

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 1247AS	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/27/2020
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NAME OF PROVIDER OR SUPPLIER WOMEN'S MED DAYTON	STREET ADDRESS, CITY, STATE, ZIP CODE 1401 E STROOP RD DAYTON, OH 45429
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C 000	Initial Comments Complaint Inspections #OH0011048, #OH0011050, #OH0011086, #OH0011087, #OH0011130 Administrator: Martin Haskell, MD County: Montgomery 2 Operating rooms	C 000		
C9999	FINAL OBSERVATIONS Surveyor observations, review of miscellaneous facility reports, review of ten medical records, and interviews with the Operations Manager and the Medical Director revealed the following: Review of the policy and procedure titled "Women's Med Group Professional Corporation (WMGPC) Implementing Ohio Department of Health's March 17, 2020 order for the Management of Non-essential Surgeries and Procedures throughout Ohio" revealed the Director of the Ohio Department of Health (ODH) issued an order for the management of non-essential surgeries and procedures throughout Ohio ("order"). ODH has ordered all non-essential or elective surgeries and procedures that utilize personal protective equipment (PPE) to cease at 5:00 PM 03/18/2020 for the purpose of preventing the spread of contagious and infectious diseases and of preserving PPE and critical hospital capacity and resources in Ohio. WMCG hereby establishes this policy in order to ensure compliance with ODH's order. Review of the policy and procedure revealed no	C9999		

Ohio Department of Health
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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C9999	<p>Continued From page 1</p> <p>non-essential surgeries and procedures that utilize PPE will be performed. WMGPC physicians will determine on a case-by-case basis whether a surgical abortion or procedure constitutes an essential surgery or procedure that may continue to be provided under the terms of the order. WMGPC physician shall rely on the director's order and should consider the following considerations for making this decision: the orders state that a surgery is essential if it cannot be delayed without undue risk to the current or future health of a patient and includes, as examples of criteria to consider, the risk to the patient of rapidly worsening to severe symptoms that make the surgery time sensitive, as well as progression of staging. Pregnancy has a duration of approximately forty weeks as measured from the first day of the woman's last menstrual period (LMP) and abortions are banned in Ohio beginning at 22 weeks LMP. Ohio Revised Code, 2919.201. In addition, while abortion is an extremely safe medical procedure, delay increases the risk to the health of the patient. The Ambulatory Surgery Center Associations' (ASC) COVID-19: Guidance for ASC's for necessary surgery, issued 03/18/20, which states that consideration of whether delay of a surgery is appropriate must account for risk to the patient of delay, including the expectation that a delay of six to eight weeks or more may be required to emerge from an environment in which COVID-19 is less prevalent. All essential surgeries and procedures that are performed by WMGPC while the order is in effect will proceed as follows: only individuals essential to conducting the surgery or procedure shall be in the surgery or procedure suite or other patient care areas where PPE is required, and every effort will be made to preserve PPE. This policy, like the underlying order, shall remain in effect until the state of</p>	C9999		

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C9999	<p>Continued From page 2</p> <p>emergency declared by the Governor no longer exists, or the director of the Ohio Department of Health rescinds or modifies the order.</p> <p>Upon entrance to the facility on 03/26/20 COVID-19 screening was being completed for all patients. PPE was being worn by all staff. There was a total of 13 patients whom were sitting at least six feet apart. Women's Medical Center of Dayton (WMCD) performed 31 surgical abortions between March 19 and March 25, 2020.</p> <p>Review of the patient check-in list, dated 03/26/20, revealed there were a total of 32 patients scheduled to be seen which included: (19) medical abortions (MAB), (10) pre-op, Ohio 24 hour consults, and (3) dilation/evacuation (DE).</p> <p>Review of 10 medical records (#1, #2, #3, #4, #5, #6, #7, #8, #9 and #10) revealed the following:</p> <ol style="list-style-type: none"> 1. Patient #1 was 20.4 weeks gestation - pregnancy terminated on 03/26/20 2. Patient #2 was 18 weeks gestation, was in the operating room (OR) during the initial tour on 03/26/20, and was having a DE 3. Patient #3 was 16.4 weeks gestation and had a consult for pregnancy termination on 03/24/20, returned to office on 03/25/20 and determined not to be a candidate for termination by non-surgical methods due to gestational age in excess of 70 days LMP, osmotic dilators inserted on 03/25/20 and patient returned for DE pregnancy termination on 03/26/20 4. Patient #4 was 16 weeks gestation - pregnancy terminated on 03/19/20 5. Patient #5 was 19 weeks gestation - pregnancy terminated on 03/19/20 6. Patient #6 was 11 weeks gestation - pregnancy 	C9999		

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C9999	<p>Continued From page 3</p> <p>terminated on 03/19/20</p> <p>7. Patient #7 was 11 weeks gestation - pregnancy terminated on 03/20/20</p> <p>8. Patient #8 was 13 weeks gestation - pregnancy terminated on 03/24/20</p> <p>9. Patient #9 was 17 weeks gestation - pregnancy terminated on 03/25/20</p> <p>10. Patient #10 was 15 weeks gestation - pregnancy terminated on 03/24/20</p> <p>Interview with the Operations Manager on 03/26/20 at 10:40 AM revealed Patient #2, was in the operating room (OR) for a procedure at the time of the tour. The medical doctor, medical assistant and the certified registered nurse anesthesiologist (CRNA) were in the OR with the patient.</p> <p>Interview with the Operations Manager, LPN on 03/26/20 at 12:16 PM revealed that the medical director was in Florida. The Operations Manager stated another physician performs the procedures and the medical director is aware.</p> <p>Interview with the Medical Director by telephone on 03/26/20 at 3:35 PM revealed the following responses to the questions asked:</p> <p>1. How many surgeries has your facility performed between 3/19/20 through 3/26/20? Answer: A total of 31 surgeries have been performed at the facility between 3/19/20 through 3/26/20. A scanned copy of the CPT code, date performed and the name of the person (s) whom performed are in the completed folder.</p> <p>2. How many of these procedures utilized PPE? Answer: All of the surgeries/procedures utilized minimal PPE. Each surgical abortion used minimal personal protective equipment (PPE).</p>	C9999		

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C9999	<p>Continued From page 4</p> <p>The list of surgical procedures is as follows:</p> <p>Procedures: 03/19/20 DC Local (6) DE IVS/GA (5)</p> <p>Procedures: 03/20/20 DC Local (13) DC Local (5) DE IVS/GA (2)</p> <p>Procedures: 03/25/20 DC/IVS/GA (1) DC Local (1) DE IVS/GA (2)</p> <p>3. Do you currently have surgeries using PPE scheduled for the duration of the Director's order? Answer: Yes.</p> <p>4. How many? Answer: There are nine surgeries scheduled that use PPE through 04/16/20. There is no end date to the Director's PPE order.</p> <p>5. Do you plan to cancel them? If no, why not? Answer: We have not canceled these surgeries because a) the patients are not able to have a medication abortion (MAB), either based on the statutory limit on providing medication abortions or the patient having contraindications that would not make a MAB possible or b) the physician has not yet evaluated the patient to determine if the surgery is essential. We are not canceling surgeries due to the gestational age past 70 days and there is limited time to have the surgery before an adverse effect on life and health of the patient.</p> <p>6. Have you changed your business operations to</p>	C9999		

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C9999	<p>Continued From page 5</p> <p>comply with the Director's order? Answer: WMCD has changed business operations to comply with the Director's PPE order. Medical director referred to policy and procedure implementing the order.</p> <p>7. Out of the surgeries completed from 3/18/20 through 3/26/20, how many were done for patients between 10 and 22 weeks gestation? Answer: The process and criteria WMCD physician's use to evaluate whether a surgery is essential is outlined in WMCD's policy implementing the order and there were 31 surgeries performed between 03/18/20 and 03/26/20.</p> <p>8. Explain the process and/or criteria by which (and by whom) you evaluated whether surgeries and procedures that you have performed were essential and not elective Answer: The process and criteria WMCD physician's use to evaluate whether a surgery is essential is outlined in WMCD's policy implementing the order and there were 31 surgeries performed between 03/18/20 and 03/26/20.</p> <p>9. What internal governance structure have you established to ensure compliance with the Director's order. Please provide any documentation related to this structure. Who established this structure and what are their qualification? What criteria were used to establish this structure? If you have not established a structure, when will you do so? Answer: WMCD's internal governance structure that has been established to ensure whether a surgery is essential is outlined in WMDC's policy implementing the order, the documentation in patient charts when a surgery is considered</p>	C9999		

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C9999	<p>Continued From page 6</p> <p>essential, and the governing body's approval of WMCD's policy.</p> <p>Further interview with the Medical Director on 03/26/20 revealed he has consulted with each physician and gave guidance on how to evaluate patients for surgical necessity of surgical abortion versus other means of terminating the pregnancy. The Medical Director also revealed that not giving patient face masks or gloves because it would use up the personal protective equipment (PPE) but disinfecting counters and other surfaces the patients touch to prevent the spread of COVID-19.</p>	C9999		