2025 Certificate of Need Application

Facility Name
Orange City Area Health System

Facility Address
1000 Lincoln Circle SE, Orange City, Iowa 51041

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Applicant and Facility Overview

Provide the applicant's name, facility location (city, county, address), and a brief description of the proposed health service or facility (e.g., type of service, target population).
The applicant is Orange City Area Health System ("OCAHS") located in Sioux County at 1000 Lincoln Circle SE, Orange City, Iowa 51041. OCAHS is a 25-licensed-bed municipal hospital that serves Orange City and the surrounding communities.

OCAHS is proposing to purchase a da Vinci robotic surgical system ("the da Vinci dv5"). The da Vinci 5 is manufactured by Intuitive Surgical and is the 5th generation of these specific devices. Illustrations of the da Vinci 5 robotic surgical system have been uploaded as "Exhibit 1 – Photos of da Vinci 5 System.pdf." The total cost of the da Vinci 5 and related equipment, including the required table, instruments, and accessories, is $3,069,712.

OCAHS works diligently to provide the Orange City community and surrounding area with access to a wide range of primary and secondary services. Relative to the proposed project, OCAHS has a skilled team of proceduralists across several specialties, including general surgery, urology, and OB/GYN. These physicians care for a wide range of complex and routine issues. In order to grow and retain this surgical practice, especially in a rural area, it is necessary for OCAHS to undertake this project. As surgical techniques have evolved, the availability of technologies like those being pursued in this project have become necessary to provide high quality clinical care. Proceduralists are now often trained on these systems and come to expect that they be available as part of their practice. In fact, many new physicians are trained first on the robotic systems as opposed to laparoscopic approaches. Because of this, they feel more comfortable completing cases robotically.

OCAHS, specifically the physicians from general surgery, OB/GYN and urology, and general surgery practices, reviewed all procedural cases over the years, and this review suggested that several hundred surgeries that are performed annually could be completed utilizing the da Vinci 5 platform. Top surgical case types include, but are not limited to, appendectomies, cholecystectomies, and hernia repairs. OCAHS expects that trend to continue once it puts the da Vinci into service.

There has been tremendous growth in the technology available to surgeons, specifically a growth in robotic surgery. Robotic surgery is the standard of care for many procedures and offers the potential for faster recovery times and reduced risk of infection. The relative proportion of cases done robotically as opposed to “open” for select surgical procedures has continued to rise and is projected to accelerate in the future.

No construction or renovations will be required at OCAHS associated with the addition of the da Vinci 5.

Current # of Beds (if changing)	**Current bed type (if changing)**
Requested # of Beds	**Requested bed type**

Document Upload
CON Bed Utilization Statistics - OCAHS.pdf

Exhibit 1 - Photos of da Vinci 5 System.pdf

Exhibit 2 - OCAHS Service Area.pdf

Describe the proposed project’s alignment with the state health plan, if applicable.
OCAHS continues to work to improve the health of the people it serves across the greater Orange City community and region. Outpatient procedural offerings are critical to the future of OCAHS. The da Vinci would be a key tool not only in recruiting replacement and additional surgeons but also in the expansion of surgical offerings—particularly in gynecology and urology. The da Vinci system is critical to OCAHS’s long-term plan to keep access and care available in Orange City and surrounding communities. Without this system, it will be challenging to recruit and retain the physicians to make that plan possible.

Retention of advanced clinicians and proceduralists in rural areas, including in the OCAHS service area, is critical to maintaining access to care in these specialties. Notably, OCAHS is committed to ensuring that it can provide high quality OB/GYN care to its service area. It has been well-reported about the maternal health gaps in rural Iowa, and OCAHS is dedicated to providing this care in its community.

Community Need and Service Gaps

Describe the unmet health need in the community, including demographic data (e.g., population size, age, health disparities) and evidence of service gaps.
As discussed above, OCAHS serves a rural population and one struggle it faces is recruiting and retaining high-quality physicians to serve this population. Adding a surgical robot provides these physicians with the set of tools they are now trained on and expect at their place of employment. Providing these tools is essential to maintain surgical services at OCAHS as this facility is one of the few in its greater region that is currently able to maintain these service lines.

Explain how the proposed service addresses the identified need and benefits the community (e.g., health outcomes, accessibility for underserved populations).
OCAHS anticipates the general surgeons who would use the da Vinci 5 will serve a general patient population. While the women seeking gynecologic care will also benefit, OCAHS believes the advanced technology may benefit patients across its population and service area. It is not expected that the da Vinci 5 will be used for pediatric patients, but the number of possible procedures is increasing across all other specialties. Thus, the project has broad applicability to OCAHS’ existing patient population.

As a larger critical access hospital, OCAHS increasingly works to provide quality access to care to patients throughout their community and region. In 2021, the American Hospital Association (AHA) reported that

although 20% of Americans live in rural communities, fewer than 10% of physicians practice there. And, unfortunately, those percentages are not improving. The National Library of Medicine also reported that 1/5 of the US population lives in rural counties, while less than 10% of clinicians practice in rural areas. This means there are less rural specialists, and these rural residents are required to travel to more urban communities to receive needed specialty services. The lack of care close to home creates a barrier for patients to receive timely care.

With new providers now trained on these advanced platforms, OCAHS' ability to recruit and retain requires that it has this type of equipment available. Without them, OCAHS risks losing access to key services and specialties (general surgery and OB/GYN) and risks exacerbating access to care challenges in the state. Surgical robots are no longer a luxury for the large medical systems – they are a necessity for all facilities including rural facilities such as OCAHS.

Provide evidence that less costly or more effective alternative methods to meet the need have been considered and are unavailable or inappropriate.
OCAHS has concluded there is not a more effective alternative to the proposed purchase. This is the newest model of surgical robots that are available. Intuitive Surgical does still market the da Vinci XI (4th generation) model at a lesser acquisition cost. Since OCAHS is entering into a long-term lease, support for the da Vinci 5 platform can be guaranteed throughout the full lease.

Impact on Existing Providers

Identify existing providers of similar services in the area and describe the potential impact on their operations (e.g., patient volume, market share).
The geographic service area for this project includes 4 counties (Lyon, Sioux, O'Brien, and Plymouth) with a combined population of 87,686. A map of the proposed geographic service area has been uploaded as "Exhibit 2 – OCAHS Service Area.pdf." The primary service area is indicated by the 25-mile circle on the map. In 2024, babies delivered at OCAHS were from more than 35 ZIP codes.

No existing facilities in the primary service area of OCAHS have a da Vinci surgery system. Patients currently need to commute to Spirit Lake, Sioux City, or Sioux Falls to receive da Vinci robotic surgery as the standard of care. All locations are commutes of approximately one hour or more.

Provide evidence that the proposed service will not result in unnecessary duplication of services in the area.
No existing facilities in the OCAHS primary service area have a da Vinci surgery system. In addition to Spirit Lake, Sioux City, and Sioux Falls (all commutes of approximately one hour or greater as referenced above) OCAHS and Sioux Center Health both currently offer Mako robotic assist surgeries for knee replacements. The Mako cannot be utilized for soft tissue surgeries like the da Vinci.

Financial and Operational Feasibility

Provide a summary budget, including total project cost, funding sources, and 3-year financial projections (revenue, expenses, break-even point).
OCAHS will lease the da Vinci 5 over a period of 84 months. The total cost of acquiring and installing the da Vinci 5 system will be $3,069,712, which consists of the following costs:

- daVinci 5 system (total cost of 7-year lease): $2,739,712.
- Trumpf OR Table: $110,000
- Stocking order of instruments and accessories: $200,000
- Third-party accessories: 20,000
- TOTAL: $3,069,712

OCAHS intends to lease the da Vinci 5 with cash on hand through operations and will not incur any debt in connection with acquiring and operating the da Vinci 5 system. OCAHS does not anticipate an operating loss in connection with operating the da Vinci 5 system. For reference, a copy of OCAHS's balance sheet dated May 31, 2025, showing sufficient resources has been uploaded as "Exhibit 3 – OCAHS Balance Sheet.pdf."

Three-year financial projections associated with the operation of the da Vinci 5 have been uploaded as "Exhibit 4 – Financial Projections." It is important to mention several assumptions relied upon to calculate these projections.

First, OCAHS has included only 35% of its historical volume of surgical cases that would be appropriate candidates for the da Vinci 5 system. (See the line labeled "Expected Retained da Vinci Surgical Volume.") Without the ability to perform robotic surgery in Orange City, it is likely some portion of patients who require surgery will elect to leave the community to obtain robotic surgery. OCAHS has taken a conservative approach and has assumed that only 35% of candidate surgery cases would leave the community for this care. As patients continue to learn the benefits of robotic surgery in terms of faster recovery times and reduced risk of infection, it is certainly possible that more than 35% of cases could be at risk of leaving the community for care in which case the projections would understate the number of cases that would be performed on the system.

Second, OCAHS has assumed that it would perform four additional cases per month in year one, five additional cases per month in year two, and six additional cases per month in year 3. (See the line labeled "Expected Incremental da Vinci Surgical Procedure Volume.) This assumption captures the growth in surgical volume that will likely result from offering robotic surgery in Orange City. These are cases that are currently leaving the community for care and therefore are not included in the hospital's historical surgery procedure volume.

It is not anticipated that the use of the da Vinci 5 will result in increased charges for patients for these types of procedures. Relevant costs are anticipated to be covered by additional volume and are viewed by OCAHS as a necessary cost to be able to recruit surgeons in the future.

Document Upload
Exhibit 3 - OCAHS Balance Sheet.pdf

Exhibit 4 - Financial Projections da Vinci.pdf

Describe the operational plan, including staffing, quality assurance measures, and compliance with state and federal regulations.
The surgeons who will be using the da Vinci 5 are highly trained. New surgeons leave their residencies having been trained on surgical robots such as the da Vinci 5 and expect the facilities in which they work to have this technology available. It is now common for surgeons to vet available equipment during the recruiting process.
OCAHS sees this specifically in areas of general surgery, urology, and OB/GYN, where providers have specifically stated their expectations that the facility will continue to invest in these newer technologies.

Provide evidence of the availability of resources, including personnel and funds, to implement and sustain the project.
As discussed above, OCAHS already has surgeons who are highly trained to perform surgery on the da Vinci 5 system because many surgeons receive this training during their residencies. In addition, OCAHS has cash on hand to implement and sustain the project, as more fully described above in response to the budget question.

Community and Economic Impact

Summarize the economic and social benefits of the project (e.g., job creation, tax revenue, community engagement).
Given its rural location, OCAHS services a large percentage of the community's aging and low-income population. The facility consistently sees that these individuals make choices about their care based on convenience and cost. Having this technology available in Orange City will continue to support OCAHS—to make care affordable and easy to access.

The project is not only critical to the ability of OCAHS to recruit quality surgeons and provide care close to home, but a strong local hospital is critical to a strong local economy. A strong hospital—including a strong surgery program—is critical for the ability of local businesses to attract and retain top talent to the area.

Describe how the project promotes efficient use of healthcare resources in the community.
Robotic surgery is an evolution of minimally invasive surgical approaches that allows scarce healthcare resources to be used more efficiently than traditional surgery. With the minimally invasive surgery performed via the da Vinci robotic surgery system, patients can experience the following benefits: fewer complications (surgical site infections, etc.), less pain and blood loss, shorter hospital stays and quicker recoveries (which results in lower costs) and smaller, less noticeable scars. With these benefits in mind and as technology continues to advance, surgeons have been shifting cases to these minimally invasive procedures when clinically appropriate.

Project Planning

Provide a timeline for project implementation, including key milestones.
Pending delivery and installation timelines, OCAHS expects to begin utilizing the equipment in the first quarter of 2026. The following sets forth anticipated milestones:
- August 2025: Board approval for da Vinci purchase, contingent on CON approval
- September / October 2025: Equipment order placed, contingent on CON approval
- October / November 2025: Staff / Surgeon training offsite
- November / December 2025: System delivery for surgical staff training prior to Operating Room deployment
- January 2026: First cases utilizing da Vinci

Describe any innovative or unique aspects of the proposed service that enhance its value to the community.
Robotic surgery is used today in many practice areas, including general surgery, urological surgery, and gynecologic surgery. Generally, surgeons will make use of robotic surgery to enhance precision, flexibility, and control during operations. A robotic arm's movement can be more exact than the movement of a human hand or arm. Surgeons have found robotic surgery allows them to see the operating site better as compared to traditional surgical techniques. Robotic surgery makes use of sophisticated cameras that provide magnified, high-definition views of the surgical area. Further, robotic surgery is an evolution of minimally invasive surgical approaches. With minimally invasive surgery, patients can experience the following benefits: fewer complications (surgical site infections, etc.), less pain and blood loss, shorter hospital stays and quicker recoveries (which results in lower costs) and smaller, less noticeable scars. With these benefits in mind and as technology continues to advance, surgeons have been shifting cases to these minimally invasive procedures when they can. The da Vinci system has seen its growth with enhanced precision, flexibility, and control during operations.

Special Criteria for Specific Services

If the project involves a new institutional health facility (e.g., hospital, nursing facility), provide evidence that the facility is needed based on current and projected utilization of similar facilities in the area.

Not applicable.

If the project involves expansion of an existing facility, demonstrate that the expansion addresses unmet needs without exceeding community capacity.
Not applicable.

If the project involves new technology or equipment, provide data on the technology's clinical efficacy, cost-effectiveness, and impact on patient outcomes.
Robotic surgery is the standard of care for many procedures and offers the potential for faster recovery times and reduced risk of infection. Surgeons will make use of robotic surgery to enhance precision, flexibility, and control during operations. A robotic arm's movement can be more exact than the movement of a human hand or arm. Surgeons have found that robotic surgery allows them to see the operating site better as compared to traditional surgical techniques. Robotic surgery makes use of sophisticated cameras that provide magnified, high-definition views of the surgical area. Further, robotic surgery is an evolution of minimally invasive surgical approaches. With minimally invasive surgery, patients can see the following benefits: fewer complications (surgical site infections, etc.), less pain and blood loss, shorter hospital stays and quicker recoveries (which results in lower costs) and smaller, less noticeable scars. With these benefits in mind and as technology continues to advance, surgeons have been shifting cases to these minimally invasive procedures when they can. The da Vinci system has seen its growth with enhanced precision, flexibility, and control during operations.

If the project involves outpatient or ambulatory services, describe how it improves access to care for underserved populations or reduces reliance on inpatient services.
OCAHS offers a wide range of primary care services. OCAHS is dedicated to overcoming barriers to access to care, and currently one of the biggest barriers across Iowa is the number of health care providers per resident. Specialty care is even more difficult to recruit to a rural market. This project will allow OCAHS to recruit physicians to continue to serve the rural population it proudly serves.

Robotic surgery allows patients to have a minimally invasive procedure that lessens pain, reduces narcotic use, facilitates early initiation of systemic chemotherapy, and allows earlier return to work. This is a more convenient alternative to patients, who do not need inpatient stays for procedures that may have previously required them.

OCAHS serves all patients, regardless of race, ethnicity, or ability to pay. OCAHS expects the project to improve access to low-income persons by enhancing the availability of advanced surgical procedures across its service area.

Finally, the da Vinci 5 will allow patients to receive this complex care closer to home. They are also likely to be able to come in for same-day surgery right in their community, which decreases the financial burden for these patients. As noted above, given its rural location, OCAHS services a large percentage of the community's aging and low-income population. The facility consistently sees that these individuals make choices about their case based on convenience and cost. Having this technology available in Orange City will continue to support OCAHS' mission to make care affordable and easy to access.

If the project requires an exemption from CON requirements (e.g., for emergency or temporary services), provide justification for the exemption, including evidence of urgent need or temporary nature.
Not applicable.

Signature

Additional Supporting Documents Upload

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Additional Supporting Documents Upload