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May 20, 2016

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VIA ELECTRONIC MAIL (POH-EXCEPTIONREQUESTS@CMS.HHS.GOV)
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Martha Kuespert, Director
Division of Technical Payment Policy
ATTN: Physician-Owned Hospital Exceptions
Centers for Medicare and Medicaid Services
7500 Security Blvd
Mail Stop C4-25-02
Baltimore, MD 21244-1850

Re: **Physician-Owned Hospital Exception Request for Deaconess Women's Hospital of Southern Indiana d/b/a The Women's Hospital**

Dear Ms. Kuespert:

We are writing on behalf of Deaconess Women's Hospital of Southern Indiana d/b/a The Women's Hospital ("TWH") to request an exception to the limitation on facility capacity expansion under Section 1877(i) of the Social Security Act (the "Act"), promulgated at 42 C.F.R. § 411.362. TWH meets the three criteria to qualify as a high Medicaid facility under Section 1877(i)(3)(F) of the Act, promulgated at 42 C.F.R. § 411.362(c)(3), because: (1) TWH is not the sole hospital in the county in which TWH is located; (2) TWH's annual total inpatient Medicaid admissions for the three most recent fiscal years (for which data are available) were greater than those of any other hospital located in the county in which TWH is located; and (3) TWH does not discriminate against federal health care program beneficiaries and does not permit physicians practicing at TWH to discriminate against these beneficiaries. Because TWH meets the exception to the limitation on facility expansion, it requests permission to expand from its current bed baseline number of 81 beds, OR suites and procedures rooms to 156 beds, OR suites and procedures rooms.

Below, we analyze why TWH meets the high Medicaid facility criteria.

1. Introduction

1.1. The Women's Hospital

TWH is a women's hospital located in Newburgh, Indiana (Warrick County).[1] It is a joint venture between Deaconess Hospital Inc. and Evansville Holdings, LLC (100% physician-owned), with TWH having 50% physician ownership. Currently, TWH is licensed for 74 beds.[2] *See* **Exhibits A** and **B**. As reflected in the chart on page 6, these 74 beds comprise 24 beds that are a Neonatal Intensive Care Unit ("NICU"), and 50 beds that are a combination of general obstetrical services (labor, delivery, recovery, and postpartum or "LDRP"), high risk antepartum, and post-surgery.

TWH furnishes a broad range of health care services to women and infants including: Level III NICU;[3] Level III obstetrical care;[4] fertility services; surgical services; and additional services. TWH has the only OB department in Warrick County, and it primarily serves patients from these four counties: Vanderburgh, Warrick, Gibson and Posey. Recently, TWH added new services lines, including in-vitro fertilization and gynecological oncology.

In Indiana, there are 92 delivering hospitals, of which 15 hospitals have identified themselves as having in-house neo-natal transport teams. Only four of the 15 hospitals have maternal-fetal transport teams. TWH is one of the four hospitals in Indiana that provides both maternal and neonatal transport services. Because TWH has a Level III NICU, it has entered into transfer agreements with four other delivering hospitals, and, as a result, TWH covers over 27 counties, including counties in Kentucky and Illinois, with its transport and obstetrics services.

Exhibit C is a map illustrating maternal transfers for Indiana residents in 2012. TWH is located in southwest Indiana, and **Exhibit C** illustrates that TWH is a Level III arrival and transfer hospital that receives maternal transfers from various hospitals across Indiana. **Exhibit D** is another map illustrating that for 2012, TWH was a hospital with at least 25% of the births from mothers residing 30 minutes away, by zip code.

Exhibit E is a map illustrating low birth weight infant transfers for Indiana residents in 2012. **Exhibit E** illustrates that TWH is a Level III arrival and transfer hospital.

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[1] TWH is located in Warrick County, Indiana.

[2] *See* **Exhibits A** and **B**. **Exhibit A** contains a copy of TWH's 2016 License. **Exhibit B** contains Indiana State Department of Health's Consumer Report for TWH, which confirms TWH is licensed for 74 beds.

[3] For more information about a Level III NICU program, please see Indiana Perinatal Hospital Standards by Level (Sept. 2012), available at:
http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/resmgr/docs/indiana_perinatal_hospital_s.pdf.

[4] For more information about a Level III OB program, please see Indiana Perinatal Hospital Standards by Level (Sept. 2012), available at:
http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/resmgr/docs/indiana_perinatal_hospital_s.pdf.

Identifying Information:

- NPI: [redacted]
- CCN:
- TIN:

2. Compliance with General Requirements

TWH complies with the general requirements set out in 42 C.F.R. § 411.362(b).

(i) Physician ownership and provider agreement. TWH had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act, 42 U.S.C. § 1395cc, in effect on that date.

(ii) Prohibition on facility expansion. TWH has had no increase in its number of operating rooms, procedure rooms, and beds beyond those for which it was licensed on March 23, 2010. On that date, TWH had 74 beds, 6 operating rooms, and one procedure room. It currently has that same number.

(iii) Disclosure of conflicts of interest.

- Although the regulation at 42 C.F.R. § 411.362(b)(3)(i) states that hospitals with physician owners or investors are to submit annual reports to CMS with detailed descriptions of the identity of each owner or investor and the nature and extent of all ownership/investment interests in the hospital, CMS has placed that requirement on hold as of the date of this letter.
- TWH requires each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his/her ownership or investment interest in the hospital (and, to the extent applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. *See* **Exhibit F**. This disclosure is required to be made in time to permit the patient to make a meaningful decision regarding the receipt of care. Additionally, at the time of their admission and upon request, TWH furnishes patients a disclosure document that identifies the physicians who have an ownership interest in the hospital. *See* **Exhibit G.**
- TWH does not condition any physician, ownership or investment interests either directly or indirectly on the physician owner's or investor's making or influencing referrals to the hospital or otherwise generating business to the hospital.
- TWH discloses on its public website and in its public advertising that the hospital is jointly owned by physicians.

(iv) Ensuring bona fide investment.

- The percentage of the total value of ownership or investment held in TWH by the physician owners or investors in the aggregate does not exceed the percentage in place as of March 23, 2010. On that date, the percentage of physician ownership was 50%, and that percentage is currently the same. No entity holds assets that include TWH, and thus there is no physician ownership or investment in such an entity.
- The ownership or investment interests that TWH offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.
- TWH, and the owners or investors of the hospital, do not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.
- Neither TWH nor any owner or investor in the hospital directly or indirectly guarantees a loan, makes a payment toward a loan, or otherwise subsidizes a loan, for any individual physician or owner or group of physician owners or investors related to acquiring any ownership or investor interest in the hospital.
- Ownership or investment returns are distributed to each owner in the hospital in an amount that is directly proportional to the ownership interest of such owner or investor in the hospital.
- Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of, or right to purchase, other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.
- TWH does not offer any physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(v) Patient safety.

- TWH has physicians available on the premises to provide services during all hours in which the hospital is providing services to its patients.
- TWH has the capacity to provide assessment and initial treatment for all patients and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that TWH is unable to address.

(vi) Prohibition on conversion from an ambulatory surgical center. TWH has not been converted from an ambulatory surgical center to a hospital on or after March 23, 2010. TWH has always been a hospital.

3. High Medicaid Facility Analysis

TWH meets the criteria to qualify as a high Medicaid facility under Section 1877(i)(3)(F) of the Act, promulgated by 42 C.F.R. § 411.362(c)(3) because it meets the following criteria:

(i) Sole Hospital. The regulation requires that the hospital "[i]s not the sole hospital in the county in which the hospital is located." 42 C.F.R. § 411.362(c)(3)(i).

TWH is not the sole hospital in Warrick County, Indiana. There are three other hospitals whose discharge data are reported for Warrick County: Heart Hospital at Deaconess Gateway, St. Mary's Warrick Hospital, and Brentwood Meadows. [5]

(ii) Medicaid Inpatient Admissions. The regulation requires that the hospital "[w]ith respect to each of the three most recent fiscal years for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. A hospital must use filed hospital cost report discharge data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located. 42 C.F.R. § 411.362(c)(3)(ii).

TWH meets this requirement. As summarized below, for the three most recent fiscal years for which data are available, TWH's annual inpatient Medicaid admissions have been greater than those of any other hospital located in Warrick County, the county in which TWH is located. To demonstrate this, TWH is submitting as an attachment to this letter an analysis performed by Veralon Partners, Inc. ("Veralon") that references data for the cost reporting periods 2012, 2013, and 2014. *See* **Exhibit H.** That data comes from CMS's Healthcare Cost Report Information System ("HCRIS"), and it shows that TWH satisfies the regulation's criteria consistent with subsection (c)(3)(ii).

[5] TWH is part of the Deaconess Health System and is located on the same campus as both The Heart Hospital at Deaconess Gateway and Deaconess Gateway Hospital. Deaconess Gateway Hospital, however, operates under the Medicare provider number of Deaconess Hospital. Deaconess Gateway's cost information, therefore, is included in Deaconess Hospital's cost reports. For cost reporting purposes, therefore, Deaconess Gateway Hospital's Medicaid inpatient discharge data are combined with those of Deaconess Hospital and not reported separately. Deaconess Hospital is located in Vanderburgh County, Indiana, not Warrick County.

The HCRIS data for years 2012, 2013, and 2014 are set forth below in Tables 1-3, and they show that TWH's Medicaid inpatient admissions/discharges[6] greatly exceeded those of other hospitals in the county.

Table 1

2012 Medicaid Inpatient Admissions for Hospitals Located in Warrick County, Indiana				
	Deaconess Women's Hospital	**Heart Hospital at Deaconess Gateway**	**St. Mary's Warrick Hospital**	**Brentwood Meadows**
Medicaid Inpatient Discharges	1,319	42	43	38
Total Discharges	3,657	1,697	528	1,106
Percent of Total Inpatient Discharges	36.1%	2.5%	8.1%	3.4%
Data Source: Medicare 2012 Cost Reports.				

[6] The regulation at 42 C.F.R. § 411.362(c)(3)(ii) refers to an analysis of Medicaid inpatient "admissions." The data upon which one may rely, however, is HCRIS data, which relates to Medicaid inpatient "discharges." Accordingly, the Veralon "admissions" analysis relies on HCRIS data addressing Medicaid inpatient "discharges."

Table 2

2013 Medicaid Inpatient Admissions for Hospitals Located in Warrick County, Indiana				
	Deaconess Women's Hospital	**Heart Hospital at Deaconess Gateway**	**St. Mary's Warrick Hospital**	**Brentwood Meadows**
Medicaid Inpatient Discharges	1,346	28	35	3
Total Discharges	3,687	1,574	318	1,928
Percent of Total Inpatient Discharges	36.5%	1.8%	11%	0.2%
Data Source: Medicare 2013 Cost Reports.				

Table 3

2014 Medicaid Inpatient Admissions for Hospitals Located in Warrick County, Indiana				
	Deaconess Women's Hospital	**Heart Hospital at Deaconess Gateway**	**St. Mary's Warrick Hospital**	**Brentwood Meadows**
Medicaid Inpatient Discharges	1,403	56	18	29
Total Discharges	3,668	1,499	236	1,158
Percent of Total Inpatient Discharges	38.2%	3.7%	7.6%	2.5%
Data Source: Medicare 2014 Cost Reports.				

(iii) Nondiscrimination. The regulation requires that the hospital "[d]oes not discriminate against beneficiaries of Federal health care programs and does not

permit physicians practicing at the hospital to discriminate against such beneficiaries." 42 C.F.R. § 411.362(c)(3)(ii).

TWH does not discriminate against federal health care program beneficiaries and does not permit physicians practicing at TWH to discriminate against these beneficiaries. **Exhibit I** contains TWH's non-discrimination policies titled "Non-Discrimination in Provision of Services" and "Ethics, Rights and Responsibilities." These documents demonstrate TWH's policy to admit and treat all persons without regard to race, color, national origin, disability, age, lifestyle or ability to pay. This policy applies fully to federal beneficiaries. Neither the Hospital nor physicians who practice at the Hospital discriminate against federal health care program beneficiaries, as reflected by the fact that roughly 35% of the Hospital's discharges are Medicaid.

4. Anticipated Bed Expansion Calculation

TWH currently is licensed for 74 beds. This baseline consists of: 24 NICU beds; 29 LDRP beds; nine high risk antepartum beds; and 12 post-surgery beds. In addition, there are six operating rooms and one procedure room. Thus, the hospital's baseline number is a total of 81 beds, OR suites and procedures rooms. TWH requests to expand by 75 beds for a total of 149 beds, with all of the increase being in facilities on the hospital's main campus. The requested increase will result in a total of 156 beds, OR suites and procedure rooms. This represents an increase of less than 200% of the baseline number of beds, OR suites and procedure rooms, which, again, would total 156 were the request approved. Below is a table, broken down by type of bed, that describes the current baseline number and the additionally requested beds, as well as OR suites and procedure rooms.

BED TYPE	CURRENT #	ADDITIONAL NEEDED	TOTAL #
NICU	24	26	50
LDRP	29	26	55
ANTEPARTUM	9	11	20
MED/SURG	12	12	24
OR SUITES	6	0	6
PROCEDURE RM.	1	0	1

5. Indiana's High Infant Mortality Rate and Initiatives in Response All Support TWH's Request

Both state and federal policy considerations lend support to the requested expansion. As detailed below, Indiana has a significant infant mortality rate ("IMR")[7] and high percentage of deliveries that occur prior to week 39 of gestation, problems seen particularly among low income

[7] The IMR is the number of infants who die in the first year of life per 1,000 live births.

and Medicaid recipients. This is contrary to good public policy from the standpoint of health outcomes. It is also contrary to good public policy when costs are considered, given that, as discussed below, earlier deliveries (those occurring prior to week 39 of gestation) often result in added costs to federal and state healthcare programs as well as to private payors. The State of Indiana is seeking to address these issues, and TWH is playing a significant role in that effort. That role that would be significantly enhanced by the expansion requested herein.

Internationally, the IMR is used to measure a country's population's health and quality of health care. The IMR is also used broadly to measure: community health status; poverty and socioeconomic status levels in a community; and availability and quality of health services and medical technology. For over 100 years, Indiana has had one of the highest IMRs in the U.S. with over seven deaths per 1,000 births. 2010 U.S. data found that Indiana's IMR was 7.5, which was the seventh highest in the U.S. compared to the national average IMR, which was 6.1.[8] The neonatal morality rate (deaths that occur between birth and 28 days) typically accounts for 2/3 of the IMR. The post neonatal mortality rate (from 28 days to one-year after birth) typically accounts for 1/3 of the IMR.

In 2013, Dr. William VanNess, the State Health Commissioner, identified reducing Indiana's IMR as the Indiana State Department of Health's ("ISDH's") top priority for the next four years. That same year, the ISDH created the Indiana Perinatal Quality Improvement Collaborative (IPQIC) to address ongoing issues related to perinatal care. Because TWH plays a significant role in providing health care services to women and infants in Indiana, TWH has been very active with the IPQIC's initiatives, such as regionalizing perinatal levels of care.

Among the IPQIC's initiative is reducing non-medically indicated early deliveries (prior to week 39 of gestation) to a rate of 3% or less. The IPQIC recently issued guidelines focused on reducing the non-medically indicated early deliveries to improve Indiana's IMR. Because early elective deliveries typically require more medical care, such deliveries result in added costs to the federal and state healthcare programs and private payors.[9]

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[8] Indiana Perinatal Quality Improvement Collaborative, "Addressing Infant Mortality in Indiana: A Report to the IPQIC Governing Council," (March 24, 2014) (citing Murphy S, Xu J, Kochanek K. *Deaths: Final data for 2010.* Hyattsville, MD: National Center for Health Statistics; 2013. Gurganus K. RE: Revised White Paper for 1.22 IPQIC QI call. In: Ganser J, Greer M, Stratton RM, eds. Email communication regarding IN's IMR. ed2014:1), available at http://www.in.gov/isdh/files/Addressing_Infant_Mortality_in_Indiana.pdf. *See* **Exhibit J** for a copy of this article.

[9] Tara Trudnak Fowler, Jeff Schiff, Mary S. Applicate, Katherine Griffith, and Gerry L. Fairbrother. "Early Elective Deliveries Accounted for Nearly 9 Percent of Births Paid for by Medicaid," Health Affairs 33, No. 12 (2014) 2170-2178, 2170 (or "Study"). The authors of the study examined 2010 data for early elective deliveries among Medicaid recipients in 22 states. The authors determined that Medicaid finances up to 48% of births in the U.S. Elective deliveries accounted for 32.3% of all births among Medicaid recipients, and 8.9 % were early elective deliveries. The authors further determined that early elective deliveries resulted in higher NICU admissions and transfers within 24 hours of delivery. *Id.* at 2175. The authors concluded that policies restricting early elective deliveries could potentially reduce NICU days by half a million per year, resulting in a one billion dollars annual cost savings, a fact that both federal and state officials have been addressing. *Id.* at 2171. *See* **Exhibit K** for a copy of this article.

To reduce these costs, federal and state agencies have launched various initiatives to reduce early deliveries and improve outcomes for infants and pregnant women, such as CMS's making reducing early elective deliveries a priority measure in its initial Core Set of Health Care Quality Measures for Adults Enrolled in Medicaid. Additionally, some state agencies are partnering with hospitals to implement "hard stop" policies, which prohibit the scheduling of deliveries before the 39 week gestational period without documenting medical necessity.[10] Indiana has adopted this policy.

As reflected above, TWH plays a key role in Indiana's efforts to (1) reduce its IMR and (2) control cost and reduce poor health outcomes associated with early elective deliveries. CMS's approval of TWH's request would allow TWH to expand this role by adding additional beds, furthering TWH's ability to provide more care to more patients. Due to the high occupancy rate of NICU beds, on average only four beds were available in 2014 for newly admitted infants. By adding beds, TWH would be able to accept additional NICU admissions and would not face the potential of turning away infants in need of immediate medical attention.

As stated earlier, sound policy considerations support the requested expansion. TWH plays a key role in reducing costs attributable to early elective deliveries and reducing Indiana's IMR. TWH is often at capacity. By having additional beds available to patients, TWH will be better able to provide the best outcome for patients. Additional beds would also aid Indiana in its mission to improve its IMR. Lastly, additional beds could result in cost savings to federal and state healthcare programs as well as to private payors because more care could be provided to patients that could result in fewer inpatient admission days.

6. Designated Representatives

For further information about the subject of this disclosure, please contact:

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7. Certification

The provider's certification is provided following this letter.

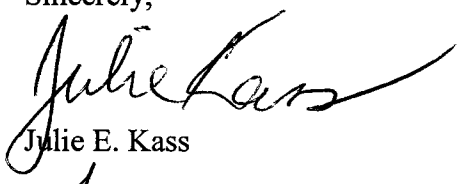
[10] *Id.* at 2171.

8. Conclusion

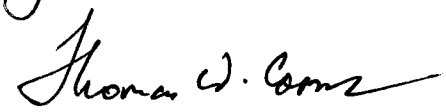
As demonstrated in the calculations above, for the three most recent fiscal years for which data are available, TWH's annual total inpatient Medicaid admissions were greater than those of any other hospital located in the county in which TWH is located, and thus meets the criteria to qualify as a high Medicaid facility under Section 1877(i)(3)(F) of the Act, promulgated by 42 C.F.R. § 411.362(c)(3), because: (1) TWH is not the sole hospital in the county in which TWH is located; (2) TWH's annual total inpatient Medicaid admissions for the three most recent fiscal years (for which data are available) were greater than those of any other hospital located in the county in which TWH is located; and (3) TWH does not discriminate against federal health care program beneficiaries and does not permit physicians practicing at TWH to discriminate against these beneficiaries. Because TWH meets the exception to the limitation on facility expansion, it requests to expand its current number of beds, OR suites and procedures rooms from its baseline number of 81 to 156 beds, OR suites and procedure rooms.

We look forward to working with you toward a successful resolution of this matter. Please do not hesitate to contact us if you require any additional information at this time.

Sincerely,



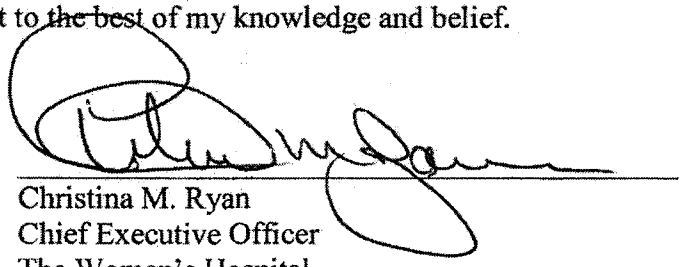
Julie E. Kass



Thomas W. Coons

CERTIFICATION

With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I, Christina M. Ryan, certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to ~~the best~~ of my knowledge and belief.



Christina M. Ryan
Chief Executive Officer
The Women's Hospital

May 20, 2016

Date