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

Primary Contact
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Facility Name
Floyd Valley Healthcare

Facility Address
714 Lincoln St. NE, Le Mars, Iowa 51031

Project Title
Purchase of DaVinci Xi Robotic Surgery

Project Type
New Equipment

Would you like to request a summary review?
Yes

1. Applicant and Facility Overview

a. Project Purpose and Objectives:
Our purpose is to bring innovative, high-quality surgical care closer to rural patients, to improve outcomes, strengthen our local hospital and reduce disparities in healthcare access. The addition of this service will help improve access to care by bringing advanced, minimally invasive surgery capability to Plymouth County, IA.

By bringing robotic-assisted surgery to our county, we reduce the care burden experienced by our most vulnerable patients and help ensure they receive timely, high-quality treatment close to home. Robotic assisted surgery is becoming the standard of care and surgeons are requesting this level of technology to care for their patients.

b. Relationship to Long-Range Development Plan:
The proposed initiative directly aligns with Floyd Valley Healthcare's Mission Excellence in the following:
1. Service Strategic Pillar - to create even more value in the Patient Experience by increasing the likelihood to recommend. By offering surgical robotics locally, the need for patients to travel for advanced care technologies is reduced. This improves access and enhances the overall patient experience by providing

modern, minimally invasive options closer to home.

2. People Strategic Pillar – Invest in our People. The program helps attract and retain high-caliber surgeons by providing access to advanced technology and training opportunities. This strengthens our reputation as a modern, desirable place to work and reduces workforce turnover. Our very own recruitment efforts for general surgeon have proven that the providers coming out medical school are trained in Robotic-assisted surgery. We feel we must improve with the times to maintain the ability to recruit when replacing retiring surgeons.

3. Quality Strategic Pillar – Robotic-assisted surgery improves surgical precision and outcomes. This supports Floyd Valley Healthcare's goal to deliver the highest quality care. Project development has included efforts to tie to strategic planning goals, including Investing in our People and creating more value in the Patient Experience. Prioritize patient benefit by ensuring robotics are used when they clearly improve outcomes.

c. Description of Proposed Service/Program:
A surgical robotics program is the proposed health service being pursued at Floyd Valley Healthcare. The technology is offered by Intuitive, Da Vinci Surgical Systems. Floyd Valley Healthcare must pursue a surgical robotics program to remain competitive in its surgical offerings. It is Floyd Valley Healthcare's intent to utilize this technology for a number of surgical specialties.

d. Target Population: Specify geographic and demographic areas.
Floyd Valley Healthcare is located in Plymouth County, Iowa and has an estimated 25,700 residents. Plymouth County includes its county seat, Le Mars, a town of 10,618 residents located in the northwest corner of Iowa. Floyd Valley Healthcare is a municipally owned, state-licensed, full-service general acute care, critical access 25-bed hospital located in Le Mars, Iowa.

e. Relation to Existing Provider Network: Summarize relationship with other health care providers/services in the region.
We collaborate closely with local and regional providers to ensure continuity of care. When required, we also facilitate transfers and referrals to larger medical centers for specialty care not offered locally. The planned surgical robotics program is designed to enhance, not duplicate, regional services.

f. Funding Sources and Financial Resources: Identify and document sources of funding and financial viability.
This initiative was presented to our Board of Trustees at their September and October 2025 monthly trustee meetings. Contingent approval, pending CON approval, will happen at the November 2025 meeting. Adequate capital exists to purchase, implement and maintain this program. An attached analysis and proforma provides a more detailed analysis of expected cost and reimbursement. The break-even point is projected to occur before the end of the equipment's expected useful life.

Current # of Beds (if changing)

Current bed type (if changing)

Requested # of Beds (if changing)

Requested bed type (if changing)

Document Upload
FVH 5 year Proforma - daVinci.pdf

2. Community Need and Service Gaps

a. Description of Need:

There are an estimated 25,700 residents of Plymouth County, Iowa. The county seat of Plymouth County is Le Mars; a town of 10,618 residents located in the northwest corner of Iowa. Floyd Valley Healthcare is a municipally owned, state-licensed, full-service general acute care, critical access 25-bed hospital located in Le Mars, Iowa.

The total area of the land in Plymouth County is 863.56 square miles. There are on average 28.8 people living within each square mile of the county. In 2023, the population was estimated to be 25,722. As of 2022 there were 10,466 households with 2.47 persons per household.

In 2022 the median household income increased to $79,963 with the per capita income in the past 12 months being $40,150. In 2022 persons living in poverty was at 5.7%. Children under 18 years of age was 6% and those 65 and older was at 8% living in poverty.

Rural residents experience higher rates of chronic conditions such as obesity, diabetes, and hypertension. These conditions increase the likelihood that surgical intervention is required (Coughlin, et al., 2020).

b. Assessment of Existing Services and Gaps:
By adding this program, Floyd Valley Healthcare will significantly improve accessibility to state-of-the-art surgical interventions for underserved populations, including older adults and low-income residents who face disproportionate challenges in accessing care (Coughlin, et al., 2020).

Robot-assisted surgery offers well-documented benefits, such as reduced complication rates and readmission rates (Stauss, et al., 2022). These outcomes are particularly important for patients with chronic conditions prevalent in the region.

The addition of this program will also enhance the health system's ability to recruit and retain skilled surgical providers. Access to advanced technology is a critical factor influencing where surgeons and specialists choose to practice. Surgeons increasingly expect robotic capabilities as part of their clinical practice, considering it essential to provide innovative care and maintaining professional development (American College of Surgeons, 2023). Investing in this technology signals Floyd Valley Healthcare's commitment to clinical excellence and innovation and will provide a foundation for improved clinical outcomes. As aforementioned in a recent recruitment of a general surgeon at FVH, the number one questions was, "Does FVH have robotic assisted surgery?" It has become a clinical standard of care to have robotic assisted surgery, especially for newly trained surgeons.

c. Alternatives Analysis:
Referrals to outside facilities for robot-assisted surgical interventions will continue to prove challenging for residents within Floyd Valley Healthcare's immediate service area. This model places significate burden on elderly, underinsured, and transportation limited patients. Referral-based care contributes to delayed access, fragmented care, and higher financial strain on patients and families.

Another alternative would be to continue with only conventional laparoscopic and open surgery. These methods remain viable in many cases, but robotic surgery has demonstrated lower complication rates and readmission rates, along with faster recovery times and shorter hospital stays (Stauss, et al., 2022).

d. Accessibility Considerations:
A primary consideration when evaluating the addition of a surgical robotics program was to eliminate geographic barriers for patients within Floyd Valley Healthcare's service area. The nearest robotics program is located over 25 miles away from FVH. This can result in delayed care, higher out-of-pocket costs due to travel, and reduced access to minimally invasive techniques associated with faster recovery. The addition of a surgical robotics program eliminates or reduces these constraints.

e. Community Input/Support:

While no formal community meetings or surveys have been conducted to date, we are committed to engaging our stakeholders throughout the process. We anticipate strong support of this program based on our organization's history of expanding access to advanced care and our ongoing efforts to meet the surgical needs of the rural population we serve.

Document Upload (if needed)

f. Non-discriminatory Access:
The surgical robotics program will be offered without discrimination to all patients regardless of race, ethnicity, gender, religion, sexual orientation, disability status, or socioeconomic background. All patients will have equitable access to robotic-assisted procedures based on medical necessity and provider recommendation in alignment with the organization's policies and applicable state and federal regulations. The program will be designed to serve the entire regional population and will be seamlessly integrated in existing surgical offerings.

3. Impact on Existing Providers

a. Impact Assessment:
No providers offer similar services within a 25-mile radius of Floyd Valley Healthcare. Considering this, there is unlikely to be a significant impact on operations at outside facilities.

b. Community and Economic Impact: Broader system effect and value-added to the community.
The addition of this program will prevent the outmigration of patients to outside facilities that offer surgical robotics services. Providing these services locally ensures that revenue is retained within the region. Local access will help reduce costs for patients by reducing travel. The addition of robotic capability will also allow for the recruitment of high-performing surgeons as noted in our recent recruitment efforts.

c. Efficiency in Use of Resources: Shared/cooperative arrangements to maximize efficiency.
We intend to operate the surgical robotics program as a shared resource within our surgical services suite, accessible to multiple specialties. This will ensure adequate volumes and maximized utilization of the surgical robotics program. This interdisciplinary model supports efficient scheduling, shared staffing, and cross-trained surgical teams.

4. Financial and Operational Feasibility

a. Financial Projections and Feasibility:
Adequate capital exists to support the purchase and ongoing maintenance of this technology. The program's focus will initially be on general surgery and urology. The initial purpose price will be approximately $2,500,000. Ongoing annual expenses associated with the program will be approximately $195,000. The investment is expected to breakeven at approximately three years, which is before the equipment's estimated useful life.

Detailed estimations of revenue, expense, and break-even projects are outlined in the attached proforma.

Document Upload (3-year budget projections)
FVH 5 year Proforma - daVinci.pdf

b. Staffing and Operations:
The surgical robotics program will be integrated into our existing surgical service line and will operate much like our conventional and laparoscopic surgical offerings. No additional staff or management will be required for the implementation of this initiative. The current operating room staff will manage robotic-assisted procedures within their existing roles and scope of practice. Robotic surgeries will be scheduled, staffed, and coordinated through our established processes for surgical case management. Training and credentialing will be provided to relevant personnel to ensure safe and effective use of the robotic system.

Surgeons will undergo manufacturer-approved training and follow internal privileging guidelines.

The primary resource requirement will be the acquisition of the robotic system and necessary instruments. No major changes to staffing, workflows, facilities, or departmental oversight are anticipated. Our operating rooms are adequately equipped to accommodate robotic-assisted procedures with minor modification.

c. Short and Long-term Viability:
This program will be supported by existing staff, and the supplementation of additional labor will not be required. Maintenance of the current workforce will ensure this program is supported. Adequate capital and financial resources exist to support the procurement and maintenance of this technology.

5. Community and Economic Impact

a. Community Engagement:
Although we have not conducted formal outreach sessions specific to this program, the surgical robotics program was pursued as part of a broader effort to increase local access to high-quality, minimally invasive procedures for the patients we serve. We believe the addition of this program will reduce the need for patients to travel to outside facilities, which disproportionately affects low-income and elderly patients.

b. Resource Availability:
Fortunately, the surgical robotics program will be supported by existing staff and management. The supplementation of additional labor and facilities will not be required to sustainably manage this program.

c. Organizational Relationships:
The surgical robotics program will be fully integrated with out existing ancillary and support services, including imaging, anesthesia, sterile processing, nursing, and postoperative care. These services are already in place to support a broad range of surgical techniques.

FVH maintains informal relationships with outside providers and may explore future collaborative opportunities. The program is designed to serve as a sustainable and self-contained service line within our health system with capacity for further growth and potential integration into broader regional care strategies.

6. Project Planning

a. Project Timeline:
The start of this program will be contingent on approval of Certificate of Need (CON), but there is intent to start performing cases in January 2026.

Key Milestones:
- IT Readiness: November 2026
- Case Observations: November 2025
- Equipment delivery and staff training: December 2025
- Perform first cases: January 2026

b. Innovative Components:
Floyd Valley Healthcare will significantly improve accessibility to state-of-the-art surgical interventions for underserved populations, including older adults and low-income residents who face disproportionate challenges in accessing care (Coughlin, et al., 2020).

The implementation of this technology stands to reduce surgical complications, readmission rates, and length of stay. These improvements are desirable to the patients within our community (Intuitive, 2025).

c. Regulatory Compliance:
We have assigned a compliance coordinator that will be involved in implementation who will be focused on ensuring all regulatory requirements are met and that all is in line with CMS guidelines. All providers will achieve appropriate credentialing prior to using the technology.

Floyd Valley Healthcare will leverage existing general surgery quality assurance measures to monitor the effectiveness and safety of the program. Surgical case quality outcomes will be compared to quality outcomes from laparoscopic and conventional open surgery to determine effectiveness. 30-day complication and readmission rates, surgical site infection rates, and accidental puncture rates will be monitored on an ongoing basis. Lastly, FVH will implement a robotics success team. This team will be responsible for case review, growth opportunities and overall success of the program. The team will consist of general surgeons, OR Manager, Chief Nursing Officer and other key stakeholders.

7. Special Criteria for Specific Services:

a. Alternative Consideration (10A.714(2)(a)):
Implementing an in-house surgical robotics program is the most practical and patient-centered solution. The proposed addition of these technologies allow Floyd Valley Healthcare to modernize its surgical services, meet rising patient needs, and ensure that high-quality care remains accessible within our health system.

b. Utilization of Similar Facilities (10A.714(2)(b)):
Floyd Valley Healthcare is the primary provider of surgical services in the immediate region and there are no local facilities offering robotic-assisted surgery within Plymouth County. This project represents an appropriate and efficient expansion of care capabilities in response to an unmet need, rather than a duplication of existing services.

c. Construction/Modernization (10A.714(2)(c)):
The addition of a surgical robotics program demonstrates Floyd Valley Healthcare's commitment to the modernization of care offerings. Robotic-assisted surgery represents a significant advancement in minimally invasive surgical intervention.

We remain open to collaboration with regional providers who would like to refer patients for robotic-assisted procedures, and will continue to explore opportunities that increase access, efficiency, and sustainability.

d. Access Concerns (10A.714(2)(d)):
The absence of robotic-assisted capabilities may compromise our ability to recruit and retain high-quality surgeons, placing further strain on access to surgical care in the region over time. Failure to implement this program will exacerbate existing disparities, limit patient choice, and threaten the long-term sustainability and competitiveness of local surgical services.

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

Signature

Additional Supporting Documents Upload