET/CT unit into our existing imaging infrastructure, cross-utilizing staff, and opening access to regional providers, this project demonstrates a high level of resource efficiency. It maximizes value to patients and the broader health system while minimizing unnecessary costs and duplication

4. Financial and Operational Feasibility

a. Financial Projections and Feasibility:

Please see attached

Document Upload (3-year budget projections)

PET CT 3 Year Projection Final.xlsx

2026 Budget Summary - Cash Flow.pdf

b. Staffing and Operations:

The successful implementation and ongoing operation of the proposed fixed PET/CT scanner at St. Anthony Regional Hospital will rely on an efficient, integrated staffing and management plan designed to ensure patient safety, clinical quality, and operational sustainability.

Staffing Plan

The PET/CT service will be staffed by a combination of existing and newly hired personnel, including:

PET/CT Technologist(s):

Certified and licensed imaging technologists with specialized training in positron emission tomography (PET/CT), nuclear medicine and computed tomography. Initial staffing will include at least one part-time PET/CT technologist, with flexibility for additional part-time or PRN coverage based on patient volumes.

Our current nuclear medicine technologist will be cross trained also to support the service line.

Radiologist Services:

PET/CT scans will be interpreted by board-certified radiologists through our existing diagnostic imaging provider agreement with Iowa Radiology. Radiologists will have experience in nuclear medicine and advanced oncologic imaging.

Nursing Support (as needed):

Nurses staff and imaging staff trained in IV placement and patient monitoring will support patients who require advanced care needs. The close proximity of the radiology department to the ER allows for easy access to nursing staff as needed.

· Scheduling and Administrative Staff:

PET/CT scheduling will be managed through the hospital's centralized scheduling system, allowing for efficient coordination with referring providers and cancer care services. Billing and insurance preauthorization processes will be managed by existing hospital administrative teams.

Operational Structure

The PET/CT scanner will be integrated within the St. Anthony Diagnostic Imaging Department, which currently provides CT, MRI, ultrasound, mammography, and other imaging modalities. Key features of the operational structure include:

Hours of Operation:

Initially, the PET/CT unit will operate three days per week, with scheduling flexibility based on demand and patient needs.

Workflow Integration:

The PET/CT unit will be incorporated into existing clinical workflows, with seamless transitions for oncology patients who also receive services from the St. Anthony Regional Cancer Center.

Compliance & Safety:

The imaging department follows all state and federal regulations regarding radiation safety, licensure, and accreditation. The PET/CT service will comply with Nuclear Regulatory Commission (NRC) and Iowa Department of Health & Human Services (HHS) guidelines.

Management & Oversight

The PET/CT service will fall under the oversight of the Director of Radiology, with clinical input from the Director of Cancer Services and medical oversight from the Chief Radiologist. Regular interdisciplinary meetings will ensure ongoing quality assurance, operational efficiency, and responsiveness to patient and provider feedback.

Resources Required

Key resources required to support the PET/CT service include:

- Acquisition and installation of the PET/CT scanner and necessary radiopharmaceutical delivery infrastructure:
- Expansion of secured imaging suite space and shielding;
- Implementation of imaging software and integration with hospital EMR systems;
- Staff training and continuing education in PET/CT protocols and safety:
- Ongoing maintenance contracts and service support for imaging equipment.

c. Short and Long-term Viability:

The installation of a permanent PET/CT unit at St. Anthony Regional Hospital is designed to meet both immediate clinical needs and support long-term sustainability within our regional healthcare system. A thorough financial, operational, and strategic evaluation has been conducted to ensure that the service will remain viable well into the future.

Short-Term Viability

· Documented Demand:

Current utilization of the mobile PET/CT service is at or near full capacity (limited to one day/week and five scans), and demand continues to rise, particularly for oncology patients. This unmet need supports a strong immediate patient volume for a fixed unit.

Existing Referral Base:

The St. Anthony Regional Cancer Center, primary care network, and affiliated specialists across West Central lowa provide a reliable and growing stream of referrals. These relationships will continue to support scan volume from both internal and external providers.

• Efficient Integration:

The PET/CT service will be integrated into the hospital's existing imaging and oncology infrastructure, allowing for shared resources, optimized staffing, and efficient operations, which reduces start-up and operating costs.

Financial Modeling:

Conservative volume projections, payer mix analysis, and reimbursement rates have been factored into the financial planning. Based on expected scan volumes and existing referral patterns, the service is projected to cover operational costs and achieve positive margins within the first 2–3 years.

Long-Term Viability

• Rising Prevalence of Cancer and Chronic Disease:

As cancer rates and chronic conditions that require advanced imaging (e.g., neurological and cardiac diseases) continue to rise, the long-term need for PET/CT imaging will only increase.

Expanded Imaging Capabilities:

The addition of PSMA PET scans and future access to advanced tracers will expand clinical indications for PET/CT, driving long-term utilization beyond oncology alone.

Technology Lifecycle Planning:

Service contracts, preventive maintenance, and planned capital reinvestment are built into the operational budget to ensure equipment longevity and reduce unexpected costs.

Ongoing Provider Engagement:

Continued collaboration with primary care providers, specialists, and regional clinics will ensure sustained referral growth and alignment with evolving clinical needs.

Institutional Commitment:

St. Anthony Regional Hospital's strategic plan includes continued investment in diagnostic and cancer care services. The PET/CT unit supports this vision and aligns with long-term goals for regional healthcare leadership.

5. Community and Economic Impact

a. Community Engagement:

St. Anthony Regional Hospital has a strong tradition of engaging with the communities it serves to ensure healthcare services reflect local needs, values, and priorities. The planning and justification for the installation of a fixed PET/CT scanner has included meaningful community outreach and consideration of the diverse populations in West Central Iowa.

Community Outreach and Input

Listening Sessions & Town Halls:

In partnership with regional leaders, St. Anthony has participated in cancer care listening sessions—including a recent events with The Iowa Environmental Council, The Harkin Institute, and the Iowa Farmers Union on August I, 2025. There are also two upcoming listening session scheduled. One with Rep. Dr. Megan Srinivas scheduled for September 24, 2025 and the 99 Counties presentation hosted by experts for the Iowa Cancer Registry. These sessions offer opportunities for community members, providers, and patients share feedback on care access, delays in diagnosis, and the challenges of traveling long distances for imaging.

Provider & Patient Feedback:

Referring providers and specialists across the region have identified limited access to PET/CT imaging as a major barrier, especially for patients requiring timely cancer staging. Patients and families have expressed concerns about long waits and the burden of traveling outside the region for care.

Surveys & Needs Assessments:

The hospital's Community Health Needs Assessment (CHNA) and ongoing internal patient satisfaction at the time of referral highlight the importance of local access to advanced imaging services—particularly among elderly, rural, and underserved populations. Inclusion of Diverse Populations

- St. Anthony serves a broad, geographically diverse region, including rural residents who are often medically underserved due to distance, transportation barriers, and limited provider access.
- Outreach and services are designed to be inclusive of:
 - -Elderly populations, who represent a large percentage of PET/CT imaging needs.
 - -Low-income individuals and uninsured/underinsured patients, with financial assistance

available

through the hospital's charity care program.

- -Patients with disabilities, for whom travel to urban imaging centers is particularly burdensome.
- -All faith backgrounds, supported by on-site pastoral care and a culture of spiritual inclusion.

Responsiveness to Community Concerns

- The proposed PET/CT project directly addresses community-identified needs: improved access, reduced travel, timely diagnosis, and continuity of care close to home.
- The hospital has worked to ensure that the project will not duplicate services, but rather fill an identified regional service gap.
- Ongoing engagement will continue post-implementation through patient feedback, provider collaboration, and community advisory input to ensure the service remains responsive to evolving

needs.

The PET/CT project reflects the voices of our community, particularly those who have been historically underserved. Through transparent engagement and a commitment to inclusive care, St. Anthony Regional Hospital continues to prioritize the health and well-being of all individuals across our service area.

b. Resource Availability:

St. Anthony Regional Hospital is well-positioned to support the installation and operation of a permanent PET/CT scanner due to the availability of skilled personnel, experienced management, and appropriate supporting infrastructure. The hospital has conducted a thorough review of current resources and future needs to ensure sustainability and avoid misallocation

Staff Availability and Readiness

Imaging Technologists:

St. Anthony currently employs certified radiologic technologists with certifications in multiple modalities, including nuclear medicine and CT. Technologists will receive specialized training in PET/CT operations and safety protocols, with staffing plans in place for part-time and supplemental support to meet volume demands.

Radiologists:

The hospital contracts with board-certified radiologists who are experienced in interpreting PET/CT studies. These professionals are prepared to manage the increased volume and complexity of imaging associated with permanent PET/CT service.

· Clinical and Support Staff:

Nursing, patient scheduling, and registration personnel are already in place and experienced in handling imaging services. These staff will be trained on PET/CT workflows, contrast protocols, and coordination

with referring providers.

Management and Oversight

- The radiology department, under the leadership of a seasoned Director of Radiology Services, will
 oversee daily operations and ensure compliance with all regulatory, safety, and quality
 standards.
 - The Director of Cancer Services will coordinate PET/CT imaging with oncology care pathways, ensuring clinical alignment and integrated care.
- Hospital administration, including the CEO, CFO and VP of Patient Services, have reviewed and approved the PET/CT business and resource plan, confirming operational and financial feasibility.

Infrastructure and Facility Readiness

- Physical space adjacent to the imaging department has been identified and allocated for the installation of the PET/CT unit, including necessary radiation shielding, ventilation, and controlled access protocols.
- The hospital's IT infrastructure is fully capable of supporting the addition of PET/CT data, image
 archiving, and integration with the electronic medical record (EMR) system for seamless provider
 access.

Alternative Resource Considerations

- The PET/CT unit is not diverting resources from other critical services. Instead, it complements and enhances existing imaging and cancer care capacity.
- No reduction in other diagnostic imaging services is expected; shared staffing and support functions

ensure efficient use of personnel without compromising other operations.

· Without this project, the hospital would continue to rely on the limited-capacity mobile

St. Anthony Regional Hospital has the staffing, leadership, and operational infrastructure in place to successfully support this project. Resources are being responsibly and strategically allocated to ensure that the PET/CT scanner enhances—not competes with—other essential services, providing long-term value to the hospital and the region it serves.

c. Organizational Relationships:

St. Anthony has established collaborations with regional medical schools and academic institutions, facilitating access to subspecialty radiology expertise, and training opportunities. These partnerships support continuous professional development for staff and enhance diagnostic capabilities.

Formal agreements with several Health Maintenance Organizations (HMOs) and insurance providers ensure patient referral pathways and reimbursement processes are optimized to support volume growth and financial sustainability of the PET/CT service.

The hospital also engages with medical specialist including urology, ENT, neurology, pulmonology and nephology services to provide onsite regional care.

Through these comprehensive organizational relationships, St. Anthony Regional Hospital is well-positioned to maximize the clinical impact, operational efficiency, and patient access benefits of the new PET/CT scanner, ultimately improving regional cancer care and diagnostic imaging services.

6. Project Planning

a. Project Timeline:

The following timeline outlines major milestones and projected dates for full operational readiness of the initiative. The timeline is structured to ensure efficient planning, implementation, and evaluation.

Milestone Target Date
Project Planning and Internal Approvals
Final Design and Scope Definition
Procurement of Equipment/Resources
Construction/Equipment Installation Begins
Staff Training and Operational Readiness
Go-Live Date

Current- Dec 2025 December 2025 January – February 2026 January 2026-July 2026 July – August 2026 September 2026

b. Innovative Components:

The proposed project includes several innovative and value-added components that enhance diagnostic capability, improve patient outcomes, and support continuity of care:

1. PSMA PET Imaging

The addition of Prostate-Specific Membrane Antigen (PSMA) PET imaging represents a significant advancement in the detection and staging of prostate cancer. PSMA PET provides superior sensitivity and specificity compared to conventional imaging modalities, allowing for earlier and more accurate identification of metastatic or recurrent disease. This capability supports more personalized and effective treatment planning, particularly for patients with biochemical recurrence.

By offering this advanced diagnostic service locally, St. Anthony Regional Hospital eliminates the need for patients to travel long distances for specialized imaging—improving access for rural populations and reducing delays in care.

2. Backup CT Scanner

As part of the project, the hospital will establish a redundant CT capability by integrating a backup scanner. This investment ensures uninterrupted access to CT services during periods of equipment maintenance, unexpected downtime, or increased patient volume. Maintaining consistent diagnostic operations is critical for trauma care, inpatient management, and oncology services where time-sensitive imaging is essential.

c. Regulatory Compliance:

St. Anthony Regional Hospital is fully committed to meeting all applicable federal, state, and local regulatory requirements throughout the development and implementation of this initiative. The hospital has well-established internal processes for radiation safety and dedicated compliance staff to ensure full adherence to all regulations governing healthcare operations.

Key regulatory considerations include:

- Licensing and Accreditation: All services and facilities involved in the initiative will meet requirements set forth by the Iowa Department of Inspections and Appeals, Iowa Department of health and Human Services and Centers for Medicare & Medicaid Services (CMS). If the project involves new clinical services, the appropriate licensure applications and inspections will be completed in advance of the launch.
- HIPAA Compliance: The project will comply with all provisions of the Health Insurance Portability and Accountability Act (HIPAA) to safeguard patient privacy and data security, especially if health IT systems or electronic records are impacted.
- Environmental and Safety Standards: The hospital will adhere to OSHA and EPA regulations related to construction, waste disposal, and employee safety, particularly if the project includes physical infrastructure changes.
- Billing and Reimbursement: All billing practices associated with this initiative will follow current CMS guidelines, as well as applicable state Medicaid and private payer requirements.
- Staff Credentialing and Scope of Practice: Clinical staff involved in the project will be appropriately licensed, credentialed, and working within their defined scope of practice per regulations.

Compliance Approach

safety

St. Anthony Regional Hospital maintains a proactive compliance infrastructure, including:

 Radiation Safety Office (RSO) and team responsible for monitoring regulatory updates and ensuring

organizational adherence.

Regular internal audits and risk assessments to identify and correct potential compliance issues.
 St.

Anthony Regional Hospital contracts with Cardinal Health to oversee and audit our radiation

program and compliance.

- Staff training and continuing education on relevant laws, standards, and procedures.
- Ongoing communication with regulatory bodies and external legal counsel to ensure up-to-date interpretations and implementation of requirements.

This comprehensive approach ensures that all components of the initiative are designed, implemented, and managed in full compliance with applicable regulatory standards, reducing risk and ensuring patient safety.

7. Special Criteria for Specific Services:

a. Alternative Consideration (10A.714(2)(a)):

In evaluating the implementation of a fixed PET/CT scanner at St. Anthony Regional Hospital, a thorough review of practical alternatives was conducted to ensure that the chosen solution is the most effective, sustainable, and beneficial for the region's patient population. The following options were considered:

1. Continued Use of Mobile PET/CT Services (Status Quo)

Alternative Considered but Rejected

St. Anthony currently utilizes a mobile PET/CT service, which operates on a limited schedule and provides constrained access to advanced imaging. While this option involves no capital construction or equipment acquisition, it poses significant limitations, including:

- Inflexible scheduling and long wait times for patients.
- Increased patient burden due to travel and limited appointment availability.
- Inability to integrate seamlessly with oncology workflows and EMR systems.
- Operational inefficiencies due to lack of on-site control and customization.

Ultimately, this alternative was deemed inadequate to meet current and projected demand or to support the quality and timeliness of cancer care required for the hospital's growing patient population.

2. Regional Equipment-Sharing Agreements

Alternative Considered but Impractical

The hospital explored potential partnerships with nearby facilities to share PET/CT equipment; however, the rural nature of West Central lowa limits the feasibility of this option. Geographic distances, differing scheduling priorities, and incompatible systems between institutions present logistical challenges that would:

- Delay diagnostic timelines.
- Fragment care coordination.
- Fail to provide predictable or scalable access to imaging for St. Anthony's oncology program. Given these constraints and the need for continuity of care within our integrated cancer services, regional equipment sharing was not a viable solution.
- 3. Expansion or Modernization of Existing Mobile Infrastructure Alternative Considered but Insufficient

While modest upgrades to the current mobile infrastructure were considered (e.g., increasing days of service or updating mobile technology), these changes would still fall short of meeting clinical needs. Mobile units lack the physical, technological, and workflow integration required for optimal use in a comprehensive cancer center environment.

Modernization of mobile capabilities would also not resolve limitations related to patient comfort, radiation safety, or data integration with hospital systems.

4. Permanent, On-Site PET/CT Installation (Preferred Solution) Selected Option

After careful evaluation, the installation of a permanent, on-site PET/CT scanner was identified as the most appropriate and cost-effective long-term solution. It offers the following advantages:

- Immediate and consistent access to advanced imaging for patients across 16 counties.
- Seamless integration into St. Anthony's oncology, radiology, and EMR systems.
- Improved efficiency, reduced delays, and enhanced quality of care.
- Better alignment with regional cancer care priorities in light of lowa's high cancer incidence.

The hospital already has suitable space and infrastructure in place to support installation, which minimizes the scope of construction and maximizes return on investment.

All practical alternatives—including continued mobile use, resource sharing, and modernization—were thoughtfully considered. The permanent installation of a PET/CT scanner emerged as the most responsible and effective solution to meet patient needs, improve cancer care, and support the hospital's mission to deliver high-quality diagnostic services across rural lowa.

b. Utilization of Similar Facilities (10A.714(2)(b)):

St. Anthony Regional Hospital has demonstrated appropriate and efficient use of similar diagnostic imaging services, including its current mobile PET/CT service and existing in-house CT and nuclear medicine capabilities. This utilization data and operational history support the case for a permanent PET/CT unit and highlight a clear progression of patient demand, technological need, and service limitations.

1. Current Mobile PET/CT Utilization

St. Anthony has consistently maximized the capacity of its contracted mobile PET/CT service, which currently operates one day per week. Over the past three years, demand for PET/CT imaging has steadily increased, often exceeding the availability of appointment slots—leading to:

- Delayed access to time-sensitive cancer diagnostics.
- Inconvenient scheduling for patients and referring providers.
- Potential disruptions in timely oncology treatment planning.

2. Appropriate Use of In-House Imaging Services

St. Anthony's Diagnostic Imaging Department effectively manages high volumes of CT, MRI, ultrasound, and nuclear medicine studies, demonstrating a track record of efficient resource use and throughput. The department has integrated advanced scheduling tools, trained cross-functional technologists, and developed streamlined workflows to maintain high efficiency and short turnaround times for both inpatient and outpatient services.

PET/CT is currently the only advanced modality not offered in-house, creating a critical gap in continuity for cancer care and staging.

3. Lack of Accessible Alternatives in the Region

The hospital serves a 16-county rural region where alternative providers offering PET/CT are limited and located 30 to 90 miles away. Referrals to these facilities:

- Disrupt continuity of care.
- Increase travel burden for elderly and oncology patients.
- Lead to longer diagnostic timelines and potential delays in treatment initiation.

The geographic isolation and undersupply of PET/CT services in this part of lowa underscore the need for localized, on-site availability.

St. Anthony Regional Hospital has clearly demonstrated responsible, appropriate, and efficient use of both its current mobile PET/CT service and all related imaging infrastructure. Utilization trends and access limitations strongly justify the transition to a permanent, in-house PET/CT unit to meet patient needs and regional demand—enhancing access, timeliness, and quality of care for lowans.

c. Construction/Modernization (10A.714(2)(c)):

St. Anthony Regional Hospital has thoroughly considered modernization and resource-sharing alternatives as part of the planning process for the installation of a permanent PET/CT scanner, and has implemented these strategies to the fullest extent practicable. During master campus planning discussion, the integration of a permanent PET/CT scanner came to the top of the list as a way to expand services and stabilize resource availability.

1. Modernization of Existing Facilities

Rather than constructing a new building or major addition, the hospital has opted to renovate and modernize existing space next to the Radiology Department to accommodate the PET/CT unit. This approach ensures:

- Cost-effective use of existing infrastructure, including utilities, HVAC systems, and access controls.
- Minimized construction footprint, reducing disruption to other hospital operations.
 - -The mobile PET/CT scanner will continue to be used during the construction period.
- Efficient integration with adjacent imaging modalities and clinical workflows.

The designated space will meet all structural and technical requirements for PET/CT installation, including radiation shielding, ventilation, and secure access, and is being upgraded to current standards for imaging technology.

d. Access Concerns (10A.714(2)(d)):

Failure to implement a permanent PET/CT scanner at St. Anthony Regional Hospital would result in significant and ongoing access barriers to critical diagnostic imaging services for a large, rural population in West Central Iowa. These concerns directly impact timely cancer detection, treatment planning, and patient outcomes.

1. Limited Mobile Access is No Longer Sufficient

Currently, PET/CT services are provided via a mobile unit available only one day per week. This limited schedule:

- Cannot meet the increasing volume of patient demand.
- Results in long wait times for appointments—delaying critical cancer diagnoses and treatment.
- Creates scheduling bottlenecks for referring providers and oncology teams.

As cancer incidence in lowa continues to rise—placing the state 2nd nationally in new cancer diagnoses—this limited access represents a growing threat to patient care.

2. Disruption to Oncology Continuity of Care

The absence of permanent, on-site PET/CT imaging undermines the hospital's integrated oncology model. Without this technology:

- Diagnostic and treatment planning processes are fragmented.
- Patients may experience gaps in care coordination and unnecessary delays in starting treatment.
- St. Anthony's ability to deliver timely, evidence-based cancer care is compromised.

Without the proposed permanent PET/CT scanner, serious access issues will persist and worsen—particularly for vulnerable rural populations who already face healthcare disparities. The project is not only

justified, but necessary to ensure timely, equitable, and high-quality cancer diagnostics for the region St. Anthony serves.

e. UIHC Special Role (10A.714(3)):

St. Anthony Regional Hospital benefits from a unique and multifaceted relationship with the University of Iowa Hospitals and Clinics (UIHC), which supports the hospital's service delivery, education, and innovation efforts in several meaningful ways:

1. Critical Access Hospital Sponsorship

UIHC serves as the sponsor hospital for St. Anthony Regional Hospital's designation as a Critical Access Hospital (CAH). This affiliation ensures compliance with federal CAH requirements and enables St. Anthony to maintain vital healthcare services in rural western lowa. The relationship strengthens clinical operations, enhances quality, and supports care access in an underserved area.

2. Oncology Partnership through Mission Cancer and Blood

In partnership with UIHC and Mission Cancer and Blood, St. Anthony Regional Cancer Center provides comprehensive medical oncology services five days per week. This collaboration brings advanced cancer care directly to the region and includes:

- Three board-certified Medical Oncologists with additional support from Advanced Practice Providers (APPs)
- Genetic Counseling Services, helping patients and families assess diagnosis specific and hereditary cancer risks
- Access to Local Clinical Trials, expanding treatment options and supporting research goals
- 24/7 Provider Coverage, ensuring seamless patient support beyond regular business hours This model allows patients to receive high-quality cancer treatment close to home while benefiting from academic-level expertise.

3. I-CAN Affiliate Network Participation

St. Anthony Regional Hospital is a member of the lowa Cancer Affiliate Network (I-CAN), coordinated by clinicians and researchers at UIHC. This collaborative network of community hospitals is dedicated to improving cancer care across lowa through:

- Shared quality improvement initiatives
- Clinical and technical guidance from UIHC experts
- Continuing education and training for community providers
- Coordinated access to specialized services and research trials

Participation in I-CAN enhances the hospital's capacity for innovation, standardizes high-quality practices, and supports the deployment of evidence-based care.

Signature



Additional Supporting Documents Upload St. Anthony Hospital Report 2020-2022 01.21.25.pdf

Cancer in Iowa Maps.docx