

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 014264	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/07/2019
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NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE, INC	STREET ADDRESS, CITY, STATE, ZIP CODE 3511 LINCOLNWAY WEST SOUTH BEND, IN 46628
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T 000	<p>INITIAL COMMENTS</p> <p>This visit was for a licensure survey and investigation of 3 licensure complaints.</p> <p>Complaint Number: IN00308566 Unsubstantiated; lack of sufficient evidence.</p> <p>Complaint Number: IN00304763 Unsubstantiated; lack of sufficient evidence.</p> <p>Complaint Number: IN00304752 Unsubstantiated; lack of sufficient evidence.</p> <p>Complaint Number: IN00312482 Unsubstantiated; lack of sufficient evidence.</p> <p>Date: 11-06 & 07-19</p> <p>Facility Number: 014264</p> <p>QA: 11/14/19</p>	T 000		
T9999	<p>MEMO</p> <p>***410 IAC 26.5-5-1(c)(5) Governing Body: Powers and Duties: Approve all appointments to or contracts with medical staff.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review & interview the Governing Body failed to approve all appointments or contracts to the medical staff for 2 of 5 medical staff files reviewed (MD #1 & MD #2).</p> <p>Findings include;</p>	T9999		

Indiana State Department of Health LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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T9999	<p>Continued From page 1</p> <ol style="list-style-type: none"> Review of MD #1 & #2's Credential files lacked documentation of Governing Board approval of appointment or contract to the medical staff. On 11/06/19 at 1615 hours staff #40 confirmed there was no documentation of the Governing Board approving appointment or contract to the medical staff for MD #1 & #2 . <p>***410 IAC 26.5-5-2 (d)(1) Appointment and conduct of medical staff: In appointing or contracting with medical staff, the governing body shall do the following: Ensure that appointments to or contracts with the medical staff are acted upon the advice and recommendation of the medical director.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review & interview the Medical Director failed to provide a recommendation for appointment to the Medical Staff for 3 of 5 medical staff files reviewed (MD #3, MD #4 & MD #5) to the Governing Board.</p> <p>Findings include;</p> <ol style="list-style-type: none"> Review of MD #3, MD #4 & MD #5's medical staff files lacked documentation of the Medical Director's recommendation for appointment to the medical staff. On 11/06/19 at 1615 hours staff #40 confirmed there was no documentation of the medical director recommending appointment to medical staff for MD #3, MD #4 & MD #5. <p>***410 IAC 26.5-5-2 (d)(3)(A)(F) Appointment and</p>	T9999		

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T9999	<p>Continued From page 2</p> <p>conduct of medical staff: In appointing or contracting with medical staff, the governing body shall do the following: Ensure that criteria for selection of medical staff include the following: Individual character. Judgment.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review the Governing Body failed to ensure the selection of medical staff included evidence of individual character & judgment for 4 of 5 medical staff files reviewed (MD #2, MD #3, MD #4 & MD #5).</p> <p>Findings include;</p> <p>1. Review of MD #2, 3, 4 & 5's medical staff files lacked evidence that selection was based on individual character & judgment.</p> <p>***410 IAC 26.5-5-1(c)(7)(B) Governing Body: Powers and Duties: Ensure that clinic policies and procedures are: reviewed at least triennially.</p> <p>This rule is not met as evidenced by;</p> <p>1. Review of facility policy & procedure manuals lacked documentation of Governing Board review / approval.</p> <p>2. On 11/06/19 at 1545 hours staff #41 confirmed there was no documentation of the policy & procedures being reviewed / approved by the governing board.</p>	T9999		

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T9999	<p>Continued From page 3</p> <p>***410 IAC 26.5-5-1(c)(8)(A) Governing Body: Powers and Duties: Establish the following: A policy and procedure for communication with physicians concerning a patient emergency.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review & interview the governing board failed to establish a policy and procedure for communication with physicians concerning a patient emergency for 1 facility.</p> <p>Findings include;</p> <ol style="list-style-type: none"> 1. Review of the facility policy & procedures lacked documentation of a policy and procedure for communication with physicians concerning a patient emergency. 2. On 11/06/19 at 1550 hours staff #40 confirmed there was no policy and procedure for communication with physicians concerning a patient emergency. <p>***410 IAC 26.5-6-2(c)(1)(B) Required Policies and procedures: The clinic shall develop, implement, and maintain the following: Policies that cover health care worker practice problems, including, but not limited to, the following: Criminal history.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review & interview the facility failed to ensure a policy & procedure for health care worker practice problems addressing</p>	T9999		

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T9999	<p>Continued From page 4</p> <p>criminal history was developed, implemented & maintained for 1 facility.</p> <p>Findings include;</p> <p>1. Review of the facility policy & procedures lacked documentation of a policy and procedure for health care worker practice problems addressing criminal history.</p> <p>2. On 11/06/19 at 1650 hours staff #41 confirmed the facility lacked a policy & procedure for health care worker practice problems addressing criminal history.</p> <p>***410 IAC 26.5-10-1(b)(2) Medical staff services The medical director must do the following; Make recommendations to the governing body on the appointment of medical staff.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review & interview the Medical Director failed to provide a recommendation for appointment to the Medical Staff for 3 of 5 medical staff files reviewed (MD #3, MD #4 & MD #5) to the Governing Board.</p> <p>Findings include;</p> <p>1. Review of MD #3, MD #4 & MD #5's medical staff files lacked documentation of the Medical Director's recommendation for appointment to the medical staff.</p> <p>2. On 11/06/19 at 1615 hours staff #40 confirmed there was no documentation of the medical director recommending appointment to medical staff for MD #3, MD #4 & MD #5.</p>	T9999		

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T9999	<p>Continued From page 5</p> <p>***410 IAC 26.5-10-1(c)(3) Medical staff services The medical director must do the following; There is a provision for personnel authorized to take a verbal order.</p> <p>This rule is not met as evidenced by;</p> <p>Based on document review & interview the medical director failed to ensure a policy & procedure for personnel authorized to take a verbal order was developed & maintained for 1 facility.</p> <p>Findings include;</p> <ol style="list-style-type: none"> 1. Review of the facility policy & procedures lacked documentation of a policy and procedure for personnel authorized to take a verbal order. 2. On 11/07/19 at 0945 hours staff #41 confirmed there was no policy & procedure for personnel authorized to take a verbal order. <p>***410 IAC 26.5-12-1(e)(2)(E)(v) Infection control administration The clinic must establish a committee to monitor and guide the infection control program in the clinic as follows: The infection control committee responsibilities must include, but are not limited to, the following: Reviewing and recommending changes in procedures, policies, and programs that are pertinent to infection control. These include, but are not limited to, the following: Reuse of disposables.</p> <p>This rule is not met as evidenced by;</p>	T9999		

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T9999	<p>Continued From page 6</p> <p>Based on interview the facility failed to have a policy & procedure on the reuse of disposables for 1 facility.</p> <p>Findings include;</p> <p>1. On 11/07/19 at 1015 hours staff #40 confirmed the facility did not have policy & procedure on the reuse of disposables.</p> <p>***410 IAC 26.5-12-1(e)(2)(E)(viii) Infection control administration The clinic must establish a committee to monitor and guide the infection control program in the clinic as follows: The infection control committee responsibilities must include, but are not limited to, the following: Reviewing and recommending changes in procedures, policies, and programs that are pertinent to infection control. These include, but are not limited to, the following: An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>This rule is not met as evidenced by;</p> <p>Based on interview the the facility failed to ensure it had developed, implemented & maintained policies addressing the communicable disease history of new personnel as well as an ongoing program for current personnel for 1 facility.</p> <p>Findings include;</p> <p>1. On 11/07/19 at 1020 hours staff #40 confirmed</p>	T9999		

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T9999	<p>Continued From page 7</p> <p>the facility did not have policies that addressed the communicable disease history of new personnel as well as an ongoing program for current personnel.</p> <p>***410 IAC 26.5-16-1(3)(D) Pharmaceutical services The clinic must provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice. The clinic must have the following; Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following; Reporting of adverse reactions and medication errors to the: physician responsible for the patient</p> <p>This rule is not met as evidenced by;</p> <p>Based on interview the facility failed to have written policies and procedures developed, implemented, maintained for reporting of adverse reactions and medication errors to the patient's physician for 1 facility.</p> <p>Findings include;</p> <p>1. On 11/07/19 at 1045 hours staff #40 confirmed the facility did not have a policy & procedure addressing the reporting of adverse reactions and medication errors to the patient's physician.</p> <p>***410 IAC 26.5-16-1(3)(B)(i) Pharmaceutical services The clinic must provide drugs and biologicals in a safe and effective manner in accordance with</p>	T9999		

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T9999	<p>Continued From page 8</p> <p>accepted professional practice. The clinic must have the following; Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following; Instructions to the patient on the use of take home medication is the responsibility of the prescribing physician.</p> <p>This rule is not met as evidenced by;</p> <p>Based on interview the facility failed to ensure the clinic had developed, implemented, maintained, and made available to personnel policy & procedures which addressed instructions to patients on the use of take home medication is the responsibility of the prescribing physician for 1 facility.</p> <p>Findings include;</p> <p>1. On 11/07/19 at 1050 hours staff #40 confirmed the facility did not have a policy & procedure that addressed that instructions to patients on the use of take home medication is the responsibility of the prescribing physician.</p> <p>***410 IAC 26.5-16-1(4) Pharmaceutical services The clinic must provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice. The clinic must have the following; A formulary.</p> <p>This rule is not met as evidenced by;</p> <p>Based on interview the facility failed to ensure the clinic had a formulary for 1 facility.</p>	T9999		

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T9999	<p>Continued From page 9</p> <p>Findings include;</p> <p>1. On 11/07/19 at 1030 hours staff #40 was requested to provide a copy of the clinic's formulary & none was provided by exit.</p> <p>***410 IAC 26.5-17-6(a)(6)(A)(B) Safety A safety management program must include, but not limited to, the following: Maintenance of written evidence of regular inspection and approval by state and local fire control agencies in accordance with the following: Clinic policy. State and local regulations.</p> <p>This rule is not met as evidenced by;</p> <p>Based on interview the the facility failed to ensure it maintained documentation of evidence of regular inspection and approval by state and local fire agencies for 1 facility.</p> <p>Findings include;</p> <p>1. On 11/07/19 at 0915 hours staff #40 was requested to provide evidence of regular inspection for fire control & none was provided by exit.</p> <p>***410 IAC 26.5-17-6(a)(7) Safety A safety management program must include, but not limited to, the following: Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>This rule is not met as evidenced by;</p>	T9999		

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T9999	<p>Continued From page 10</p> <p>Based on interview the facility failed to ensure the that emergency & disaster preparedness was coordinated with an appropriate community, state and federal agencies for 1 facility.</p> <p>Findings include;</p> <p>1. On 11/07/19 at 0925 hours documentation of emergency & disaster preparedness that was coordinated with an appropriate community, state and federal agencies was requested from staff #40. None was provided prior to exit.</p> <p>***410 IAC 26.5-9-1 Sec. 1. (1) (a) 2(E) (F) (i) (iii) Personnel policies and records. The abortion clinic shall maintain current and accurate personnel records for all employees. Personnel records shall: (2) include personal data that includes: (E) evidence of participation in job-related education and training activities, (F) health records of employees that relate to post offer and subsequent: (i) physical examinations (iii) Immunizations.</p> <p>Based on document review and interview, the facility failed to provide take home medication packaging training for 2 of 2 staff members (S3 and S4) who package take home medications and failed to ensure documentation of Post offer Physical and Immunizations for 5 of 5 personnel files reviewed (S1, S2, S3, S4, S5) .</p> <p>Findings include:</p> <p>1. Review of personnel files for staff S3 and S4 lacked training on medication packaging.</p> <p>2. Interview on 11/06/2019, at approximately 3:11 hours, with staff #40 indicated S3 and S4</p>	T9999		

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T9999	Continued From page 11 packaged medications for patients to take home. 3. Review of personnel files S1, S2, S3, S4 and S5 lacked documentation of Post offer Physical and Immunizations. 4. Interview on 11/06/2019, at 12:51 hours, with staff #40 confirmed personnel files lacked documentation of post offer physical and immunizations.	T9999		