

2025 Certificate of Need Application

Facility Name WinnMed

Facility Address
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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 WinnMed, a 25-bed critical access hospital located in Winneshiek County at 901 Montgomery Street, Decorah, Iowa 52101.

WinnMed is a non-profit organization that serves Winneshiek County and the surrounding communities of northeast Iowa and southeast Minnesota. WinnMed is committed to providing the most comprehensive and specialized care services in the region. WinnMed's goal is to deliver care in a way that maintains the personal experience of a community hospital while providing patients with the very best in health care through the newest medical technology.

WinnMed intends to lease a da Vinci 5 robotic surgical system over seven years. This would be the first robotic surgical system installed at WinnMed and the first in WinnMed's service area.

The da Vinci 5 robotic surgical system is manufactured by Intuitive Surgical Systems and is the 5th generation of these specific surgical systems. 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 expenses is \$2,536,000. No construction or facility modifications will be required to accommodate the da Vinci 5. WinnMed recently completed a surgical addition with new operating rooms. The design of the new operating rooms contemplated the future addition of a da Vinci 5.

WinnMed has a diverse field of specialists who provide surgery services at the hospital—specifically to this project, general surgeons and OB/GYNs. These physicians provide multiple levels of care for a diverse patient population. As WinnMed looks to grow its capabilities for patient care, the need for innovative surgical technology is not a question of "if"—it is a question of "when." Robotic surgery is increasingly becoming the standard of care. In addition, robotic surgery is a key method by which residency programs now train new surgeons in multiple specialties.

WinnMed must be able to offer robotic surgery to remain competitive in the surgical landscape. In recent years robotic surgery has surpassed traditional laparoscopy as the dominant form of surgical approach. Within these robotic cases, 60% are used for general surgery, 24% for gynecology, and 11% for urology. The growth of robotic surgery is driven by numerous factors that benefit both patients and surgeons. In robotic-assisted procedures, the surgeon operates from a console in the operating room controlling the robotic platform and arms perform the surgery at the patient's side. The da Vinci robot offers several advantages over other robotic surgery systems, including the following:

- enhanced, magnified visualization of the abdominal cavity;
- instrument controls that mimic the natural movement of the wrist for precise dissection and suturing;
- technology to filter out hand tremors and to scale motion for greater accuracy; and
- the ergonomic, seated position supports surgeon comfort and performance, potentially extending career longevity.

The benefits robotic surgery provides to the surgeon translate directly into improved outcomes for patients. According to a meta-analysis of peer-reviewed literature, patients undergoing robotic surgery are less likely to require conversion to open procedures, experience a reduced need for blood transfusions, have shorter hospital stays and quicker recoveries, face fewer 30-day complications, require fewer opioids after surgery, and benefit from smaller, less noticeable scars.

The da Vinci system will support surgeon recruitment, reduce patient transfers to larger facilities, and help preserve inpatient capacity by keeping beds and resources available locally. Currently, most patients who require robotic surgery leave the state to receive care at Mayo Clinic (Rochester, Minnesota) or Emplify Health (La Crosse, Wisconsin). A da Vinci at WinnMed will allow these patients to receive care closer to home in Iowa.

WinnMed estimates that approximately 170 current surgical cases performed annually could be performed robotically. Additionally, with access to this technology, WinnMed anticipates performing an additional 15—20 new cases per year that might have otherwise required referral out plus gaining market share in other cases where patients are currently requesting to go to an organization with robotic capabilities.

The da Vinci 5 system would primarily support general surgery and OB/GYN, with the potential to expand into urology cases in the future.

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

Requested # of Beds Requested bed type

Document Upload

CON Bed Utilization Statistics - WinnMed.pdf

Describe the proposed project's alignment with the state health plan, if applicable.

WinnMed is continuously working to improve the level of care offered to Winneshiek County and the greater northeast region of lowa. WinnMed is currently in the late phases of a project known as "Transforming Tomorrow," an expansion project to enhance the existing footprint of the hospital. Within this project, WinnMed has already completed construction on a new and fully renovated birthing unit featuring six new Labor, Delivery, Recovery, Postpartum (LDRP) suites and direct access from Obstetrics to Surgery for c-sections. A surgery expansion has also been completed that includes larger rooms to accommodate new technology and additional operating rooms to meet the hospital's growing volume of surgical cases. WinnMed also plans a two-story addition to house an expanded primary and specialty clinic for additional access, growth, and a better patient experience.

WinnMed is seeking the addition of the da Vinci 5 to continue advancing care for its patients. This is a necessity to continue to provide advanced specialty care to a rural population and maintain access for the community. Without the robotic surgical system, WinnMed may face recruitment and retention issues that hinder the hospital's long-term development plan that is supported by its other larger scale projects.

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.

Critical access hospitals, such as WinnMed, are increasingly faced with health disparities regarding access, quality, and availability. These disparities lead to health discrepancies and a growing need for specialty care in rural communities.

First, the addition of a da Vinci 5 robotic surgical system at WinnMed will help to address the unmet health needs of patients in rural northeast Iowa. Reports from the National Rural Health Association found that about 20% of Americans live in a rural area. Yet, on average, there are only 13.1 physicians per 10,000 people and only 30 specialists per 100,000 people. In urban areas, by contrast, there are about 31.2 physicians per 10,000 people and 263 specialists per 100,000 people. As a result of this disparity, rural residents typically have no choice but to travel to urban areas for specialty services. This lack of care close to home creates a barrier to receive timely care. In fact, most patients in WinnMed's service area who require robotic surgery leave the state to receive care at Mayo Clinic or Emplify Health. A da Vinci at WinnMed will help to fill this unmet health need by allowing these patient to receive care closer to home.

Second, the addition of a da Vinci 5 robotic surgical system will help to recruit additional specialists to the region. New providers are now being trained on robotic surgical systems making these systems even more crucial to physician recruitment and retention. For example, WinnMed recently recruited a general surgeon who only signed due to WinnMed having the purchase of the robotic surgery system on its strategic plan. WinnMed also has a posting for an OB/GYN and expects the pool of applicants to be severely restricted without having a da Vinci robot. Surgical robots like the da Vinci are no longer a luxury but instead are becoming the standard of care.

Explain how the proposed service addresses the identified need and benefits the community (e.g., health outcomes, accessibility for underserved populations).

Most patients in WinnMed's service area who require robotic surgery leave the state to receive care at Mayo Clinic or Emplify Health. Without this technology, patients in the community will have to continue to travel for this service. Not being able to offer the technology will also have long-term impacts on recruitment and retention of surgical specialists, which will not only impact access to robotic surgery, but will also impact access to those specialties in general.

Provide evidence that less costly or more effective alternative methods to meet the need have been considered and are unavailable or inappropriate.

As discussed above, most patients in WinnMed's service area who require robotic surgery leave the state to receive care at Mayo Clinic or Emplify Health, so maintaining the status quo is not a feasible option especially as the patient demand to have cases done robotically increases. To meet the need for robotic surgery, WinnMed considered the purchase of a da Vinci XI surgical system (the 4th generation) rather than the latest 5th generation da Vinci 5 system. The 4th generation costs \$500,000 less but it does not offer the same features and benefits.

For example, the newest generation offers force feedback so surgeons can have tactile feel versus only visualization. It also has enhanced visuals and more realistic 3D imaging. The da Vinci 5 also has enhanced ergonomics to minimize surgeon discomfort during long surgeries and enhanced surgeon autonomy so they can control more items. Finally, the newest generation offers data capture and real time

case observation to further collaboration and comparisons to benchmark data. These features translate into improved outcomes for patients.

Along with the additional benefits, the da Vinci XI system has been out for 10 years and its long-term support from the company is unknown. This means WinnMed runs the risk of purchasing this model and needing to upgrade shortly in the future.

Overall, when comparing the two models it was clear that the additional benefits of the da Vinci 5 and the certainty of future support of the platform was worth the extra cost associated with it.

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 six counties with a combined population of over 90,000 people. A map of the proposed geographic service area has been uploaded as "Exhibit 2 — WinnMed Service Area." The areas shaded in blue on the map represent the primary service area for the project. There are no other providers of robotic surgery in the service area. As a result, most patients in WinnMed's service area who require robotic surgery leave the state to receive care at Mayo Clinic (Rochester, Minnesota) or Emplify Health (La Crosse, Wisconsin). A da Vinci at WinnMed will allow these patients to remain closer to home.

Provide evidence that the proposed service will not result in unnecessary duplication of services in the area.

No existing facilities in WinnMed's primary service area offer robotic surgery, so this project will not result in unnecessary duplication of services. This project represents the first time robotic surgery will be offered in the service area. Without this technology, patients in the community will have to continue to travel for this service—typically to Minnesota or Wisconsin.

Financial and Operational Feasibility

Provide a summary budget, including total project cost, funding sources, and 3-year financial projections (revenue, expenses, break-even point).

The da Vinci 5 will be leased over a 7-year term from Intuitive with a capital expense of \$2,536,000. Annual payments are \$384,813 on a 5% lease. WinnMed anticipates an operating loss of \$48,213 associated with the system in the first year of operation and an operating loss of \$14,393 in the second year of operation. WinnMed anticipates a break-even point in the third year of operation, generating a profit of \$146,017. See attached three year projection.

WinnMed will fund the lease of the da Vinci 5 system from cash on hand. For reference, a copy of WinnMed's balance sheet dated April 30, 2025, showing sufficient resources is attached as "Exhibit 3 – WinnMed Balance Sheet."

Additionally, WinnMed has been selected by Congresswoman Ashley Hinson's office for a federal appropriation grant that would provide \$700,000 towards the robotic surgical system (pending federal budget approval).

Use of the da Vinci 5 will not result in changes to current charges a patient would receive for any procedure typically performed without a robotic surgical system. WinnMed will cover new costs by being able to perform surgeries locally that otherwise would be referred elsewhere.

Document Upload

Exhibit 1 - Photos of da Vinci 5 System.pdf

Exhibit 2 - WinnMed Service Area.pdf

Exhibit 3 - Balance Sheet.pdf

Exhibit 4 - da Vinci 5 3-Year Pro Forma.pdf

Describe the operational plan, including staffing, quality assurance measures, and compliance with state and federal regulations.

The da Vinci robot will be used by physicians under three different employers with privileges at WinnMed: physicians employed by WinnMed directly; physicians employed through a professional services agreement with Mayo Clinic Health System; and Emplify surgeons who have privileges at WinnMed. The Emplify surgeons also support three other hospitals in the region and will be able to provide care for patients who would benefit from robotic surgery in Northeast Iowa instead of travelling to Emplify's main campus in La Crosse, Wisconsin. Other surrounding hospitals and physician groups will also have the opportunity to refer patients to a site closer to home.

Robotic surgery cases performed at WinnMed will mainly consist of general surgery and OB/GYN. Specifically in general surgery, WinnMed anticipates five general surgeons will utilize the platform. These general surgeons cover multiple hospitals within the region, so this technology will benefit a broad array of patients geographically and demographically. The following are the surgeons will utilize the da Vinci 5 system:

- Caroline Schwickerath (General Surgery, Mayo Clinic Health System)
- Erik Brink (General Surgery, WinnMed)
- Anthonie Lopez Cortes (OB/GYN, Mayo Clinic Health System)
- Chris Winters (General Surgery, Emplify Health)
- Michael LaBelle (General Surgery, Emplify Health)
- Elleson Schurtz (General Surgery, Emplify Health)

Provide evidence of the availability of resources, including personnel and funds, to implement and sustain the project.

WinnMed currently has two general surgeons who are highly trained on the equipment. One surgeon used the da Vinci system extensively during residency. The other used the da Vinci system in his prior practice in Mason City, Iowa. Other surgeons who will use the technology will undergo appropriate training (similar to any new technology).

Community and Economic Impact

Summarize the economic and social benefits of the project (e.g., job creation, tax revenue, community engagement).

WinnMed is a designated critical access hospital offering a wide range of primary and secondary care services. As stated above, a current barrier in rural health care is the low number of providers per resident. Specialty care is challenging to recruit for in rural areas like Winneshiek County. Adding the da Vinci 5 at WinnMed would allow for the continuation of specialty services for the region and a strengthened ability to recruit physicians.

As discussed above, most patients in WinnMed's service area who require robotic surgery leave the state to receive care at Mayo Clinic (Rochester, Minnesota) or Emplify Health (La Crosse, Wisconsin). A da Vinci at WinnMed will allow these patients to receive this service closer to home in Iowa.

Describe how the project promotes efficient use of healthcare resources in the community.

Robotic surgery has been shown to provide benefits such as: less likely to convert to an open procedure, decreased rate of blood transfusion, shorter hospital stays and quicker recoveries, lower chance for 30-day complications, reduced need for opioids post-surgery, and smaller/less noticeable scars. Bringing this

technology to WinnMed would allow the community to receive the best form of care without leaving the community. This can decrease travel times and other costs associated with seeking care outside of the community. WinnMed serves in a rural location, and offering robotic surgery will add to the specialty services the hospital can provide to the region.

Project Planning

Provide a timeline for project implementation, including key milestones.

Pending CON approval, WinnMed expects to commence offering da Vinci 5 services in the first quarter of 2026. The WinnMed Board of Trustees approved moving forward with CON Application on June 4, 2025. Once approved, WinnMed will be able to proceed with purchasing the equipment with installation to be complete prior to the end of the fourth quarter of 2025.

Describe any innovative or unique aspects of the proposed service that enhance its value to the community.

No existing facilities in WinnMed's primary service area offer robotic surgery. This project represents the first time robotic surgery will be offered in the service area. Without this technology, patients in the community will have to continue to travel for this service—typically to Minnesota or Wisconsin.

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 allows patients to have a minimally invasive procedure that lessens pain, reduces narcotic use, 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 inpatient care.

WinnMed serves a diverse patient population and expects this project will increase the availability of advanced surgical procedures in Winneshiek County. In the greater region of northeast lowa there is a lack of this kind of technology, and by offering this service WinnMed will increase access to a broader population.

The da Vinci 5 will allow patients to receive complex care closer to home. It will also increase their ability to come in for same-day surgery right in their community. Offering this service will further decrease the financial costs associated with travel for these patients.

If the project involves outpatient or ambulatory services, describe how it improves access to care for underserved populations or reduces reliance on inpatient services.

Reports from the National Rural Health Association found that about 20% of Americans live in a rural area. Yet, on average, there are only 13.1 physicians per 10,000 people and only 30 specialists per 100,000 people. In urban areas, by contrast, there are about 31.2 physicians per 10,000 people and 263 specialists per 100,000 people. Due to the lack of rural specialists, rural residents typically have no choice but to travel for specialty services. This lack of care close to home creates a barrier to receive timely care. In fact, most patients in WinnMed's service area who require robotic surgery leave the state to receive care at

Mayo Clinic or Emplify Health. A da Vinci at WinnMed will allow these patients to remain closer to home for surgery.

New providers are now being trained on robotic surgical systems making these systems even more crucial to physician recruitment and retention. For example, WinnMed recently recruited a general surgeon who only signed due to WinnMed having the purchase of the robot on its strategic plan. WinnMed also has a posting for an OB/GYN and expects the pool of applicants to be severely restricted without having a da Vinci robot available.

With the lack of physicians interested in coming to rural America, rural facilities must offer advanced technology. Without this technology, WinnMed risks losing access to key services and furthering challenges related to access and timely care. Surgical robots like the da Vinci are not a luxury anymore but instead are becoming the standard of care.

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

Steve Slower

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