



2026 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 Iowa Code 10A.714, as needed, to complete the application. 4. Upload additional documentation, as needed.

Primary Contact

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Mahaska County Hospital d/b/a Mahaska Health Partnership

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Facility Name

Mahaska County Hospital

Facility Address

1229 C Avenue East, Oskaloosa, Iowa 52577

Project Title

Mahaska Health Partnership PET/CT Acquisition

Project Type

New Equipment

Would you like to request a summary review?

Yes

1. Applicant and Facility Overview

a. Project Purpose and Objectives:

Mahaska County Hospital d/b/a Mahaska Health Partnership (“Mahaska” or “Hospital”) is a Critical Access Hospital located in Oskaloosa, Mahaska County, Iowa. Mahaska seeks approval to acquire and install a fixed PET/CT, the Biograph Trinion EP, to improve timely access to advanced oncologic and cardiovascular diagnostics for rural southeastern Iowans and to support integrated care delivery. Mahaska’s main campus is located at 1229 C Avenue East, Oskaloosa, IA 52577. The project includes equipment purchase and site remodeling with shielding, HVAC, electrical, architectural services, and installation and training within an existing building. The anticipated PET/CT model is the Siemens Healthineers Biograph Trinion EP with cardiac capability. Mahaska is thrilled that this proposed project has also been awarded grant funds under Iowa’s HHS Healthy Hometowns grant.

Mahaska Health’s objective is to convert current weeks-long waits for its mobile PET/CT into days, keep patients closer to home, reduce transfers and rural bypass, and coordinate imaging directly with in-house medical oncology and cardiology teams. This project aligns with Mahaska’s recent growth in oncology and cardiology services and its established regional referral network serving patients from 35 counties.

Mahaska is equipped with an integrated care model that includes a full-time medical oncologist, expanded surgical services and surgical oncology services, growth in cardiology, increased screening capacity, and a multidisciplinary cancer team that convenes regular tumor boards with broad statewide participation. This infrastructure combined with physician and nursing alignment is well-suited to integrate fixed PET/CT services.

Mahaska's current and projected PET/CT demand, coupled with regional need, supports this project. The Hospital's care teams are simultaneously growing cardiology capacity, including additional echo capability and radiology remodels for women's imaging, and are recruiting for key specialties to sustain comprehensive diagnostics and treatment. An in-house PET/CT with cardiac capability will reduce patient transfers, improve scheduling certainty, and allow Mahaska Health to meet the standard of care locally for oncology and advanced cardiovascular diagnostics.

The fixed PET/CT with cardiac capability offers high diagnostic performance and operational advantages. The Biograph Trinion EP provides quantitative blood flow and coronary flow reserve, with shorter procedure times compared to SPECT, lower radiation exposure due to short half-life radiotracers, and fewer attenuation artifacts in patients with increased chest wall thickness. For oncology, a fixed PET/CT will accelerate staging, guide therapy selection, and support response assessment and survivorship planning. These capabilities will integrate with Mahaska Health's nurse navigation, social work, genetics, pharmacy, and palliative care services to deliver coordinated, patient-centered care.

Additional supporting documentation and specifications related to the PET/CT system and related renovations are being submitted with this Application.

b. Relationship to Long-Range Development Plan:

As a physician and nurse-led hospital, Mahaska provides care to patients receiving specialized care by our on-call physicians 24/7. Celebrating its 48th year of recognition as one of seven Critical Access Hospitals in Iowa to achieve the Joint Commission Gold Seal of Approval, Mahaska meets the growing regional need for specialty care. Today, Mahaska has more than 102 medical professionals, 18 Physician Medical Directors supported by 710 team members and 78 volunteers who work together to provide premier cancer care in southeast Iowa.

Mahaska Health's current and projected PET/CT demand, coupled with regional need, supports this project. Mahaska's care teams are simultaneously growing cardiology capacity, including additional echo capability and radiology remodels for women's imaging, and recruited key specialties in OB/GYN, ENT, Urology, PM&R and cancer care to sustain comprehensive diagnostics and treatment. An in-house PET/CT with cardiac capability will reduce patient transfers, improve scheduling certainty, and allow Mahaska Health to meet the standard of care locally for oncology and advanced cardiovascular diagnostics. In addition, the CT side of the PET will be used for lung screening along with other diagnostic testing if the PET is not scheduled further enhancing the treatment capabilities along with freeing up our very busy CT that services our ER and Inpatient departments.

The project is consistent with Mahaska Health's ongoing strategic investment in cancer and cardiovascular care, including recruitment of oncology and cardiology specialists, expansion of surgical capacity, radiology remodeling plans for women's imaging, and the build-out of a multidisciplinary cancer program that is pursuing Commission on Cancer (CoC) accreditation, which will be the first CoC accredited critical access hospital in Iowa. The addition of a fixed PET/CT is a natural progression to sustain this integrated model and meet regional demand.

c. Description of Proposed Service/Program:

The fixed PET/CT program will support oncology staging, restaging, and response assessment, and advanced cardiovascular diagnostics including quantitative myocardial perfusion and coronary flow reserve. These services will be embedded within Mahaska Health's existing care pathways, including

nurse navigation, social work, genetics, pharmacy, palliative care, and multidisciplinary tumor boards. Installing the Biograph Trinion EP PET/CT system and corresponding materials will require Mahaska to remodel an area adjacent to its radiology department to house the system. This construction is included in the total estimated cost, which is \$4,439,456.00, with major cost categories including the equipment purchase, accessories, software, installation, training, warranty/service, and construction to remodel space adjacent to radiology to house the PET/CT system with appropriate shielding, HVAC, and electrical support.

The present total cost is \$4,439,456.00. This is \$54,405 less than the total cost of \$4,493,861 identified in the Letter of Intent. Mahaska obtained a lower quote due to fluctuations in price of components of the PET/CT machine. This proposed project has been awarded grant funds under Iowa's HHS Healthy Hometowns grant.

d. Target Population: Specify geographic and demographic areas.

Mahaska serves patients from across southeastern Iowa, with documented referrals and patient travel from 35 counties due to the availability of integrated specialty services in a rural setting. A fixed PET/CT at Mahaska Health will address access barriers for oncology and cardiology patients across this multi-county network. No other hospital around Mahaska Health has a fixed PET/CT or the coordinated physician care teams to support the program. With corporate hospitals shuttering services each year, southeast Iowa is in need of comprehensive, coordinated care specifically for cancer and cardiology patients.

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

Mahaska Health has nurtured partnerships across rural southeastern Iowa that strengthen its clinical programs. These partnerships include hospitals that rely on Mahaska Health for specialty care, community organizations that support families through social determinants of health challenges, and tertiary care centers that collaborate on advanced diagnostics and treatments. Each partnership reinforces the stability of Mahaska Health's Centers of Excellence in labor & delivery, cardiology, oncology, and surgical and surgical oncology enhances the professional environment for incoming clinicians.

Surgical partnerships extend across emergency departments in surrounding counties. Rural hospitals, such as Monroe County Hospital, Davis County Hospital, Lucas County Health Center, MercyOne Centerville Medical Center, Knoxville Hospital & Clinics, Keokuk County Hospital & Clinics, UnityPoint Health Grinnell, Ottumwa Regional Health Center and Jefferson County Health Center frequently transfer patients to Mahaska Health when surgical needs surpass their capacity or do not offer the services needed due to the lack of specialists.

The in-house PET/CT will streamline coordination, reduce out-of-region referrals, and support local and regional providers with faster diagnostic turnaround.

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

The estimated total cost is approximately \$4,439,456.00, with roughly \$1,370,967 to be funded from internal operating cash and the remainder to be paid via an Iowa HHS grant. The total cost includes construction, shielding, HVAC, electrical, installation, training, workstation, accessories, software, and a 12-month service warranty through Bayer. The quote for the Biograph Trinion EP PET/CT system and corresponding materials from Siemens Healthineers accompanying the Letter of Intent is valid through February 28, 2026.

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:

Today, southeast Iowans frequently face weeks-long waits and must travel for PET/CT imaging, delaying diagnosis and treatment initiation. By installing a fixed PET/CT, Mahaska Health will convert those waits from weeks to days, keep patients closer to home, and coordinate imaging directly with our medical oncology and cardiology teams to reduce readmissions, transfers, and rural bypass. In recent years, Mahaska Health has built the clinical infrastructure to support high-quality, integrated oncology and cardiovascular care teams across 35 counties, including recruitment of a full-time medical oncologist, full-time cardiologist, full-time surgical oncologist, full-time urologist and two full-time OB/GYNs, expanded surgical services, growth in cardiology, increased screening capacity in multiple modalities, and establishment of a multidisciplinary cancer team that conducts regular tumor boards with robust participation across Iowa. With 10 hospitals around Mahaska Health closing labor & deliver services including no full-time general surgeons or cardiologist our organizational readiness and regional referral network underscore the appropriateness of a fixed PET/CT with cardiac capability at Mahaska Health.

b. Assessment of Existing Services and Gaps:

Existing regional PET/CT access is constrained and largely dependent on out-of-region travel or infrequent mobile availability in rural areas, producing delays and fragmented care. Mahaska's mobile PET/CT has processed 625 orders since 2022. Cardiology and oncology together have seen patients from 35 counties with 2,069 oncology patients and 2,818 cardiology patients over the last two years alone. These patients – and more – will benefit from the addition of an in-house PET/CT at Mahaska. Mahaska Health's integrated oncology and cardiology programs have expanded rapidly, indicating sustained, unmet diagnostic demand that a fixed PET/CT can address.

c. Alternatives Analysis:

Continued mobile PET/CT: As discussed in the foregoing section, Mahaska's mobile PET/CT has processed 625 orders since 2022. Cardiology and oncology together have seen patients from 35 counties with 2,069 oncology patients and 2,818 cardiology patients over the last two years alone. These patients – and more – will benefit from the addition of an in-house PET/CT at Mahaska Health, as described in more detail below. The cost of the mobile PET/CT is currently \$50,000 per month. It would be more fiscally responsible to purchase the PET/CT outright and bring that revenue in-house. This is going to be a triple win for patients, Mahaska Health's revenue, and for coordinated care with 5 days a week for providers to order a test and access for patients.

Continued use of the mobile PET/CT may be less capital-intensive initially but fails to resolve scheduling bottlenecks, delays, and care fragmentation. This option remains inadequate for urgent/complex cases.

Out of region referral: This option ensures access but increases travel costs, time, disrupts coordination, and delays the commencement of treatment and adjustments.

Case in point, the average diagnosis to treatment timeframe for cancer patients is 22 days. At Mahaska Health it is 12 days, which is significant for patients satisfaction and peace of mind knowing that patients can receive high quality care close to home with proven care coordination.

d. Accessibility Considerations:

Local PET/CT access will reduce transportation time and costs, minimize time away from work and family, and improve equity for rural patients by providing advanced diagnostics closer to home in a Critical Access Hospital setting. Many times, family members have to take time off work, adding to the cost and inefficiency of not having this modality locally. It improves convenience by removing substantial transportation costs for low-income rural patients, less travel downtime, and allows expedited imaging for

those in more remote rural areas. Services will be available for patients regardless of the patient's ability to pay.

Mahaska Health's cancer care team has reduced the average diagnosis to treatment care plan from 22 days to 12, which is significant for cancer patients. Dr. Kiron Nair our Medical Oncologist has praised our cancer care team for the impressive care coordination that is taking place, which is faster than our tertiary counterparts.

e. Community Input/Support:

Mahaska Health's clinical leadership and multidisciplinary teams have built robust referral and collaboration networks, demonstrating sustained community and provider support for advanced diagnostics at Mahaska Health. Local primary care physicians attend our multidisciplinary cancer tumor boards to learn about how their patients will be cared for and what the treatment plan will be so that their primary care follow up will be more coordinated. This model strengthens outcomes and reduces emergency driven deliveries, turning into a natural hub and spoke model where patients closest to the 9 hospitals around us who do not have comprehensive medical oncology, surgical oncology or general surgery services receive care at Mahaska Health and then return to their local primary care provider. This peer-to-peer relationship has garnered trust and improved the health and wellbeing of southeastern Iowans without fear of corporate medicine stealing their patients.

Document Upload (if needed)

f. Non-discriminatory Access:

As a Critical Access County Hospital that also receives local tax funding, we pride ourselves in serving diverse rural communities, Mahaska has and will continue to offer PET/CT services without discrimination and accept referrals from area physicians as part of its integrated regional hub and spoke model of care.

3. Impact on Existing Providers

a. Impact Assessment:

Local PET/CT capacity at Mahaska Health will reduce forced referrals to distant metro centers and relieve pressure on limited regional mobile capacity, addressing a documented access gap while enhancing coordination and timeliness for oncology and cardiology patients reducing diagnosis to treatment times. This right-sized addition in a rural setting is designed to minimize unnecessary duplication by meeting demonstrated demand within Mahaska's established referral network. Internal data projects that the new PET/CT can serve at least 300 people annually, double our current annual average of 150 over the last 4 years.

The main health benefits of an onsite PET/CT come from early identification of disease based on cellular function. This allows for more accurate characterization and localization of abnormalities – namely cancer tumors and metastasis. Integrated functional and anatomical information improve treatment planning by the radiologist and care team.

b. Community and Economic Impact: Broader system effect and value-added to the community.

The project will strengthen continuity of care, reduce travel burdens for families, and help retain care in the community, particularly given Mahaska Health's leadership role in rural tumor boards and collaborative peer-to-peer relationships with surrounding hospitals and physicians.

c. Efficiency in Use of Resources: Shared/cooperative arrangements to maximize efficiency.

Mahaska Health will integrate the PET/CT with cardiac capability programming within its existing radiology and specialty service lines to maximize efficiency and resource utilization. Key shared arrangements include in-house medical and surgical oncology and their care teams, in-house cardiology and their care teams along with in-house radiologist expertise who will provide the reading and clinical follow-up between services, which will maximize efficiency of care for patients. The existing technologist and radiology support resources will be combined within to reduce staging to treatment times from 22 days (national average) to 12 days. Mahaska Health also maintains established vendor supply relationships and

coordinated referral networks with regional providers from seven critical access hospitals, allowing the PET/CT service to operate efficiently within an existing care network.

4. Financial and Operational Feasibility

a. Financial Projections and Feasibility:

Mahaska Health estimates the total project cost at approximately \$4,439,456.00, inclusive of equipment, installation, training, warranty/service, and required renovations. Funding will come from internal reserves for approximately \$1,370,967 with the balance to be paid from an Iowa HHS grant. Siemens Healthineers has confirmed that the quotation will remain valid through February 28, 2026.

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b. Staffing and Operations:

Our Radiology Director has invested in Chloe Fowler, an existing radiology technologist with a Master's degree and ARRT certifications in MRI, CT, and X-ray to become our full-time PET/CT technologist. Mahaska Health will pay for her to attend Weber State University; she should graduate their program within three semesters with double certification in Nuclear Medicine and PET/CT. Upon successful completion, she will work weekdays from 7:00 a.m. to 3:30 p.m., ensuring consistent PET/CT coverage and patient access five days per week.

Our current radiopharmaceutical supply chain from Des Moines highlights the importance of having early morning scheduling. Transporting radioactive materials during early morning hours minimizes traffic-related delays and supports the timely and safe delivery of isotopes. This schedule also provides important clinical benefits, especially for diabetic patients for whom we receive the best images early in the day prior to insulin level fluctuations and for patients who have to fast prior to their scans as it improves patient tolerance and compliance.

As PET/CT volumes grow, we plan to hire an individual full-time within the next 2–3 years, allowing for overlapping schedules that will expand service availability and improve operational flexibility. We plan recruitment of staff two years in advance and have stayed in contact with a certified technologist who has expressed an interest in joining our radiology team as volumes increase. Having two staff members trained to provide PET/CT scans will provide essential coverage for PTO, support higher patient volumes, and ensure additional assistance for patients who require extra care, ultimately strengthening continuity, safety, and patient experience within our PET/CT program. In the interim, if needed, we will work with Ironside or Medical Solutions for emergency coverage.

Chloe will also complete manufacture-specific education and training modules including Essential Education Level 2 (MI)(PET), designed specifically to meet the education needs of a current Siemens PET/CT department with a more demanding clinical workload. Components of this education package include:

- A 12-month subscription to our continuing education platform, Siemens Healthineers Academy, including access to up to 50 CEU credits.
- On-site hands-on training by a Siemens Clinical Education Specialist for up to 28 hours over four consecutive business days.
- Ongoing access to pre-scheduled, live-remote, one-on-one training sessions for 12 months. Browse topics and register your sessions at Siemens Healthineers Academy.
- A multi-day Siemens Online Classroom, chosen from a variety of defined offerings. Browse class offerings and register at Siemens Healthineers Academy.
- Live-remote training by a Siemens professional Clinical Education Specialist for up to 24 hours over three consecutive business days.

She will also complete Essential Training PH 1 (Onsite-24) PET (CT Specific Training) that includes up to 24 hours of on-site clinical education training that covers agenda items on the ASRT approved checklist if applicable.

Operationally, the Biograph Trinion EP supports advanced cardiology diagnostics, including absolute myocardial blood flow quantification and coronary flow reserve, with shorter procedure times and lower

radiation exposure than SPECT due to short half-life radiotracers. These efficiencies support patient quality. For oncology, fixed PET/CT will accelerate staging and treatment planning and integrate into the Hospital's multidisciplinary care team workflows.

c. Short and Long-term Viability:

Viability is supported by documented need, like medical oncology, surgical oncology and urology growth. Mahaska Health's staffing model includes an established, multidisciplinary cancer care team, a full-time medical oncologist, and growing cardiology resources, with active recruitment to sustain comprehensive diagnostics and treatment. This infrastructure supports successful integration and utilization of the PET/CT service, both in the short and long-term.

5. Community and Economic Impact

a. Community Engagement:

A fixed PET/CT will provide rural families earlier diagnoses and faster treatment initiation, reduce travel and associated costs, and strengthen care continuity by aligning imaging with Mahaska Health's on-site oncology and cardiology services. This investment also supports the Hospital's Center of Excellence initiatives and pursuit of Commission on Cancer (CoC) accreditation, which fosters regional capacity-building through tumor boards and professional peer-to-peer collaboration.

b. Resource Availability:

During 2022, Mahaska's Cancer Care Committee was formed, and the list of services grew with the addition of urology, and rheumatology care, stereotactic biopsies, and remote patient monitoring. In 2023, Mahaska added a new surgical oncologist/general surgeon – 1 of only 10 surgical oncologists in Iowa, 2 obstetrician/gynecologists, a cardiologist, infectious disease physician, 2 emergency physicians, ENT physician, physical and rehabilitative physician, sports medicine physician, palliative care physician, 3 hospitalists, a pediatrician, 5 primary care physicians, an ultrasound technician, 3 echocardiology technicians, and 6 ambulatory pharmacists in addition to medical care staff in wound care, social work, urology, and orthopedics.

For the PET/CT, Canon provides comprehensive applications training, QA tools, remote diagnostics, and service coverage, ensuring availability and appropriateness of technical and management resources.

c. Organizational Relationships:

The PET/CT program supports regional referral relationships by reducing diversions to metro centers and facilitating coordinated care locally. Furthermore, Mahaska Health has existing workflows in place with local partners for advance imaging referrals. This existing infrastructure can be leveraged for this service line as well.

6. Project Planning

a. Project Timeline:

Service initiation will follow construction, installation, and staff training, sequenced within the Siemens Healthineers quote validity window through February 29, 2026. Formal public bidding for construction will occur after CON approval, and installation/commissioning will be coordinated with the vendor. It is anticipated that the construction associated with obtaining the PET/CT will be initiated after the bidding process is finalized and this could take place between July and August, 2026.

Installation Timeline:

Board approval
February-March 2026

Secure Certificate of Need
February – June 2026

Space renovation
12 weeks after CON received

Mechanical Installation
1 week after renovation complete

Startup
1 week after renovation complete
Calibrations and Physicist
1-2 weeks after installation

Applications and training staff
1-2 weeks after installation

b. Innovative Components:

The Biograph Trinion EP has an LSO-based digital detector, which offers spatial resolution and ultra-fast time of flight. It additionally has an air-cooled system and a smart power-save mode which can result in substantial energy savings, making it a sustainable investment. This technology also reduces the throughput time further reducing the scanning time needed to produce high definition 3D imaging. PET has the following advantages for cardiac imaging, both to monitor side effects from cancer treatment and for cardiac care:

- High diagnostic accuracy at 90% sensitivity and 90% sensitivity for detecting myocardial ischemia compared to 70% sensitivity and 70% sensitivity for regular stress testing and stress echo at 80% sensitivity and 85% specificity.
- Provides quantitative blood flow for absolute myocardial blood flow quantification and coronary flow reserve.
- Lower radiation exposure compared to nuclear SPECT imaging due to short half-life of PET radiotracers.
- Reduced artifacts from breast and chest wall thickness (obesity) that you with echo or SPECT imaging.
- Shorter procedure time with image acquisition in 20-40 minutes instead of SPECT of 2-3 hours.

c. Regulatory Compliance:

Mahaska will satisfy all applicable regulatory requirements (e.g., shielding, HVAC/electrical codes, QA and dose standards, equipment licensing for calibration sources) and coordinate permits, site specs, and Siemens Healthineers site preparation guidelines.

7. Special Criteria for Specific Services:

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

Continued reliance on mobile PET/CT or out-of-region referral would not resolve documented scheduling bottlenecks, weeks-long waiting times, or the care fragmentation experienced by rural families. A fixed PET/CT at Mahaska Health is the prudent alternative to ensure timely access and integrated care.

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

Existing regional access is limited and no other hospital around us has a fixed PET/CT and often requires travel to metro centers, indicating that local fixed capacity at Mahaska Health would be appropriately utilized within its established multi-county referral network.

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

The project entails remodeling adjacent to radiology with targeted shielding, HVAC, and electrical upgrades aligned to manufacturer specifications, representing a prudent modernization to integrate PET/CT with existing services.

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

Without the project, serious access problems persist, including weeks-long delays with diagnosis to treatment taking longer than 22 days and travel to distant metro centers for timely care; with the project, waits can be reduced to days and coordinated locally with oncology and cardiology services.

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

Not applicable.

Signature

Tara Hall

Additional Supporting Documents Upload

26.02.23 Mahaska CON PET-CT Application.pdf

26.02.23 Attachments to Mahaska CON PET-CT Application.pdf