

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

WHOLE WOMAN’S HEALTH ALLIANCE;)	
ALL-OPTIONS, INC.; and JEFFREY)	CASE NO. 1:18-cv-1904-SEB-MJD
GLAZER, M.D.,)	
)	CIVIL ACTION
Plaintiffs,)	
)	
v.)	
)	
CURTIS T. HILL, JR., Attorney General of)	
the State of Indiana, in his official capacity;)	
KRISTINA BOX, M.D., Commissioner of the)	
Indiana State Department of Health, in her)	
official capacity; JOHN STROBEL, M.D.,)	
President of the Medical Licensing Board of)	
Indiana, in his official capacity; and)	
KENNETH P. COTTER, St. Joseph County)	
Prosecutor, in his official capacity,)	
)	
Defendants.)	

**PLAINTIFFS’ MOTION FOR LEAVE TO SUPPLEMENT THE RECORD
AND FOR EXPEDITED BRIEFING AND DECISION**

Plaintiffs respectfully move the Court for leave to supplement the record in this case with the Statement of Deficiencies and Plan of Correction that resulted from the recent inspection by Defendant Indiana State Department of Health (“Department”) of the abortion clinic operated by Plaintiff Whole Woman’s Health Alliance (“WWHA”) in South Bend, Indiana. Plaintiffs further ask the Court to set an expedited briefing schedule and decide the motion by February 14, 2020, so that, if the motion is granted, Plaintiffs can cite the Statement of Deficiencies and Plan of Correction in their brief in opposition to Defendants’ petition for a writ of certiorari currently pending at the Supreme Court.

1. On May 31, 2019, this Court entered a preliminary injunction enabling WWHA to begin providing medication abortions at its South Bend clinic. *Whole Woman’s Health*

- All. v. Hill*, 388 F. Supp. 3d 1010, 1049 (S.D. Ind. 2019).
2. Defendants appealed that decision, and on August 22, 2019, the U.S. Court of Appeals for the Seventh Circuit affirmed it with modifications. *Whole Woman's Health All. v. Hill*, 937 F.3d 864, 879-80 (7th Cir. 2019).
 3. On November 6-7, 2019, the Department conducted an inspection of the South Bend clinic. *See* Statement of Deficiencies and Plan of Correction at 1 (attached hereto as Exhibit A). On December 20, 2019, the Department transmitted its inspection findings to WWHA in the form of a twelve-page Statement of Deficiencies. *See id.* at 1-12. The Statement of Deficiencies included a column for WWHA to enter a Plan of Correction. *See id.* WWHA did so and returned the completed document to the Department on January 3, 2020.¹ *See id.* at 1.
 4. The Statement of Deficiencies and Plan of Correction attached hereto as Exhibit A is a true and correct copy of the Statement of Deficiencies issued by the Department on December 20, 2019, and the Plan of Correction entered by WWHA on January 3, 2020.
 5. On December 9, 2019, Defendants filed a petition for a writ of certiorari seeking review of the Seventh Circuit's decision affirming entry of the preliminary injunction. Pet. for Writ of Cert. ("Pet."), *Hill v. Whole Woman's Health All.* (Dec. 9, 2019) (No. 19-743).
 6. On January 21, 2020, the Supreme Court requested that Plaintiffs file a response to the petition by February 20, 2020.
 7. The petition states: "The point of the provisional license provided by state law is to permit a clinic to operate and then undergo an inspection prior to permanent licensing so that the Department can review the clinic's actual operations and, if necessary, order

¹ Due to a typographical error, the Plan of Correction is dated January 3, 2019.

early corrective action by the clinic. The injunction required by the Seventh Circuit and ordered by the district court plainly compromises that authority.” Pet. at 26.

8. Plaintiffs seek to supplement the record with the Statement of Deficiencies and Plan of Correction to aid the Supreme Court in evaluating that claim.
9. The Statement of Deficiencies and Plan of Correction may also aid this Court in deciding Defendants’ motion for summary judgment (ECF No. 213), which has been fully briefed.
10. To meet the filing deadline set by the Supreme Court, Plaintiffs must send the final version of their brief in opposition to the printer on February 18, 2020, by 8:00 a.m. Central Standard Time. *See* Email from Cockle Legal Briefs to Stephanie Toti (January 22, 2020) (attached hereto as Exhibit B).
11. Plaintiffs request expedited briefing and decision on this motion so that, if the motion is granted, Plaintiffs can cite the Statement of Deficiencies and Plan of Correction in their brief in opposition. Specifically, Plaintiffs request that the Court direct Defendants to file their response to this motion by February 7, 2020, seven days from today, and that the Court issue a decision, if possible, by February 14, 2020.

WHEREFORE, Plaintiffs respectfully request that the Court enter an order granting them leave to supplement the record with the attached Statement of Deficiencies and Plan of Correction. Plaintiffs further request that the Court direct Defendants to respond to this motion by February 7, 2020, and that the Court issue a decision, if possible, by February 14, 2020.

Dated: January 31, 2020

Respectfully submitted,

/s/ Dipti Singh

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*Admitted *pro hac vice*

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that, on January 31, 2020, a true and correct copy of the foregoing document was served on all counsel of record via the Court's Electronic Court Filing (ECF) system.

Dated: January 31, 2020

/s/ Dipti Singh

Dipti Singh

Exhibit A

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 C 11/07/2019
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NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

WHOLE WOMAN'S HEALTH ALLIANCE, INC

**3511 LINCOLNWAY WEST
SOUTH BEND, IN 46628**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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) COMPLETE DATE
T 000	INITIAL COMMENTS This visit was for a licensure survey and investigation of 3 licensure complaints. Complaint Number: IN00308566 Unsubstantiated; lack of sufficient evidence. Complaint Number: IN00304763 Unsubstantiated; lack of sufficient evidence. Complaint Number: IN00304752 Unsubstantiated; lack of sufficient evidence. Complaint Number: IN00312482 Unsubstantiated; lack of sufficient evidence. Date: 11-06 & 07-19 Facility Number: 014264 QA: 11/14/19	T 000		
T9999	MEMO ***410 IAC 26.5-5-1(c)(5) Governing Body: Powers and Duties: Approve all appointments to or contracts with medical staff. This rule is not met as evidenced by; 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). Findings include;	T9999	410 IAC 26.5-5-1(c)(5) 1) For each existing appointment, including reappointment, to or contract with medical staff, the Governing Body shall write a statement that the Governing Body approves the appointment or contract and the basis for its approval (such as review of credentials, qualifications, experience, and/or references). The statement shall be placed in the personnel record of the medical staff member. We will refer to this statement as the "Medical Staff Approval Statement." 2) For any future appointment to or contract with medical staff, the Governing Body shall write a Medical Staff Approval Statement providing that the Governing Body approves the appointment or contract and the basis for its approval (such as review of credentials, qualifications, experience, and/or references). The statement shall be placed in the personnel record of the medical staff member.	1/19/2020

Indiana State Department of Health

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

1/3/19

Indiana State Department of Health

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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		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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) COMPLETE DATE
T9999	<p>Continued From page 1</p> <p>1. Review of MD #1 & #2's Credential files lacked documentation of Governing Board approval of appointment or contract to the medical staff.</p> <p>2. 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> <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> <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> <p>***410 IAC 26.5-5-2 (d)(3)(A)(F) Appointment and</p>	T9999	<p>(Continued from page 1)The Governing Body Policy shall be revised to reflect that a Medical Staff Approval Statement shall be added to a medical staff member's personnel record whenever the facility appoints or enters into a contract with the medical staff member.</p> <p>3)The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-5-2(d)(1)</p> <p>1) For each existing appointment to or contract with medical staff, the Governing Body shall require that the Medical Director provide a statement documenting their approval and recommendation of such appointment or contract and the basis for their approval and recommendation. The Medical Director Recommendation shall be placed in the personnel record of the medical staff member. We will refer to this statement as the Medical Director Recommendation.</p> <p>2) For any future appointment to or contract with medical staff, the Governing Body shall require that the Medical Director provide a Medical Director Recommendation documenting their approval and recommendation of such appointment or contract and the basis for their approval and recommendation. The Medical Director Recommendation shall be placed in the personnel record of the medical staff member. The Governing Body Policy shall be revised to require that a Medical Director Recommendation shall be included in medical staff personnel records to document that the Governing Body has ensured that appointments to or contracts with medical staff are acted upon with the Medical Director's advice and recommendation.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-5-2(d)(3)(A) and (F)</p>		<p>1/19/20</p> <p>1/19/20</p>

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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	<p>(Continued from page 2)</p> <p>1) For each existing appointment or contract with a member of the medical staff, the Governing Body shall require that the Medical Staff Approval Statement include the basis for the Governing Body's opinion that the medical staff member possesses the requisite individual character and judgment. Copies of emails, letters of recommendations, or documentation of reference calls relied upon by the Governing Body to conclude that a medical staff member possesses the requisite degree of individual character and judgment shall be placed in the medical staff member's personnel record.</p> <p>2) For any future appointment or contract with a member of the medical staff, the Governing Body shall require that the Medical Staff Approval Statement include the basis for the Governing Body's opinion that the medical staff member possesses the requisite individual character and judgment. Copies of emails, letters of recommendations, or documentation of reference calls relied upon by the Governing Body to conclude that the medical staff member possesses the requisite individual character and judgment shall be placed in the medical staff member's personnel record.</p> <p>The Governing Body Policy shall be revised to provide that criteria for selection of medical staff must include individual character, competence, education, training, experience, and judgment pursuant to 410 IAC 26.5-5-2(d)(3). The policy shall be further revised to provide that the Governing Body shall ensure that individual character and judgment are assessed for any member of the medical staff based on letters of recommendation or reference calls, and that copies of such letters or documentation of such calls shall be placed in the personnel record of the medical staff member.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p>	

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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> <p>1. Review of the facility policy & procedures lacked documentation of a policy and procedure for communication with physicians concerning a patient emergency.</p> <p>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> <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	<p>410 IAC 26.5-5-1(c)(7)(B)</p> <p>1) The Governing Body shall revise the Governing Body Policy to provide that facility policies and procedures must be reviewed at least triennially. The policy shall be further revised to state that the facility's policies and procedures must be reviewed in 2022, and every three years after 2022. The Governing Body Policy shall set forth the standards for review, the staff responsible, and documentation of each triennial review.</p> <p>2) The Governing Body shall ensure that the Governing Body Policy retains the requirement that facility policies and procedures be reviewed at least triennially.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-5-1(c)(8)(A)</p> <p>1) The Governing Body shall establish a policy and procedure for communication with physicians concerning a patient emergency. Such policy shall be included in the facility policies and procedures.</p> <p>2) The Governing Body shall ensure that the policy and procedure for communication with physicians concerning a patient emergency is retained in the facility policies and procedures.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-6-2(c)(1)(B)</p> <p>1) The facility shall develop a policy and procedure concerning criminal history as a health care worker practice problem. The policy shall require the facility to conduct a criminal record background check prior to retaining a health care worker, either as an employee or on a contract basis, and to document the results of the background check in the employee's personnel record. This policy shall be included in the facility policies and procedures.</p> <p>2) The criminal history policy shall set forth the</p>	<p>1/19/20</p> <p>1/19/20</p> <p>1/19/20</p>

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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	<p>(Continued from page 4) following to ensure the policy is implemented and maintained: 1) person or persons responsible for conducting the criminal background check; 2) procedures for documenting the criminal background check in the employee's personnel record; and 3) procedures for updating the policy. 3)The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-10-1(b)(2) 1)As set forth above, for each existing appointment, including reappointment, to or contract with medical staff, the Governing Body shall require that the Medical Director provide a Medical Director Recommendation documenting their approval and recommendation of the appointment or contract and the basis for the approval and recommendation. The statement shall be placed in the personnel record of the medical staff member. 2)For any future appointment to or contract with medical staff, the Governing Body shall require that the Medical Director provide a Medical Director Recommendation documenting their approval and recommendation of the appointment or contract and the basis for the approval or recommendation. The statement shall be placed in the personnel record of the medical staff member. The Governing Body Policy shall be revised to reflect that a Medical Director Recommendation shall be added to all medical staff personnel records to document that the Governing Body has ensured that appointments to or contracts with medical staff are acted upon with the Medical Director's advice and recommendation.</p>	1/19/20

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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> <p>1. Review of the facility policy & procedures lacked documentation of a policy and procedure for personnel authorized to take a verbal order.</p> <p>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> <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	<p>(Continued from page 5)</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-10-1(c)(3)</p> <p>1)The Medical Director shall develop a policy and procedure concerning personnel authorized to take verbal orders. The policy shall include the type of medical personnel authorized to take verbal orders consistent with Indiana law and the medical personnel's scope of practice. The policy shall also include a process for maintaining the policy, including periodic review.</p> <p>2) The Governing Body shall ensure that the verbal order policy is developed and maintained consistent with the criteria above. The Governing Body shall ensure that the verbal order policy is retained in the facility policies and procedures.</p> <p>3)The Governing Body shall be responsible for ensuring the Medical Director completes number 1 above. The Governing Body shall be responsible for ensuring number 2 above.</p> <p>410 IAC 26.5-12-1(e)(2)(E)(v)</p> <p>1)The Infection Control Program Policy shall be revised to provide for a policy on the reuse of disposables. If the clinic does not reuse any disposables, the policy shall state that.</p> <p>2) The Infection Control Program's policy on the reuse of disposables shall include a provision for the Infection Control Committee's review of such policy and a process for making recommended changes. The Governing Body shall ensure that the policy on reuse of disposables is retained in the Infection Control Program.</p>	1/19/20
				1/19/20

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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	<p>(Continued from page 6)</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-12-1(e)(2)(E)(viii) 1)The Infection Control Program Policy shall be revised to provide for a policy and procedure concerning the communicable disease history of new personnel. The policy shall include standards for collecting information on new personnel's communicable disease history and provisions for documenting such history. The policy shall be consistent with recommendations and requirements from the Centers for Disease Control and Prevention and applicable Indiana law. The Infection Control Program Policy shall be further revised to provide for a policy to develop and implement an ongoing program addressing communicable diseases for current personnel. The policy shall provide standards and timelines for the program, including a process for documenting completion of the program. The policy shall be consistent with recommendations and requirements from the Centers for Disease Control and Prevention and applicable Indiana law. 2)The Infection Control Program's communicable disease policy shall include a provision for the Infection Control Committee's review of the policy, a process for making recommended changes, and provisions to ensure that the policy remains consistent with recommendations and requirements from the Centers for Disease Control and Prevention and applicable Indiana law. The Governing Body</p>	1/19/20

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 C 11/07/2019
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE, INC		STREET ADDRESS, CITY, STATE, ZIP CODE 3511 LINCOLNWAY WEST SOUTH BEND, IN 46628		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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) COMPLETE DATE
T9999	Continued From page 7 the facility did not have policies that addressed the communicable disease history of new personnel as well as an ongoing program for current personnel. ***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 This rule is not met as evidenced by; 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. Findings include; 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.	T9999	(Continued from page 7) shall ensure that the communicable disease policy is retained in the Infection Control Program. 3) The Governing Body shall be responsible for numbers 1 and 2 above. 410 IAC 26.5-16-1(3)(D) 1) The clinic shall develop a policy to provide that instructions to patients on the use of take home medication is the responsibility of the prescribing physician. The policy shall provide that the prescribing physician must review any written instructions given to patients concerning such medication and personally provide any verbal instructions concerning such medication. The policy shall be made available to facility personnel. 2) The Governing Body shall ensure that this policy is retained in the clinic's policies and procedures and remains available to facility personnel. 3) The Governing Body shall be responsible for numbers 1 and 2 above.	1/19/20
	***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		410 IAC 26.5-16-1(3)(B)(i) 1) The clinic shall revise its Adverse Events policy to provide that any facility personnel must report any adverse reactions and	1/19/20

Indiana State Department of Health

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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	<p>(Continued from page 8) medication errors to the physician responsible for the patient. The policy shall be made available to facility personnel.</p> <p>2)The Governing Body shall ensure that this policy is retained in the facility's policies and procedures and remains available to facility personnel.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-16-1(4) 1) The facility shall create a formulary. 2)The clinic's formulary shall be readily available for facility personnel and surveyors. The facility shall establish a process by which to revise the formulary on an annual basis. 3)The Governing Body shall be responsible for numbers 1 and 2 above.</p>	1/19/20	

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3511 LINCOLNWAY WEST
SOUTH BEND, IN 46628

Indiana State Department of Health
STATE FORM 6899 TMV11 If continuation sheet 10 of 12

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 C 11/07/2019
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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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	<p>(Continued from page 10) copies of emails or other correspondence containing requests for such coordination. Such written documentation shall be retained in the facility's policies and procedures.</p> <p>2) The facility shall, on an annual basis, continue to attempt to coordinate with a community, state, or federal agency regarding emergency disaster preparedness. In doing so, the facility shall contact the Indiana State Department of Health Emergency Preparedness Resource Center on an annual basis and document such attempts to coordinate with it. The facility shall continue to document in writing in accordance with the standards above all attempts to coordinate with a community, state, or federal agency regarding emergency disaster preparedness.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-9-1(a)(2)(E)</p> <p>1) The facility shall ensure that existing staff who are responsible for packaging medications are trained to package medications and document such training. The facility shall ensure that staff members who repack drugs do so consistent with their scope of practice and Indiana State Board of Pharmacy rules. Documentation of such training shall be placed in the staff member's personnel record.</p> <p>2) The facility shall ensure that any staff hired in the future who are responsible for packaging medications are trained to package medications and document such training. The facility shall ensure that such staff members who repack drugs do so consistent with their scope of practice and Indiana State Board of Pharmacy rules. Documentation of such training shall be placed in the staff member's personnel record.</p> <p>3) The Governing Body shall be responsible for numbers 1 and 2 above.</p> <p>410 IAC 26.5-9-1(a)(2)(F)(i) and (iii)</p> <p>1) The clinic shall ensure that personnel records of existing employees include the employee's post-offer and subsequent health records, including physical examinations and immunizations. If they have not</p>	<p>1/19/20</p> <p>1/19/20</p>

Indiana State Department of Health

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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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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	(Continued from page 11) already, existing employees shall undergo a physical exam; evidence of such examination shall be documented in the employee's personnel record. If they have not already, existing employees shall undergo any immunizations recommended by the Centers on Disease Control and Prevention, based on the employee's immunization status, and provide documentation of such immunizations and their prior immunization status. Such documentation must be kept in the employee's personnel record. The clinic shall ensure existing employees have undergone the appropriate physical examination and immunizations and update the personnel records pursuant to the standards above. 2) The facility shall establish and implement a policy to ensure that personnel records of all employees include the employee's post-offer and subsequent health records, including physical examinations and immunizations. The policy shall require that all personnel undergo a physical exam within 30 days of the start of their employment; evidence of such examination shall be documented in the employee's personnel file. The policy shall also require all personnel to undergo any immunizations recommended by the Centers on Disease Control and Prevention within 30 days of the start of their employment, based on the employee's immunization status, and to provide documentation of such immunizations and their prior immunization status. Such documentation must be kept in the employee's personnel record. The policy shall provide that each employee's health records must be updated on an annual basis. 3) The Governing Body shall be responsible for numbers 1 and 2 above.	

Exhibit B

Stephanie Toti

From: Cockle Legal Briefs <contact@cocklelegalbriefs.com>
Sent: Wednesday, January 22, 2020 11:26 AM
To: Stephanie Toti
Subject: #19-743; Curtis T. Hill, Jr., et al. v. Whole Woman's Health Alliance, et al.

stoti@lawyeringproject.org

January 22, 2020

RE: #19-743; Curtis T. Hill, Jr., et al. v. Whole Woman's Health Alliance, et al.

Dear Ms. Toti:

Thank you for choosing Cockle Legal Briefs to prepare your U.S. Supreme Court brief. This email is to confirm that you will be sending us your documents by **8:00 AM Central** on the date indicated:

Brief In Opposition

Brief Arrival

02/18/20

When you send us your document(s), please include a service list. This list must contain the counsel of record's name, address, telephone number, email address and language stating the party they represent.

IMPORTANT: New word count limits for party merits briefs and certain amicus merits briefs. Click [here](#) to review changes to Rule 33.1(g).

AND: Click [here](#) for important new guidelines for amicus filings.

Sincerely,

Andy

Andy Cockle
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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

WHOLE WOMAN’S HEALTH ALLIANCE;)	
ALL-OPTIONS, INC.; and JEFFREY)	CASE NO. 1:18-cv-1904-SEB-MJD
GLAZER, M.D.,)	
)	
Plaintiffs,)	CIVIL ACTION
)	
v.)	
)	
CURTIS T. HILL, JR., Attorney General of)	
the State of Indiana, in his official capacity;)	
KRISTINA BOX, M.D., Commissioner of the)	
Indiana State Department of Health, in her)	
official capacity; JOHN STROBEL, M.D.,)	
President of the Medical Licensing Board of)	
Indiana, in his official capacity; and)	
KENNETH P. COTTER, St. Joseph County)	
Prosecutor, in his official capacity,)	
)	
Defendants.)	

ORDER

The Court has considered Plaintiffs’ request for expedited briefing and decision in connection with their Motion for Leave to Supplement the Record and finds that good cause exists to grant the request.

Accordingly, it is hereby ORDERED that Defendants shall file their response to Plaintiffs’ Motion for Leave to Supplement the Record on or before February 7, 2020.

Dated: February ____, 2020

HON.

Distribution: All CM/ECF registered counsel of record

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

WHOLE WOMAN’S HEALTH ALLIANCE;)	
ALL-OPTIONS, INC.; and JEFFREY)	CASE NO. 1:18-cv-1904-SEB-MJD
GLAZER, M.D.,)	
)	
Plaintiffs,)	CIVIL ACTION
)	
v.)	
)	
CURTIS T. HILL, JR., Attorney General of)	
the State of Indiana, in his official capacity;)	
KRISTINA BOX, M.D., Commissioner of the)	
Indiana State Department of Health, in her)	
official capacity; JOHN STROBEL, M.D.,)	
President of the Medical Licensing Board of)	
Indiana, in his official capacity; and)	
KENNETH P. COTTER, St. Joseph County)	
Prosecutor, in his official capacity,)	
)	
Defendants.)	

ORDER

The Court has considered Plaintiffs’ Motion for Leave to Supplement the Record and finds that good cause exists to grant the motion.

Accordingly, it is hereby ORDERED that the Statement of Deficiencies and Plan of Correction attached to Plaintiffs’ motion is entered into this Court’s official record of the case.

Dated: February ____, 2020

HON.

Distribution: All CM/ECF registered counsel of record