STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	150058	A. BUILDING 00 B. WING	08/07/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
MEMORIAL HOSPITAL OF SOUTH BEND	615 N MICHIGAN ST SOUTH BEND, IN 46601

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
S 0000 Bldg. 00	This visit was for an offsite investigation of a state licensure hospital complaint. Complaint Number: IN00437251 - Deficiency related to allegations is cited at Tag A0102. Survey Dates: 07/17/2024 and 08/07/2024 Facility Number: 005053 QA: 7/23/24 and 8/12/24	S 0000		
S 0102 Bldg. 00	410 IAC 15-1.2-1 COMPLIANCE WITH RULES 410 IAC 15-1.2-1 (a) (a) All hospitals shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules. Based on document review & interview the facility failed to ensure that IC 16-34-2-5 was followed for 1 of 1 Terminated Pregnancy Report (TPR)(Pt #1). Findings include: 1. Review of IC 16-34-2-5 indicates the following; (a) Every health care provider who performs a surgical abortion or provides, prescribes, administers, or dispenses an abortion inducing drug for the purposes of inducing an abortion shall report the performance of the abortion or the provision, prescribing, administration, or dispensing of an abortion inducing drug on a form drafted by the state department, the purpose and function of which shall be the improvement of maternal health	S 0102	Upon notification of this complaint from Indiana Department of Health (IDOH), Hospital leaders initiated an investigation which began with identifying the specific case in question. The physician responsible for the patient's care was interviewed and confirmed the Terminated Pregnancy Report (TPR) for care provided on 1/19/2024 was not finalized and submitted to IDOH until 03/22/2024. The physician reported that at the time of the case they were unaware of the 30-day deadline to file the TPR. Once the provider became aware	10/11/2024

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Michelle Thompson, MD	VPMA	10/11/2024

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	and life through the compilation of relevant maternal life and health factors and data, and a further purpose and function shall be to monitor all abortions performed in Indiana to assure the abortions are done only under the authorized provisions of the law. For each abortion performed and abortion inducing drug provided, prescribed, administered, or dispensed, the report shall include, among other things, the following: (1) The age of the patient. (2) Whether a waiver of consent under section 4 of this chapter was obtained. (3) Whether a waiver of notification under section 4 of this chapter was obtained. (4) The date and location, including the facility name and city or town, where the: (A) pregnant woman: (i) provided consent; and (ii) received all information; required under section 1.1 of this chapter; and (B) abortion was performed or the abortion inducing drug was provided, prescribed, administered, or dispensed. (5) The health care provider's full name and address, including the name of the physicians performing the abortion or providing, prescribing, administering, or dispensing the abortion inducing drug. (6) The city and county where the pregnancy termination occurred. (7) The age of the father, or the approximate age of the father if the father's age is unknown. (8) The patient's county and state of residence. (9) The marital status of the patient. (10) The educational level of the patient. (11) The race of the patient. (12) The ethnicity of the patient. (13) The number of the patient's previous live		of the deadline, they attempted to file the report but was unable to do so due to the lack of access to the reporting system. The physician submitted the TPR once the issues with access were resolved. The organization's interpretation of the new requirements set forth in IC 16-34-2-5 as it relates to the health care providers' completion and submission of the TPR, placed responsibility on the physician. It was not understood that the hospital had an obligation to ensure physicians, including those who are not employed by the hospital, were in compliance with all aspects of the code and submission of the TPR. A process has since been developed that provides the hospital with the ability to track the physician's completion and submission of the TPR on all future cases that meet reporting requirements. This process includes the following components: 1 A report is being built in the electronic medical record to capture all patient care events applicable to the reporting requirements defined in IC 16-34-2-5. This report will be automatically pushed out to the hospital Risk Manager and health system Executive Director of Enterprise Risk Management anytime there is a qualifying event.	

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	births. (14) The number of the patient's deceased children. (15) The number of the patient's spontaneous pregnancy terminations. (16) The number of the patient's previous induced terminations. (17) The date of the patient's last menses. (18) The physician's determination of the gestation of the fetus in weeks. (19) Whether the patient indicated that the patient was seeking an abortion as a result of being: (A) abused; (B) coerced; (C) harassed; or (D) trafficked. (20) The following information concerning the abortion or the provision, prescribing, administration, or dispensing of the abortion inducing drug: (A) The postfertilization age of the fetus (in weeks). (B) The manner in which the postfertilization age was determined. (C) The gender of the fetus, if detectable. (D) Whether the fetus has been diagnosed with or has a potential diagnosis of having Down syndrome or any other disability. (E) If after the earlier of the time the fetus obtains viability or the time the postfertilization age of the fetus is at least twenty (20) weeks, the medical reason for the performance of the abortion or the provision, prescribing, administration, or dispensing of the abortion inducing drug. (21) For a surgical abortion, the medical procedure used for the abortion and, if the fetus was viable or had a postfertilization age of at least twenty (20) weeks:		a **Interim Event Notification Plan:** Effective 10/10/2024, leaders over the Child Birth Unit and Surgery Department shall notify the hospital Risk Manager via electronic messaging, email or verbal communication of all qualifying events until the build of the electronic report is complete and operational. 2 The Risk Manager, and in their absence their designee, shall use the information received via the interim event notification plan and the electronic medical record report to populate an event log which monitors the status of completion and submission of the TPR. a When notification of a new event is received, the Risk Manager or designee shall contact the physician responsible for the patient's care to ensure they are aware of the TPR requirements and have the necessary access to submit the report. b The Physician shall complete and submit the TPR, then provide the hospital Risk Manager with key components including date of event, patient identifier, date submitted to IDOH and TPR submission confirmation number. c Risk Manager shall document the information provided by physician on the corresponding entry on the event log. 3 Risk Manager shall monitor	

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	(A) whether the procedure, in the reasonable judgment of the health care provider, gave the fetus the best opportunity to survive; (B) the basis for the determination that the pregnant woman had a condition described in this chapter that required the abortion to avert the death of or serious impairment to the pregnant woman; and (C) the name of the second doctor present, as required under IC 16-34-2-3(a)(3). (22) For a nonsurgical abortion, the precise drugs provided, prescribed, administered, or dispensed, and the means of delivery of the drugs to the patient. (23) For a nonsurgical abortion, that the manufacturer's instructions were provided to the patient and that the patient signed the patient agreement. (24) For an early pre-viability termination, the medical indication by diagnosis code for the fetus and the mother. (25) The mother's obstetrical history, including dates of other abortions, if any. (26) Any preexisting medical conditions of the patient that may complicate the abortion. (27) The results of pathological examinations if performed. (28) For a surgical abortion, whether the fetus was delivered alive, and if so, how long the fetus lived. (29) Records of all maternal deaths occurring at the location where the abortion was performed or the abortion inducing drug was provided, prescribed, administered, or dispensed. (30) The date the form was transmitted to the state department and, if applicable, separately to the department of child services. (b) The health care provider shall complete the		event log and prompt physicians to complete TPR process if communication of submission has not yet been received 7 days prior to 30-day deadline. a Risk Manager shall forward any instances of non-compliance with completion and submission of TPR within 30 days of the date of the event to the Medical Staff Office for investigation under the provider peer review process. 4 The OB Committee will oversee the TPR process by reviewing data, provided monthly by the Risk Manager, on qualifying events and compliance with TPR submission. The OB Committee shall help identify process improvement strategies should the data reflect a potential barrier to reporting. **Communication of Corrective Action** The Vice President of Medical Affairs (VPMA) and Risk Manager attended the OB Committee meeting on October 8, 2024, and provided background of the circumstances surrounding this complaint and the resulting citation. The VPMA outlined the new process which the hospital will use to verify completion and submission of the TPR and set forth the expectations of the physicians.	

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	form provided for in subsection (a) and shall transmit the completed form to the state department, in the manner specified on the form, within thirty (30) days after the date of each abortion. 2. Review of documentation from the Indiana Department of Health (IDOH) Vital Records, Pt #1's TPR indicated the patient had an abortion on 01/19/2024. The TPR documentation indicated the TPR was initiated on 03/22/2024. 3. On 07/17/2024 at 1331 hours, IDOH #1 indicated via email that Pt #1's TPR was initiated on 03/22/2024. 4. On 08/07/2024 at 1456 hours via email, staff #40 confirmed that MD#1 completed the TPR on 03/22/2024.			