CentegraHealthSystem

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May 26, 2017

Ms. Courtney Avery
Administrator
Illinois Health Facilities and Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, IL 62761

Re: **Project #17-002, Mercy Health Hospital and Medical Center, Crystal Lake**

Report of Certificate of Need ("CON") Application Deficiencies

Dear Ms. Avery,

I am Senior Vice President of Strategy and Development for Centegra Health System. I am submitting this written comment in opposition to Project #17-002 on behalf of Centegra Health System, Centegra Hospital-McHenry, Centegra Hospital-Woodstock, and Centegra Hospital-Huntley.

The Illinois Health Facilities and Services Review Board ("IHFSRB") should deny the Certificate of Need ("CON") application for Project #17-002.[1] The applicants request a permit to establish a new hospital named Mercy Health Hospital and Medical Center Crystal Lake. This is the third application for a hospital at this site, with this filing preceded by Project #03-049 and Project #10-089. The first of these projects was overturned by a court based on the determination that the project failed to substantially comply with state standards and the second project was rejected by this Board twice based upon the identical determination. The IHFSRB should deny this application as well because:

(1) The application fails to meet—or even address—numerous IHFSRB regulations and review criteria.

(2) The applicants fail to provide appropriate/sufficient documentation, justification, or support for a number of assertions and statements, rendering the application inaccurate, unreliable, and in conflict with existing and available data.

(3) The proposed project will significantly and negatively impact the Harvard, Illinois community.

(4) The applicants fail to demonstrate compliance with hospital standards set by the Centers for Medicare and Medicaid Services ("CMS").

[1] IHFSRB received the application on January 24, 2017, and received additional information, corrections, and modifications on February 2, 2017, February 9, 2017, March 24, 2017, March 29, 2017, and April 28, 2017.

First, the applicants fail to meet or address numerous IHFSRB regulations and review standards. Each deficiency is explained in detail throughout the following report. Examples of these deficiencies include:

- As discussed at page 9 below, the application fails to meet IHFSRB requirements under Section 1110.530 for the medical/surgical and ICU bed categories of services in that:
  - The number of requested medical/surgical (11) beds is drastically below the State standard within a MSA of a minimum of 100 beds.
  - The number of requested ICU (2) beds is below the State standard of 4 beds.
  - The planning area already has an excess of 43 medical/surgical and 3 ICU beds.
  - The proposed facility will decrease the utilization of other area providers, duplicate the services of existing facilities, and increase the maldistribution of services within the State.
  - The applicants fail to provide required historical data for the projected inpatient referrals, despite showing an ability to do in Project #10-089 for many of the same physicians attesting to referrals for Project #17-002.
  - The *projected* utilization level is below the State standard for ICU beds.
  - There is no identifiable service restriction in place at existing area facilities.
- As discussed at page 16 below, the application fails to meet requirements under Section 1110.3030 for the additional categories of services, in that:
  - The application fails to follow IHFSRB instructions and fails to meet the criteria for establishing service to the planning area.
  - The application fails to document the required indicators for establishing a projected demand for the diagnostic imaging, emergency, and surgery services.
  - The applications fail to document the proposed project's impact on area providers; when available data unequivocally confirms that existing providers are already underutilized.
- As discussed at page 6 below, Project #17-002 is programmatically and architecturally interdependent with the applicants' additional proposal for a medical office building (Project #17-001). Under IHFSRB regulations at 77 Ill. Adm. Code 1130.310(b)(1), these projects should be considered as a single application, which raises the cost of the proposed project to $8 million per bed.

Second, as discussed throughout the following report, statements that are inaccurate, unreliable, and in conflict with available data proliferate the application. For example:

- The applicants state: "There is no hospital with emergency services in Crystal Lake or the planning/market area." This is false. In actuality, there are 5 hospitals with emergency services located within the 30-minute planning/market area.

- As discussed at page 34 below, the applicants neither justify nor explain why a 13-bed hospital requires nearly the same non-clinical space as a 70-bed facility. The project proposes a 13-bed hospital over 68,000 sq. ft. of non-clinical space, with only 43,000 sq. ft. of clinical space. The same applicants proposed a 70-bed hospital in Project #10-089 with 91,000 sq. ft. of clinical space and approximately 75,000 in non-clinical space.

- The applicants have a documented history of refusing to collaborate with community-based organizations in the area yet, they indicate they will now seek such collaboration. In fact, as discussed at page 33 below, the application ignore the results of community health studies, as it does not address behavioral health at all – yet the diagnosis of "psychoses" was the **#1 Reason** for hospital admissions per the 2014 McHenry County Healthy Community Study.

- As discussed at page 31 below, the applicants indicate the proposed design will result in "lower costs." However, this will only be possible due to the fact that the applicants will not provide critical care services to the community, such as Trauma Level Emergency Services, Advanced Stroke Care, and Cardiac Care Services.

- In an effort to lead this Board to believe that they are presenting something novel or unique, the applicants label the proposed facility a "Micro Hospital," yet they fail to meet any of the typical characteristics for this care venue as outlined by the very sources cited by the applicants. In fact, per the Advisory Board, a source cited by the applicants, a "Micro Hospital" generally:
  - Has between 8 and 10 inpatient beds;
  - Costs between $7 to $30 million;
  - Is of a size between 15,000 to 50,000 square feet (average major hospital is typically 74,600 square feet; and
  - Is built to fill identified gaps in service.

  Here, none of these factors exists. Rather, the proposed facility will include 13 inpatient beds, will approximately cost in excess of $50 million above the industry standard, will be more than double in size, and will be built in an area that already has 5 full-service, acute care hospitals located within a driving distance of 30 minutes.

Third, as discussed at pages 28 and 32 below, Project #17-002 would negatively and significantly impact the Harvard, Illinois community. The applicants propose to reduce the number of beds at Mercy Hospital Harvard as part of this project, and consistently misrepresent data in this regard. In fact, Mercy Harvard Hospital had an Average Daily Census of 4.6 patients in 2015. This means more than 4 patients on average required services at the hospital every day. **The applicants' proposed reduction to 4 medical/surgical beds in Harvard would render the hospital unable to meet its AVERAGE patient volume on a daily basis.** The peak census – meaning the most patients at the hospital on any given day – was 11 in 2015. Also, per the Environmental System Research Institute, Harvard's population is

anticipated to grow 7.4% by 2021, whereas Crystal Lake's population is projected to remain constant. Thus patient need would be unmet by a 4-bed facility. Furthermore, Harvard has a median income of $56,426, whereas Crystal Lake has a median income of $88,000. This data unveils the applicants' true intent with this project – to better position themselves for financial gain through the provision of ***outpatient*** healthcare services. The Harvard community, however, will suffer as a result.

Fourth, the applicants' proposed "Micro-Hospital" design for Project #17-002 fails to meet federal standards for a hospital and will therefore be subject to intense regulatory scrutiny from CMS. Federal regulations require that a hospital be "primarily engaged" in providing inpatient services to be approved for participation in the Medicare and Medicaid programs. Based on this standard, CMS has denied certification to hospitals with a small number of inpatient beds that provide significantly more outpatient than inpatient services. By the applicants' own admissions, and as discussed in more detail at page 34 below, the proposed venture fails to meet this federally-mandated standard, significantly jeopardizing the ability to serve Medicare and Medicaid beneficiaries.

For all of these reasons, the IHFSRB should deny Project #17-002. The following report provides a more definitive and comprehensive analysis of the application's deficiencies, inaccuracies, and omissions.

Respectfully submitted,

By: Hadley Streng

Hadley Streng
Senior Vice President of Strategy and Development
Centegra Health System

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REPORT OF DEFICIENCIES

I. Interdependence with Application #17-001: The proposed project should be denied based on its interdependence with Mercy Health's simultaneous Application #17-001, a medical office building which, by Mercy's admission, will be "physically and programmatically connected" to the proposed hospital.

Established review criteria provides that:

> "Components of construction or modification that are interdependent must be grouped together. Interdependence occurs when components of construction or modification are architecturally and/or programmatically interrelated to the extent that undertaking one or more of the components compels the other components to be undertaken."[2]

In both the original application and the March 24, 2017 modification to this application, Mercy states: "In a separate but related permit application, the co-applicants propose construction of a medical office building, physically and programmatically connected to the new hospital." Additionally, Javon Bea, President/CEO of Mercy, submitted written testimony dated February 21, 2017, in which he addressed both applications as a single scope. On page 1 of his testimony, Mr. Bea describes the proposed hospital as being "adjacent and integrated" to the medical office building. On Page 2, Mr. Bea specifically refers to both applications as in the singular, describing the applications as "this proposed project," and also describes Mercy's success as dependent on "coordinated care, with physicians and hospitals and associated services provided by one integrated system." On page 3, Mr. Bea again describes Mercy's intent of this proposal to establish "hospital and physician offices [as] part of the same organizational entity" dependent on "integrated coordinated care." Mercy further proves the interdependence of its applications, again via its February 2, 2017 and March 24, 2017 letters to the Board, by supplying modifications for both proposed projects under this single filing.

The statements within the application, Mr. Bea's written testimony, and the continuous procedural treatment of these applications as a singular component demonstrate that the proposed hospital project compels the medical office building project, and vice versa, as Mercy's goal to establish these facilities on the same site to achieve the purported level of coordination and integration would not be possible absent both filings. Treating #17-002 as a separate application therefore violates the existing CON review criteria per Illinois regulation, as these applications are "interdependent."

[2] 77 Ill. Adm. Code 1130.310(b)(1).

As a result of this "interdependence," the true cost per bed of the proposed hospital rises to approximately $8 million. These high costs should not be borne by the residents of the proposed Metropolitan Statistical Area. However, this will be the result should the Board approve the project.

For all the foregoing reasons, the Board should deny Application #17-002 on the basis of its "interdependence" with Application #17-001, and to avoid the pass-through of the at least $8 million cost per bed of this project to patients of the proposed Metropolitan Statistical Area.

II. Failure to Meet Illinois Standards and Review Criteria: The proposed project should be denied based on its failure to meet the requirements specified in a number of the State of Illinois' regulatory criteria and CON application instructions.

For organizational purposes, the applicants' failures to meet defined regulatory standards are addressed below in the order of the attachments for the CON filing:

A. Attachment 2: Proof of Ownership or Control of the Site

The application for Project #17-002 fails to provide documentation of the ownership and control of the proposed site location by the applicants, as is required within the CON application instructions.

The Trustees Deed provided at Attachment 2 simply displays the ownership rights of Mercy Health System Corporation, Inc. While Mercy Health System Corporation, Inc. is a related party to the operating entity, Mercy Crystal Lake Hospital and Medical Center, Inc., Mercy Health System Corporation, Inc. is not **a** co-applicant within the application or a parent of the operating entity.

The documentation of the ownership or control of the site provided in Attachment 2 should establish the **operating entity's** ownership or control of the proposed site. The applicants provided no documentation satisfying this requirement within the filed application.

B. Attachment 3: Operating Identity/License

The application for Project #17-002 does not identify persons with greater than 5% ownership interest in the licensee/operating entity within Attachment 3, as is required by the CON application directives on Page 3.

Per the CON application instructions: "Information to be considered must be included with the applicable Section attachments. References to appended material not included within the appropriate Section will NOT be considered." Accordingly, Attachment 3 appears to be an invalid response to the application directive, as the organizational chart within Attachment 4 clearly displays Mercy Health Corporation is a parent entity of the operating entity, Mercy Crystal Lake Hospital and Medical Center, Inc.

C. Attachment 12: Project Purpose

Although the applicants provide a response to each of the required questions, there are numerous issues with the applicants' responses. The issues may be pervasive enough to lead to a deficient finding on the applicants' ability to meet the requirements for these criteria. The issues are outlined in more detail is Section III(A) below.

D. Attachment 13: Alternatives

The CON application for Attachment 13 state: "The applicant shall provide empirical evidence, including quantified outcome data that verifies improved quality of care, as available."

The applicants fail to provide any empirical evidence to support the assertions within Attachment 13, including the absence of any evidence that verifies the project will improve the quality care. Here, however, the applicants fail to even address that this requirement exists, failing to discuss it in any manner for the IHFSRB's review.

The CON applications instruction provide, in part, that: "ALL APPLICABLE CRITERIA for each applicable section must be addressed. If a criterion is NOT APPLICABLE, label it as such and state the reason why."

The applicants' response to Attachment 13 is deficient without addressing each of the required response items within the CON applications.

E. Attachment 15: Project Services Utilization

Despite failing to meet the minimum 4-bed ICU standard, the applicants are still unable to demonstrate the ability to meet the minimum facility utilization rates required for the ICU categories of service with only 2 ICU beds. The established review criteria provide that:

a. "Facilities that provide intensive care services should operate those beds at or above an annual minimum occupancy rate of 60%."[3]

The application clearly documents within Attachment 15 that the applicants cannot create a projection that would meet the 60% occupancy standards. The applicants request 2 ICU beds, but can only project a 17% occupancy rate. Further, it is unclear why the applicants, as discussed on Page 82 of the applications, believe the Crystal Lake Hospital would require a second ICU bed for max capacity, while Mercy Harvard Hospital will not require a second ICU bed.

b. Additional deficiencies with the provided information provided within Attachment 15 is discussed in more detail in the analysis of Attachment 20 and Attachment 34 in the following sections.

F. Attachment 20: Criterion 1110.530 - Medical/Surgical, Obstetric, Pediatric and Intensive Care

a. 1110.530(c)(1) - Planning Area Need

The applicants fail to document that the number of beds (11 medical/surgical & 2 ICU) are necessary to serve the planning area (A-10, McHenry County) population based on the regulatory requirements.

Specifically, the application fails to document:

(1) The establishment of 11 medical/surgical beds at the new hospital is in conformance with the projected bed excess of 43 medical/surgical beds within the planning area; and

(2) The establishment of 2 ICU beds is in conformance with the projected bed excess of 3 ICU beds within the planning area.

The applicants attempt to circumvent these deficiencies by "transferring beds" from Mercy Harvard Hospital. The application is for the establishment of a new hospital, not the relocation of Mercy Harvard Hospital. A "transfer" of beds from one operational facility to an unrelated facility does not meet the regulatory requirement. Even so, relocation equals establishment per the regulations and must meet the same standards.

[3] 77 Ill. Adm. Code 1100.540(c).

b. *1110.530(c)(3) - Planning Area Need - Service Demand - Establishment of Category of Service*

The applicants fail to appropriately document the projected number of referrals for the proposed medical/surgical and ICU bed categories of service.

The regulations under section 1110.530(c)(3)(B)(i) require that the applicants submit physician referral letters "that attest to the physician's total number of patients (by zip code of residence) who have received care at existing facilities located in the area during the 12-month period prior to submission of the application."

The applicants provided physician referral letters that fail to meet this requirement. The referral letters are not based upon patients that have received care at existing facilities located in the area during the 12-month period prior to the submission of the application. Instead, the physician letters attest to committing a percentage of their "patient panels" for the family practitioners and internists with no direct reference to care at area facilities. The "patient panel" referrals compose the majority of the projected patient referrals.

Adding to the confusion is the fact the applicants state the necessary patient information is unavailable due to how patients are tracked for admission to area hospitals. Notably, Mercy Health was able to provide patient referral history for many of the same physicians within its submission for Project #10-089.

For example, in Project 10-089, the following Mercy physicians, who provide attested referrals within Project #17-002, provided and attested to the historical numbers of patients who received care at area facilities in Fiscal Year 2010:

- Bibiano Ronquillo
- Emily Shen
- Nathan Kakish
- Roshi Gulati
- Monica Gavran
- Joseph Fotjik
- Steven Campau
- Graziella Bistriceanu
- Kim Alrbight
- Mabria Loqman
- Camelia Marian

Because the applicants fail to provide the required information under section 1110.530(c)(3)(B)(i), they fail to provide documentation sufficient to confirm that the "The

anticipated number of referrals [does not] exceed the physician's documented historical caseload," as is required under 1110.530(c)(3)(B)(ii).

The applicants cannot avoid the regulatory requirements by promulgating their own standards for review. The methodology used by the applicants in their physician referrals fails to meet the State's requirements for establishing projected referrals for medical/surgical and ICU beds.

c. *1110.530(c)(5) - Planning Area Need - Service Accessibility*

The applicants fail to document that at least one (1) of the five (5) service restrictions factors outlined within section 1110.530(c)(5) exists within the planning area. As a result, the planning area does not demonstrate a need for the proposed project and the establishment of the medical/surgical and ICU beds in Crystal Lake is unnecessary to improve access for planning area residents.

Specifically, the applicants fail to demonstrate any of the following factors exist:

1. The absence of the proposed service within the planning area;
2. Access limitations due to payor status of patients, including, but not limited to, individuals with health care coverage through Medicare, Medicaid, managed care or charity care;
3. Restrictive admission policies of existing providers;
4. The area population and existing care system exhibit indicators of medical care problems, such as an average family income level below the State average poverty level, high infant mortality, or designation by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;
5. For purposes of this subsection (c)(5) only, all services within the 45-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

The applicants make a failed attempt to meet the State requirements by simply referencing both (1) continuity of care not being "optimized" for patients of Mercy Health physicians who are hospitalized within another system and (2) duplicative testing occurring for patients of Mercy Health physicians due to lack of complete care records.

Notably, the applicants fail to provide even one source or citation to support the assertions within this section of the application. The regulations require the applicants to provide, among

other documentation, "An assessment of area population characteristics that document that access problems exist". 77 Ill. Adm. Code 1110.530(c)(5)(B)(vi). Mercy does not include any such assessment within the application. This is a clear failure of the applicants to document the asserted conditions exists within the planning area.

Finally, any assertions that continuity of care will be addressed by the proposed project sidesteps the obvious question of whether Mercy has assessed the costs and potential to increase continuity of care through the implementation of Electronic Medical Record (EMR) technology that is compatible with area hospitals. This would appear to be a feasible method for reducing duplicative testing on a timely, potentially more cost effective, and comprehensive basis for patients of Mercy Health physicians.

d. 1110.530(d)(1) - Unnecessary Duplication of Services

The applicants fail to document that Project #17-002 will not result in an unnecessary duplication of services for medical/surgical and ICU beds within the area.

The applicants state: "The relocation of the 11 medical/surgical beds and 2 ICU beds from Mercy Harvard Hospital in the same Planning Area A-10 does not result in a duplication of existing beds." The applicants then document the zip codes, population, and health care facilities located within 30 minutes of the proposed location without additional comment.

Contrary to the applicants' statement, the documentation clearly demonstrates that there are more beds within 30 minutes of the proposed location than there are within the entire Planning Area A-10.

Project #17-002 Planning Area (30 Minute Travel Radius)[4]			
Hospital	**Adjusted Travel Time**	**Med/Surg Occupancy**	**ICU Occupancy**
Advocate Good Shepherd Hospital	12.65 minutes	112	32
Advocate Sherman Hospital	24.15	189	30
Centegra Hospital – Huntley	16.1	100	8
Centegra Hospital – McHenry	12.65	116	18
Centegra Hospital – Woodstock	18.4	60	12
Totals		**577**	**100**

[4] See page 105 & 107, Attachment 20, of Project #17-002; See also Illinois Health Facilities and Services Review Board, Hospital Profiles 2015. https://www.illinois.gov/sites/hfsrb/InventoriesData/FacilityProfiles/Pages/default.aspx.

State Planning Area A-10 (McHenry County)[5]		
Hospital	**Med/Surg Occupancy**	**ICU Occupancy**
Mercy Harvard Hospital	15	3
Centegra Hospital – Huntley	100	8
Centegra Hospital – McHenry	116	18
Centegra Hospital – Woodstock	60	12
Totals	**291**	**41**
Excess Beds	**43**	**3**

Planning Area A-10, as well as three (3) of the adjacent IHFSRB Planning Areas, already have an identified excess of medical/surgical and ICU beds. Clearly, the proposed discontinuation of 13 total beds at Mercy Harvard Hospital to Crystal Lake will unnecessarily duplicate the extensive services already available within 30 minutes of the proposed location.

The fact that Mercy plans to close an equal number of beds within Planning Area A-10 at Mercy Harvard Hospital, at the same it plans to establish the new hospital, does not alter the fact that the establishment of addition medical/surgical and ICU beds is an unnecessary duplication of services. The State regulations recognize this fact by requiring applicants to list the health care facilities offering the same services ***within 30 minutes*** of the proposed facility for purposes of this assessment. The services available within the area immediately surrounding the proposed facility are much more relevant to the duplication of services than the closure of a facility more than 30 minutes away.

e. *1110.530(d)(2) - Maldistribution*

The applicants fail to document that the project will not result in the maldistribution of services.

Per the section 1110.530(d)(2)(B), maldistribution exists when the historical utilization for existing facilities and services in the identified area are below the established occupancy standards. The existing facilities within the area offer the proposed services and are operating below the established occupancy standards.

[5] See Illinois Health Facilities and Services Review Board – 2015 Inventory of Health Care Facilities and Services and Need Determinations. https://www.illinois.gov/sites/hfsrb/InventoriesData/HealthCareFacilities/Pages/default.aspx.

Per the 2015 Hospital Profiles published by the IHFSRB, and the 2016 standards reported to the IHFSRB by Centegra, the area facilities have the following utilization levels that fall below the state standards:

Underutilized Medical/Surgical Beds			
Underutilized Facility	2015 Utilization Rate (CON Standard)	2016 (CON Standard)	Distance from Site
Centegra Hospital – McHenry	62.4% (85%)	66.1% (85%)	7.2 miles
Advocate Sherman Hospital	71.4% (85%)	2016 Unavailable	12.6 miles
Centegra Hospital - Woodstock	59.7% (80%)	54.9% (80%)	8.1 miles
Centegra Hospital - Huntley	N/A Opened 2016	31.8% (80%)	8.8 miles

Underutilized Intensive Care Beds			
Underutilized Facility	2015 Utilization Rate (CON Standard)	2016 (CON Standard)	Distance from Site
Advocate Sherman Hospital	54.8% (60%)	2016 Unavailable	12.6 miles
Centegra Hospital - Woodstock	52.1% (60%)	46.3% (60%)	8.1 miles

As such, an increase in medical/surgical and ICU beds will only cause these utilization levels to fall even further below these standards. The applicants fail to address this fact. The applicants rely upon an assessment of the ratio of beds to population within the area, in comparison to the state averages, to declare maldistribution does not exist within the planning area. This argument fails to meet the regulatory requirements and ignores clear evidence that the establishment of medical/surgical and ICU beds in Crystal Lake will result in maldistribution of serves within Planning Area A-10 due to the substandard utilization of existing area providers.

Likewise, the applicants' reference to the project's impact on the total beds within Planning Area A-10 is inapplicable to determining whether maldistribution exists within the area. In fact, **the proposed "relocation" of beds will exacerbate the maldistribution within the Planning Area by moving beds from area with fewer services to an area served by a dense cluster of existing providers with low utilization levels.**

The evidence clearly demonstrates that maldistribution within the area exists and that the proposed facility will compound the issue.

f. 1110.530(d)(3) - Impact of Project on Other Area Providers

The applicants fail to document that the proposed project will not lower the utilization of other area providers below the occupancy standards, or lower to a further extent the utilization of other area hospitals that are already operating below the occupancy standards.

The applicants admit that the 780 patients projected to be inpatients at the facility will be diverted from the area providers.[6] With four (4) hospitals within 30 minutes (Centegra Hospital – McHenry, Centegra Hospital – Woodstock, Advocate Sherman Hospital, and Centegra Hospital – Huntley) already operating below the established utilization standards for medical/surgical and ICU beds, it is clear the impact on area providers will be detrimental to an already difficult patient volume environment.

The assertion by the applicants that the proposed facility's impact on area providers is minimal is immaterial to compliance with the regulations. It also fails to acknowledge that the proposed medical/surgical and ICU beds are the basis for even more extensive outpatient services which will also detrimentally affect the utilization of other area providers. This issue is outlined in more detail in Section II(G) below.

g. 1110.530(g) - Performance Requirements

The application for Project #17-002 fails to meet the requirements for the minimum number of medical/surgical and ICU beds.

The proposed facility is eighty-nine (89) beds short of the requirement that "The minimum bed capacity for a new medical-surgical category of service within a Metropolitan Statistical Area (MSA) is 100 beds." 77 Ill. Adm. Code 1110.530(g)(1).

The proposed facility is two (2) beds short of the requirement that "The minimum unit size for an intensive care unit is 4 beds." 77 Ill. Adm. Code 1110.530(g)(3).

[6] See page 107, Attachment 20 of Project #17-002.

Significantly, the failure to meet this requirement has been upheld as the basis for the denial of an application by Illinois courts. [7]

The applicants attempt to assuage concern over this deficiency by stating, "...this project is the shifting of beds being relocated from an existing hospital more so than the establishment of a new hospital." This has no relevancy to the regulatory requirement and is a clear disregard for the minimum bed standards consistently upheld by the IHFSRB when promulgating the rules throughout the years.

As the applicants state, "...construction of a full-service hospital with the minimum number of beds is not consistent with the needs of the planning area."

This is a true statement and should be provided greater deference and consideration for its acknowledgement of the facts and regulations than is afforded to the unsubstantiated argument by the applicants that 11 medical/surgical beds and 2 ICU beds are necessary within Crystal Lake.

G. Attachment 34: Criterion 1110.3030 - Clinical Service Areas other than Categories of Service:

a. *1110.3030(c)(1) - Need Determination – Establishment – Service to the Planning Area Residents*

The applicants fail to meet the regulatory requirement to document that the primary purpose of the project is to provide care to residents of the service area.

The applicants reference section 1110.530(c)(3), as support for the ability of the project to meet section 1110.3030 requirements:

"As demonstrated in Service Demand – Establishment of Planning Area Need 1110.530(c)(2) and (c)(3), 70% of patients come from 30 zip codes within a 30 minute travel time area."

However, as discussed in Section II(F)(b) above, the applicants fail to meet the regulatory requirements of section 1110.530(c)(3). The reference to a deficient section of the application

[7] Memorandum Opinion and Order of Circuit Judge Maureen P. McIntyre dated May 6, 2005. Case ID: 04MR000106. http://68.21.116.46/wow65/runApp?pj_savedHTML=1495559679621.

to meet the requirements appears to make the applicants' response deficient under the requirements of section 1110.3030(c)(1).

The applicants further violate the regulatory requirements by failing to provide "Documentation [that] consist[s] of strategic plans or market studies conducted, indicating the historical and projected incidence of disease or health conditions, or use rates of the population," as is required by section 1110.3030(c)(1)(b) within Attachment 34.

In addition, any reference to materials included within previous attachments and sections should not be considered when assessing whether the application meets the requirements of Attachment 34 and section 1110.3030(c)(1). Per the CON application instructions: "Information to be considered must be included with the applicable Section attachments. References to appended material not included within the appropriate Section will NOT be considered."

b. *1110.3030(c)(2) - Need Determination – Establishment – Service Demand*

The applicants fail to "document one or more of the indicators presented in subsections (c)(2)(A) through (D)" and do not demonstrate a need for the proposed services.

First, as with the response to criterion 1110.3030(c)(1), the applicants inappropriately reference their response to Attachment 15 to provide the required support and documentation of their response to criterion 1110.3030(c)(2) within Attachment 34. This is in violation of the CON instructions and should not be considered in assessing compliance with this criteria.

Should the Attachment 15 responses be considered, the responses within Attachment 15 still do not meet the regulatory requirements under section 1110.3030(c)(2). Specifically, section 1110.3030(c)(2) requires that the applicants demonstrate each of the proposed clinical service areas demonstrate that at least one the following indicators exist in order to justify the service:

- **Referrals from Inpatient Base**: For CSAs that will serve as a support or adjunct service to existing inpatient services, the applicant shall document a minimum two-year historical and two-year projected number of inpatients requiring the subject CSA.
- **Physician Referrals**: For CSAs that require physician referrals to create and maintain a patient base volume, the applicant shall document patient origin information for the

referrals. The applicant shall submit original signed and notarized referral letters, containing certification by the physicians that the representations contained in the letters are true and correct.

- **Historical Referrals to Other Providers**: If, during the latest 12-month period, patients have been sent to other area providers for the proposed CSA services, due to the absence of those services at the applicant facility, the applicant shall submit verification of those referrals, specifying: the service needed; patient origin by zip code; recipient facility; date of referral; and physician certification that the representations contained in the verifications are true and correct.

- **Population Incidence**: The applicant shall submit documentation of incidence of service based upon IDPH statistics or category of service statistics.

Application deficiencies in this regard are addressed by service line below (in the same format as prescribed within the application):

Diagnostic Imaging: The applicants use four different data items to justify one (1) unit of each of the following imaging services: General X-Ray, Fluoroscopy, Dexa/bone densitometry, MRI, CT, Nuclear Medicine, Ultrasound, Mammography, and Cardiac Testing (Echo/Stress Testing).

Specifically, the applicants assert "Imaging volumes at the new facility will incorporate imaging (1) now done at three existing Mercyhealth clinics in the area, to be transferred to the new facility; (2) capturing of an estimated 70% of the outpatient imaging volumes sent to other locations by Mercyhealth physicians; (3) imaging tests on inpatients at the proposed new hospital; and (4) imaging tests on Emergency Department patients at the proposed new hospital." The failure of these four data items to meet the regulatory requirements under section 1110.3030 are examined below.

1. Data item (1) fails to meet the requirements of section 1110.3030(c)(2) as the applicants simply provide an unverified table of FY 2015 and 2016 imaging data from three Mercy clinics. This information is not based **Referrals from Inpatient Base**. The applicants do not provide physician referrals with patient origin by zip code and signed, notarized physician certifications to meet the **Physician Referrals**. The applicants do not provide physician-certified, verified historical referrals with the patient zip codes, recipient facility and date of referral for these imaging services to meet the **Historical Referrals to Other Providers**. Finally, the data is not based upon **Population Incidence**.

2. Data item (2) fails to meet the requirements of Section 1110.3030(c)(2) as the applicants reference **Historical Referrals to Other Providers**, but fail to provide any of the required

physician certification, patient zip code, recipient facility, or date of referral information required to substantiate the data listed within the application.

3. Data item (3) fails to meet the requirements of Section 1110.3030(c)(2) as the applicants appear to reference **Referrals from Inpatient Base**, but fail to document the required "minimum two-year historical and two-year projected number of inpatients requiring the subject CSA." As discussed in Section II(F)(b), the applicants never provide appropriate historical documentation for the projected inpatients.

   If the intent is for this data to be a projection based upon **Population Incidence** rates, the applicants still fail to substantiate their incidence rates with clearly identifiable IDPH or category service statistics.

   Finally, the chart included on Page 84 of the application for data item (3) includes 692 medical patients and 44 surgical patients. These figures are never explained, as the rest of Attachment 15 references 737 medical admissions and 43 surgical admissions.

4. Data item (4) fails to meet the requirements of Section 1110.3030(c)(2) as the applicants appear to reference a **Population Incidence** based upon the incidence rates for each imaging service per Emergency Department patient. These projections are faulty due to the unsubstantiated incidence rate (there is no citation to a public data source for these rates) and the underlying Emergency Department patient volumes, which are also unsubstantiated and fail to meet the regulatory requirements to verify the service demand projections.

Each of the projected diagnostic service volumes, with the exception of the Cardiac Testing, are required per Section 1110.Appendix B. However, the applicants fail to appropriately document and justify any of these diagnostic imaging services due to the various deficiencies with each of the four (4) data items they provided to substantiate their Service Demand projections.

Particularly egregious is the obvious disregard by the applicants for documenting the historical and projected physician referrals and the facilities these referrals will be diverted from as a result of the project. This makes it impossible for the public or the IHFSRB to have a clear vision of the impact on other area providers, which is a requirement examined in more detail in Section II(G)(c) below.

Emergency Services: The applicants do not appropriately explain and document the **Population Incidence** rates that are used to project the Service Demand for emergency services within this application.

The applicants project that the new Emergency Room ("ER") will primarily serve the communities of Crystal Lake, Algonquin, Cary, Lake in the Hills, and Fox River Grove, with approximately 75% of the visits coming from these 5 communities, providing a chart breaking down the expected ER patient capture volume from each community calculated by applying a percentage to the total 2015 ER visits per zip code.

There is no documentation or explanation of the percentage rates used for each community. For example, beyond a simple reference to distance, the applicants provide no support for the assertion that "The new ER will serve 50% of the ER visits in Crystal Lake and Cary..." The response does not include any consideration of clinical capabilities and EMS transfer designations that are relevant to the expected patient capture rates.

Further, there is no discussions about why area patients would utilize the 7 bed, low-acuity ER at the proposed facility instead of the larger, higher-acuity ERs within the area. With the proposed location surrounded by existing facilities with low utilization levels, it appears to be a very relevant issue to discuss.

Surgery: The applicants do not appropriately document the surgical data used to support the Service Demand for two (2) operating rooms and two (2) procedure rooms.

Specifically, the applicants reference multiple "physicians" who are not yet identified or connected with the applicants or the area. For example, the applicants reference:

- 389 hours for a general surgeon to be recruited by Mercyhealth in support of the ORs;
- 839 hours for a gastroenterologist to be recruited by Mercyhealth in support of the procedure rooms; and
- 219 hours for a part time pain management physician to be hired in support of the procedure rooms.

There is no way to verify these figures as they fail to meet any of the regulatory support factors for referrals or incidence rates.

Further, the applicants allege:

> "Mercyhealth physicians performed outpatient procedures on 613 patients last year. There were 1.24 procedures per patient, resulting in a total of 762 procedures" to project 685 hours in support of the procedure rooms.

Again, the applicants fail to provide any documentation to support these alleged procedures or explain why such rates would lead to procedures at the proposed facility. These "Mercyhealth physicians" could be located in Wisconsin and have no relation to expected Service Demand within Crystal Lake or the surrounding service area.

The purpose of section 1110.3030 requiring applicants provide information that demonstrates a demand for services, such as attested physician referrals based on historical volumes, is to ensure the IHFSRB can be assured the applicants have a reasonable basis for their projections.

On multiple occasions, the applicants fail to include: a physician attestation to the projection, historical data to support the assertion, or logical population incidence data to support the service projections. For this reason, the applicants fail to meet the requirements of section 1110.3030(c)(2).

c. *1110.3030(c)(3) - Need Determination – Establishment – Impact of the Proposed Project on Other Area Providers*

The applicants fail to document that the proposed project will not lower the utilization of other area providers below the occupancy standards, or lower to a further extent the utilization of other area providers that are already operating below the utilization standards for each of the following services:

- X-Ray/Flrouroscopy
- DEXA bone densitometry
- MRI
- CT
- Nuclear Medicine
- Ultrasound
- Mammography
- Emergency Services
- Surgery – Operating Rooms
- Surgery – Procedure Rooms

The applicants simply state that "The impact on any hospital or clinic provider of inpatient/outpatient surgery, emergency care, diagnostic imaging and other services due to a shift of service to the proposed new hospital is minimal." This is an unsubstantiated statement by the applicants that is inapplicable to determining compliance with Section 1110(c)(3).

Evaluating the truth of the statement is made even more difficult by the failure (as demonstrated above) of the applicants to provide appropriate justification and documentation of their service projections. For example, when the applicants commit thousands of hours in procedure room time from "to be identified sources" it is prohibitively difficult to identify the impact on specific facilities, furthering frustrating the intent of the IHFSRB rules.

It is clear that the proposed project will not be pulling its patients from Mercy Harvard Hospital, which is the purported "source" of the "transferred" beds for the project. Per the IHA COMPdata from January 1, 2016 – December 31, 2016, 69% of Mercy Harvard Hospital's inpatients originated from zip code 60033 in Harvard, Illinois. The applicants do not predict that any patients for the new facility will originate in Harvard, Illinois, and the second highest zip code of origin makes up less than 5% of Mercy Harvard's inpatient population.

The proposed project is simply removing beds from Harvard to create unnecessary beds in Crystal Lake, depleting the patient base for the existing providers within the planning area for Project #17-002.

The facts plainly evidence that the proposed project will lower the utilization of area providers. Just looking at hospital providers in the area, the following chart summarizes providers already below utilization levels for the services requested within the proposed project:

Services	Underutilized Area Providers (Hospitals Only)			
Emergency Services	Centegra Hospital–McHenry	Centegra Hospital–Woodstock	Advocate–Good Shepherd	
Operating Rooms	Centegra Hospital–McHenry	Centegra Hospital–Woodstock		
Procedure Rooms	Centegra Hospital–McHenry	Centegra Hospital–Woodstock	Advocate–Good Shepherd	
Ultrasound	Centegra Hospital–McHenry	Advocate–Sherman Hospital	Centegra Hospital–Woodstock	Advocate–Good Shepherd
MRI	Centegra Hospital–McHenry			

Mammography	Advocate–Sherman Hospital			
Fluoroscopy	Centegra Hospital-McHenry	Advocate–Sherman Hospital	Centegra Hospital–Woodstock	Advocate–Good Shepherd
Nuclear Medicine	Centegra Hospital–McHenry	Centegra Hospital–Woodstock		

d. 1110.3030(c)(4) - Need Determination – Establishment – Utilization

As identified in above sections, the applicants fail to meet the regulatory requirements in documenting various service demand projections for the services falling under section 1110.3030 requirements.

Each of the services enumerated in Section III(G)(b) above, which fail to provide sufficient documentation to establish the service demand, are also deficient with the utilization levels outlined in Section 1110.Appendix B and required to be met under this criterion. In particular, without the 1,743 hours used in support of the procedure rooms, the applicants fail to justify two (2) procedure rooms at 1,500 hours a room.

III. Inaccurate and Unreliable Statements: The proposed project should be denied based on its failure to provide appropriate/sufficient documentation, justification, or support for a number of assertions and statements, rendering the application inaccurate, unreliable, and in conflict with available data.

A. Attachment 12: Purpose of the Project

In response to the questions/requirements outlined within the CON application for Attachment 12, which is based upon section 1110.230, the applicants make numerous statements, which are inaccurate, unreliable, or conflict with available data.

a. In response to the requirement to "Document that the Project will provide health services that improve the health care or well-being of the market population to be served," the applicants provide that the proposed hospital design will: "...provide more immediate acute and emergency care when time matter." The applicants go on to reiterate that "The Project will improve the health care and well-being of the market area population for residents of Crystal

Lake and its surrounding communities by providing care at the right time in the appropriate setting."

Both of the statements are unreliable as they mislead the public and IHFSRB regarding the ability of the proposed facility to serve the emergency needs of the community. Two common emergency ailments are illustrative of why the applicants' assertion that the project will improve the health care or well-being of the market population through more immediate acute or emergency care is inaccurate and misleading.

i. **Cardiac Care**: Every 43 seconds someone in the United States has a heart attack.[8] This adds up to about 735,000 Americans being diagnosed with a heart attack each year. However, the proposed project does not include advanced cardiac care options to treat serious cardiac events.

   The comments made in written testimony opposing this project by Carlie Lesher, a certified cardiovascular care coordinator nurse and Chest Pain Coordinator for Centegra Health System, are insightful to this issue. As she relates, time is of the essence during a heart attack. If 911 is utilized, stabilizing treatment will be provided by first responders and if an EKG reveals the need for emergency intervention, "...the gold standard for care is to bypass any hospital that does not have a cardiac catheterization laboratory." Project #17-002 includes no such service. Meanwhile, **four existing area providers** serve the same market area and do **offer these advanced cardiac care services**.

   The real issue is when a patient drives to the Emergency Department at the proposed hospital, instead of the area providers properly equipped to address their emergency. As Carlie Lesher related, "If a patient who was suffering a heart attack walked into the emergency department at the proposed Crystal Lake micro-hospital, he would need to be triaged and then transferred for almost any type of cardiac care." This creates a critical delay in intervention that can result in increased damage to the heart muscle.

   Many health care consumers do not know the difference between an emergency department with advanced cardiac care, and those without. The proposed hospital will not

[8] https://www.cdc.gov/heartdisease/heart_attack.htm

improve cardiac care options for the community, but it may lead confused customers to arrive at the wrong hospital. Indeed, the issue is already being recognized within literature about micro-hospitals, with one article stating: "While a traditional hospital is preferable if a patient suffers a heart attack or major medical trauma, a micro-hospital is a good option for low-acuity illnesses.[9]

The applicants' statements lead one to believe the facility will provide emergency care for time sensitive care. Unfortunately, the proposed facility will not improve the immediate acute and emergency care for heart attack patients within the community.

ii. **Stroke Care**: Stroke kills more than 130,000 Americans each year, or 1 out of every 20 deaths.[10] More than 795,000 people in the United States have a stroke every year. With every 30-minute delay in advanced stroke care, your chances of a good outcome drop by 14%.[11]

The applicants do not specify the level of stroke care the proposed facility will provide to patients. Instead, Mercy praises the level of stroke care offered at its hospital in Harvard, Illinois and Walworth, Wisconsin. The stroke certification Mercy obtained at those rural, critical access hospitals (Acute Stroke Ready) is not one desired or appropriate for a facility in a Metropolitan Statistical Area.

This is not a low-priority issue. Indeed, all five of the other hospitals located in the planning area for Project #17-002 have a higher certification known as Primary Stroke Center. The existing area providers have made a commitment to ensuring the community receives time-sensitive stroke care. The applicants do not appear to be making the same commitment.

It is misleading and inaccurate to state that Project #17-002 will provide more immediate acute and emergency care to the community when common ailments that are the most time-sensitive are not being addressed by the facility.

[9] https://www.mbfinancial.com/insights/manage/articles/2017/20170330-microhospitals/index.aspx
[10] https://www.cdc.gov/stroke/facts.htm
[11] https://my.clevelandclinic.org/-/scassets/files/org/locations/marymount-hospital/specialties/marymount-stroke-infographic_2.ashx?la=en

b. In response to the requirement to "Identify the existing problems or issues that need to be addressed as applicable and appropriate for the project," the applicants provided three "problems or issues" on pages 62-64 of the application. The following are identified issues with the statements made by the applicants:

i. The applicants state: "There is insufficient access to care for indigent population in the market area."

1. The applicants provide no factual justification for this assertion. Neither the State of Illinois nor the Federal Government (U.S. Department of Health and Human Services Health Resources and Services Administration, HHS/HRSA) have identified the primary service area for this project (Crystal Lake, Algonquin, Lake in the Hills, Cary and Fox River Grove – as identified on Page 61 of the application) as being either a Medically Underserved Population or Medically Underserved Area.

ii. The applicants state: "There are insufficient health services to the growing geriatric population."

1. Again, the applicants fail to provide any support for this assertion, as they simply recite geriatric population statistics without any context for the service available to the geriatric population. Citing disease incident rates without an identified deficiency in available services for the geriatric community is an unreliable and inaccurate method for identifying an "issue or problem" within the market area.
2. As related by Sandy Montalvo, Manager of Social Services and Care Coordination at Centegra Health System, within her written opposition to Project #17-002, the applicants fail to consider the specific services available within the community today. For example, Centegra Health System places Nurse Practitioners within skilled nursing facilities throughout the region. The Nurse Practitioners manage patients and their chronic health issues to prevent readmissions when possible.

iii. The applicants state: "There is a shortage of primary care physicians and select specialists in McHenry County."

1. The applicants' statements regarding physician shortages is unreliable for the purposes of identifying an issue or problem within the 30-minute planning area of the proposed project because it only references McHenry County as a whole.
2. The applicants cite to sources of physician supply information that is available by zip code, yet fail to provide an analysis tailored for the 30-minute planning area of the proposed hospital, which is the focus of this section of the applications.
3. Neither the State of Illinois nor the Federal government has identified the area as a Healthcare Professional Shortage Area (HPSA).
4. Finally, as related in Section III(A)(c)(ii) below, this issue should not be accorded any weight by the IHFSRB is arriving at their decision to approve or deny the project.

iv. The applicants state: "There is no continuum of care for patients of Mercyhealth physicians in Crystal Lake and the immediate surrounding communities. There is no hospital with emergency services in Crystal Lake or the planning/market area."

1. The statement regarding emergency services being unavailable within the 30-minute planning/market area is factually inaccurate. There are four (4) hospitals with operational emergency departments within the adjusted 30-minute drive time of the proposed location. Not zero, four.
2. The applicants provide no support for the assertion regarding the continuum of care. Conversely, within her opposition letter to Project #17-002 Sandy Montalvo, Manager of Social Services and Care Coordination at Centegra Health System, confirmed, "[Centegra] hospitals work with all providers – those employed by our health system, those who are independent and those who work for Mercy – in the same way to ensure patients receive the highest level of care." It is difficult to understand why Mercy believes there is a care coordination issue if they do not provide any supporting documentation/information.

v. The applicants state: "There is a lack of population health management services in Crystal Lake, despite a demonstrated high incidence of chronic disease."

1. The applicants contradict their own assertion by providing supporting documentation for the assertion that "McHenry County's incidence of chronic disease is similar to that

experienced nationwide." Chronic disease similar to that experienced nationwide does not demonstrate a lack of health management services in Crystal Lake.

2. The applicant's statement is unreliable, as the applicants have failed to participate in the McHenry County Healthy Community Study in 2010, 2014, and 2017, which included Centegra, Advocate Health System, McHenry County Department of Health, McHenry County Mental Health Board, McHenry County Substance Abuse Coalition, and the United Way of Greater McHenry County. Mercy's refusal to participate in the community studies is also documented in Robert Vavrik's opposition letter for Project #17-002.

vi. The applicants state: "There is opportunity for significant enhancement of care coordination and efficiencies, and reduced costs, for McHenry County residents through the availability of a full integrated health care system in Crystal Lake and the deployment of an accountable care organization in the same market."

1. The applicants mischaracterize the "issue" of care coordination as one that must be resolved by the proposed project. There are already examples of integration between health systems and unrelated organizations for delivery health care and even deploying accountable care organizations within the planning/market area.
2. For example, both Advocate Physician Partners Accountable Care, Inc., and Centegra Health & Wellness Network Accountable Care Organization, LLC are ACOs already serving the area with independent physician group membership.
3. In addition, the collaborative community studies the applicants have refused to participate in would lend the applicants a better understanding of how the current population is being served by existing hospitals.
4. The actual "issue" appears to be Mercy physicians' unwillingness to work with existing area providers to increase their patients' care coordination and reduce costs.

vii. The applicants state that there is an "Inappropriate distribution of health care resources within McHenry County" and reference the low population growth of Harvard, IL, the utilization levels of Mercy Harvard Hospital, and the population density of Crystal lake to support the statement. However, existing and actual data does not support these conclusions.

Rather, Project #17-002 would negatively and significantly impact the Harvard, Illinois community. The applicants propose to reduce the number of beds at Mercy Hospital Harvard as part of this project, and consistently misrepresent data in this regard. In fact, Mercy Harvard Hospital had an Average Daily Census of 4.6 patients in 2015. This means more than 4 patients required services at the hospital on average every day. The applicants' proposed reduction to 4 medical/surgical beds in Harvard would render the hospital unable to meet its AVERAGE patient volume on a daily basis. The peak census – meaning the most patients at the hospital on any given day – was 11 in 2015. Patient need would therefore be woefully under met by a 4-bed facility.

Furthermore, Harvard has a median income of $56,426, whereas Crystal Lake has a median income of $88,000; and per the Environmental System Research Institute, Harvard's population is anticipated to grow 7.4% by 2021, whereas Crystal Lake's population is projected to remain constant. This data unveils the applicants' true intent with this project – to better position themselves for financial gain through the provision of healthcare services. The Harvard community, however, will suffer as a result.

viii. The proposed project omits any reference to behavioral health issues. This is done despite the fact that the diagnosis of "psychoses" was the **#1 Reason** for hospital admission per the 2014 McHenry County Healthy Community Study. The applicants even reference this same study as a source of information within the response under Attachment 12.

c. In response to the requirement to "Detail how the project will address or improve the previously referenced issues, as well as the population's health status and well-being." The applicants continue to make statements that are inaccurate, unreliable, or that conflict with available data.

i. "In furtherance of its mission to serve the indigent, Mercyhealth will reach out to community-based organizations in an efforts to collaborate in the provision of care to the indigent"

1. Mercy Health has refused to participate in collaborative community need assessments three times since 2010.

2. With a record of refusing to participate in coordinated community research with community providers, the applicants' statement on this issue is unreliable for veracity.

ii. The applicants state: "Mercyhealth will recruit physicians to address the current shortage. Mercyhealth believes that the shortage of specialty physicians is one of the primary reasons that residents of McHenry County are leaving the county in order to seek medical care."

1. The Circuit Court for McHenry County has already ruled **this issue is irrelevant to the approval of a hospital application in Crystal Lake by the applicants**. The Circuit Court determined the IHFSRB's decision to approve Project #03-049 was arbitrary and capricious when based upon the IHFSRB considering a supposed "physician shortage" argument. This is not an established criterion for the approval of the application. The IHFSRB should not give this purported issue any credence in reviewing the application and be cognizant of the previous treatment by the Circuit Court.
2. Further, the shortage of specialty physicians has not been recognized by the federal government as a reason for out-migration of health services, as the 30-minute market/planning area has not been designated a Health Professional Shortage Area.
3. The outmigration of McHenry County is not equal to a finding regarding the 30-minute market/planning area surrounding the proposed location.
4. Out-migration from McHenry County can be partly attributed to sensible use of facilities located in adjacent counties by residents located on the county borders. McHenry has a high concentration of population on the southeast borders, conveniently located near providers situated close to the county borders.
5. Assuming a shortage did exist, the applicants simply state they will recruit additional physicians, such as a general surgeon, pain management physicians, and hematologist/oncologist. There is no reason physicians could not be recruited to serve patients at existing facilities within the area.

iii. "....Mercyhealth will construct a micro-hospital in Crystal Lake"

Per the Advisory Board, a source cited by the applicants, a micro-hospital is generally one with:

a. A size of between 8 and 10 inpatient beds;
b. A cost of between 7 to 30 million dollars;
c. A size of between 15,000 to 50,000 square feet (The average major hospital is typically 74,600 square feet[12] in the United States); and
d. Built to fill identified gaps in service;

Conversely, the proposed facility is 13 inpatient beds, approximately 80 million dollars, 111,000 square feet (**150% of the average major hospital square footage**), and being built in an area with five hospitals within 30 minutes of the proposed facility. As discussed throughout this document, these five facilities negate the need for the proposed facility and services.

iv. "Micro hospitals better utilize health care resources in an economical fashion to meet the needs of the communities they serve. This innovative model provides accessibility at a lower cost by providing care at the right time in the appropriate setting."

1. The source referenced by the applicants for the above statement is from an NPR article that discusses costs for the provider of services, not patients.

   Specifically, the article states: "[Micro Hospitals] are generally affiliated with larger health care systems, which can use the smaller facility to expand in an area without incurring the cost of a full-scale hospital."

2. In fact, the article cited by the applicants actually goes on to state:

   "The big opportunity for these is for health systems that want to establish a strong foothold in a really attractive market," says Fred Bentley, a vice president at the Center for Payment & Delivery Innovation at Avalere Health, a consulting firm. "If you're an affluent consumer and you need services, they can fill a need."

   In keeping with this statement, and contrary to their assertion that the project is design to increase "access to care for the indigent population in the market area," the

[12] https://www.usnews.com/news/healthcare-of-tomorrow/articles/2017-04-24/micro-hospitals-offer-an-alternative-health-care-model-for-local-communities

applicants appear to be targeting an affluent community at the expense of the low-income Harvard, IL community.

3. Finally, the applicants' response in the April 28, 2017 "Additional Documentation" filing regarding the project costs contradicts this "lower costs" assertion, as the applicants state: "The smaller the unit, the greater are the costs apportioned to the individual bed rooms for functions that are part of the clinical space on the unit."

   If the per bed construction costs are rising, it would make sense the per-bed operational costs would also rise. The only cost savings that would remain under such a model would appear to be the savings from not offering high-cost, non-profitable, critical care services such as Trauma Level Emergency Services, Advanced Stroke Care, and Cardiac Care Services.

B. Attachment 13: Alternatives

The applicants continue to reiterate inaccurate and unreliable information within the responses to Attachment 13.

d. Under Alternative #3, the applicants state: "the proposed project enhances efficiency by redistributing beds to where they are most needed, while maintaining the right number of beds to support the average daily census at Mercy Harvard Hospital."

   Confusingly, the applicants are asserting that 4 medical/surgical beds will be sufficient to support an average daily census (ADC) at Mercy Harvard Hospital of 4.6 patients. This means that on **AVERAGE** the daily demand exceeds 4 inpatient beds at Mercy Harvard Hospital, and there are some days where the demand exceeds 4 inpatient beds by multiple patients. The applicants even acknowledge this should be a concern for patient safety and care when the applicants attempt to justify the request for a second ICU bed:

   "126 ICU patient days is an average daily census of 35% in a one bed unit. While this is below the 60% standard and not sufficient to justify a second bed, two ICU beds are requested. Based on the experience at Mercy Walworth Hospital and Medical Center, it is anticipated that

the need for two ICU rooms to be occupied at the same time will occur between 25 and 30 times per year at the proposed Crystal Lake facility."

The applicants confuse the issues and create questions about their reliability when they use arguments about maximum bed usage to justify the ICU aspect of the application, while ignoring the same argument in seeking to justify the removal of 11 beds from Mercy Harvard Hospital and the relocation of the hospital beds to Crystal Lake.

e. Under Alterative #4, the applicants state: "This option [Building an ASTC and Medical Office Building without acute care beds] did not address the need for acute care beds to serve patients of Mercyhealth physicians in central McHenry County."

As discussed within this document, the applicants never establish why patients of physicians affiliated or employed by Mercy Health are not being served by the existing hospital providers within McHenry County and the surrounding area. Further, the applicants refer to a need in "central McHenry County," but are proposing a hospital in the southeast portion of the county. Absent evidence to the contrary, it would seem logical that the existing Centegra Hospital - Woodstock location in central McHenry County would be a suitable location for patients to receive inpatient treatment today and in the future.

IV. Failure to Meet Community Needs: The proposed project should be denied based on its failure to address documented community needs, specifically relating to Behavioral/Mental Health.

The applicants fail to address documented community needs, rather focusing attention on unsubstantiated issues, such a geriatric services, and misconstruing the actual services required in the market/planning area.

In particular, the 2014 McHenry County Healthy Community Study, which the applicants cite to for support, identifies the diagnoses of "psychoses" as the #1 Reason for hospital admissions within McHenry County. In fact, air quality and behavioral/mental health services were the only features not rated highly by Crystal Lake residents within their community. These findings on behavioral health have been within each of the McHenry County Healthy Community Studies in 2006, 2010, 2014, and 2017.

As stated by Todd Schroll, Director of Behavioral Health Services at Centegra Health System, "The provision of high-quality mental health care is difficult and comes at a cost to health systems." In recent years, this cost has been the highest cost category of health conditions in the United States, outpacing heart conditions, trauma, and cancer.[13]

Based on the available data, it is clear behavioral/mental health is a key component of the community needs, but is also one with a high cost to health systems. Project #17-002 does not address this issue and offers no assistance to alleviate the identified community need. As such, the IHFSRB should deny this project.

V. Excessive, Unnecessary and Costly Non-Clinical Space: The proposed project should be denied based in its failure to explain or justify the excessive, unnecessary, and costly Non-Clinical Space for a 13-bed Hospital.

It is difficult to understand why a 13-bed hospital requires nearly the same non-clinical space as a 70-bed facility. The proposed project proposes a 13-bed hospital over 68,000 sq. ft. of non-clinical space, with only around 43,000 sq. ft. of clinical space.

The same applicants proposed a 70-bed hospital in Project #10-089 with approximately 91,000 sq. ft. of clinical space and approximately 75,000 in non-clinical space. The administrative space is over 3,000 sq. ft. larger than the same space in Project #10-089 and Project #03-049 combined. Although the non-clinical space is not "reviewable" by the IHFSRB, the costs for the project are relevant to the consideration of the impact upon the community.

When including the non-clinical space, the cost per bed are over 6 million dollars. The applicants response within the April 28, 2017 "Additional Documentation" response to the cost per bed issue with respect to the clinical areas. Based on both clinical and non-clinical space, Project #17-002 is prohibitively expensive and it is unclear how such a project will benefit a community already serviced by five (5) existing hospital located within 30-minutes, with one (Centegra Hospital – Huntley) only becoming operational in August of 2016. As such, the IHFSRB should deny this project.

[13] *See* Huffington Post, The Highest Health Care Cost In America? Mental Disorders, available at http://www.huffingtonpost.com/entry/highest-health-costs-mental_us_574302b8e4b045cc9a716371 (last visited May 9, 2017).

VI. Failure to Meet CMS Standards: The proposed project should be denied due to its failure to meet the federal definition of a hospital, as the facility will not be "primarily engaged" in servicing inpatients.

Mercy Health fails to demonstrate the ability to meet the statutory definition of a hospital for Project #17-002, as it will not be "primarily engaged" in serving inpatients. Rather, with only eleven (11) medical/surgical beds and two (2) Intensive Care Unit ("ICU") beds, the proposed hospital has a very low capacity to treat inpatients. Comparatively, the application projects that the hospital will provide a substantial amount of outpatient services as a hospital.

Project Number 17-002 - Application Data	
Inpatient/Outpatient	**Volume**
Inpatients Days (excluding observation days that CMS does not consider as inpatient stays)	2,595
Outpatient Visits (ED, Observation, Surgery)	20,113
Inpatient/Outpatient Ratio:	**12.9%**

Federal regulations at 42 C.F.R. §488.3(a)(1) state that a prospective provider or supplier must meet the applicable statutory definitions in (among others) section 1861 of the Social Security Act in order to be approved for participation in or coverage under the Medicare program. The Act defines "hospital" at §1861(e) as an institution that "...is primarily engaged in providing by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick person, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons..."

There is no established test for what constitutes being "primarily engaged" in providing inpatient services. Instead, CMS evaluates whether a provider is primarily engaged in providing inpatient services on a case-by-case basis, looking at the unique facts and circumstances presented in each hospital certification application. However, CMS has provided some parameters on how this evaluation is conducted and executed through previous enforcement actions.

CMS personnel have confirmed that:

> Being "primarily engaged" in providing inpatient services means actually providing inpatient services. Having the hypothetical or potential capacity to provide care is not the equivalent of actually providing such care. An institution that merely has the capacity to provide inpatient services, **but provides a greater volume of outpatient services**, is not primarily engaged in providing inpatient services and therefore not eligible to participate in the Medicare program as a hospital.

This guidance is confirmed by examining key factors CMS has previously cited in denying certification to providers (which have also been upheld on appeal). These factors include:

> The volume of inpatient versus outpatient services. This has been the primary fact cited in CMS's denials of hospital certifications, typically for hospitals that do not provide a significant volume of inpatient services. Conversely, CMS has not focused on volume ratios for large institutions providing a significant volume of services to inpatients. One institution was denied Medicare certification when only providing 4.6% of its services to inpatients. Further, CMS cited to the fact that even 17% of the services being provided to inpatients would be insufficient to meet the definition of a hospital.[14]
>
> The ratio of staff dedicated to inpatient versus outpatient services. For example, a factor in the denial of a 4-bed hospital was the use of 42.5 nurses for a 4-bed hospital, evidencing a focus on outpatient, not inpatient services.[15]
>
> The small number of inpatient beds. CMS typically focuses its enforcement actions upon hospitals with a low inpatient bed count, while tacitly acknowledging larger institutions with high outpatient volume or ratio are not in danger of failing to meet the statutory definition.[16]
>
> NOTE: The Illinois CON regulations require a minimum of 100 beds for a hospital located within a Metropolitan Statistical Area ("MSA"). This requirement aligns with CMS's enforcement of the definition of a hospital to be primarily engaged in inpatient services and focusing its recent enforcement against hospitals located in urban areas with a minimal number of inpatient beds.

Based on previous CMS enforcement action history in denying hospital certification, the facility proposed by Mercy Health under Project 17-002 fails to meet this federal "primarily engaged" standard. The proposed facility is a 13-bed hospital, projected to provide less than 13% of its services to inpatients, with a significant volume of outpatient services.

These CMS enforcement actions have not gone unnoticed within the health care community. A blog post as recently as December of 2016 discussed the recent denial of Medicare certification for Wills Eye Hospital and implications for micro-hospitals, stating:

> Health care institutions must be careful when considering the opening of a micro hospital. Albeit small, a micro hospital must still meet all of the requirements of a hospital under both state and federal law. Reliance on state licensure or even state agency survey results is no guarantee that CMS will agree with these determinations. There have been several recent instances, of which Wills Eye Hospital is only the latest, that have found both new and converting facilities failing to

[14] *See Wills Eye Hospital*, DAB No. 2743 (2016).
[15] *Id.*
[16] *See, e.g., Arizona Surgical Hospital, LLC*, DAB No. 1890 (2003); *Freedom Pain Hospital v. CMS*; CR4530 (2016); and *Kearney Regional Medical Center*, DAB No. 2639 (2015).

> meet the inpatient definitional threshold to qualify as a hospital. It appears that CMS will continue to scrutinize this area heavily.[17]

The applicants fail to address this issue within the application for Project #17-002, instead providing the view that there is widespread support for these new facilities. However, based on this CMS enforcement action, the federal government will deny certification to hospitals that fail to meet the "primarily engaged" standard. As such, the proposed project will be subject to federal regulatory scrutiny, which significantly jeopardizes the ability to service Medicare and Medicaid patients.

[17] *See* Bricker & Eckler, Micro hospital fails to meet the definition of a hospital for Medicare enrollment, available at http://www.bricker.com/industries-practices/health-care/insights-resources/publications/micro-hospital-fails-to-meet-the-definition-of-a-hospital-for-medicare-enrollment (last visited May 9, 2017).