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. *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.
- 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

Dipti Singh dsingh@lawyeringproject.org LAWYERING PROJECT 3371 Glendale Blvd., # 320 Los Angeles, CA 90039 (646) 480-8973

Rupali Sharma rsharma@lawyeringproject.org LAWYERING PROJECT 110 Winter St., #4 Portland, ME 04102 (908) 930-6645

Amanda Allen*
aallen@lawyeringproject.org
Juanluis Rodriguez*
prodriguez@lawyeringproject.org
Stephanie Toti
stoti@lawyeringproject.org
LAWYERING PROJECT
25 Broadway, Fl. 9
New York, NY 10004
(646) 490-1083

Kathrine D. Jack kjack@lawoffice.com JACK LAW OFFICE LLC One Courthouse Plaza P.O. Box 813 Greenfield, IN 46140 (317) 477-2300

Paul M. Eckles*
paul.eckles@probonolaw.com
Athanasia Charmani*
thania.charmani@probonolaw.com
Michelle Honor*
michelle.honor@probonolaw.com
Mollie M. Kornreich*
mollie.kornreich@probonolaw.com
Morgan Petkovich*
morgan.petkovich@probonolaw.com
Michael M. Powell*
michael.powell@probonolaw.com
4 Times Square, Fl. 24
New York, New York 10036
(212) 735-3000

Attorneys for Plaintiffs

^{*}Admitted *pro hac vice*

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

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Indiana State Department of Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING: C B. WING 014264 11/07/2019 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) T 000 INITIAL COMMENTS T 000 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 T9999 MEMO T9999 410 IAC 26.5-5-1(c)(5) 1/19/2020 1) For each existing appointment, including reappointment, to or contract with medical staff, the ***410 IAC 26.5-5-1(c)(5) Governing Body: Governing Body shall write a statement that the Powers and Duties: Governing Body approves the appointment or Approve all appointments to or contracts with contract and the basis for its approval (such as medical staff. review of credentials, qualifications, experience, and/or references). The statement shall be placed in This rule is not met as evidenced by; the personnel record of the medical staff member. We will refer to this statement as the "Medical Staff Based on document review & interview the Approval Statement." Governing Body failed to approve all 2) For any future appointment to or contract with appointments or contracts to the medical staff for medical staff, the Governing Body shall write a 2 of 5 medical staff files reviewed (MD #1 & MD Medical Staff Approval Statement providing that #2). the Governing Body approves the appointment or contract and the basis for its approval (such as Findings include; review of credentials, qualifications, experience, and/or references). The statement shall be placed in the personnel record of the medical staff member.

Indiana State Department of Health

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

TITLE

(X6) DATE

1/3/19

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Indiana State Department of Health (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA **IDENTIFICATION NUMBER:** COMPLETED AND PLAN OF CORRECTION A. BUILDING: C B. WING 11/07/2019 014264 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE **PREFIX** PRÉFIX DATE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) T9999 T9999 Continued From page 1 (Continued from page 1) The Governing Body Policy shall be revised to reflect that a Medical Staff 1. Review of MD #1 & #2's Credential files lacked Approval Statement shall be added to a medical staff documentation of Governing Board approval of member's personnel record whenever the facility appointment or contract to the medical staff. appoints or enters into a contract with the medical staff member. 2. On 11/06/19 at 1615 hours staff #40 confirmed there was no documentation of the Governing 3) The Governing Body shall be responsible for Board approving appointment or contract to the numbers 1 and 2 above. medical staff for MD #1 & #2. 1/19/20 ***410 IAC 26.5-5-2 (d)(1) Appointment and 410 IAC 26.5-5-2(d)(1) conduct of medical staff: 1) For each existing appointment to or contract with In appointing or contracting with medical staff, the medical staff, the Governing Body shall require that the Medical Director provide a statement governing body shall do the following: documenting their approval and recommendation of Ensure that appointments to or contracts with the such appointment or contract and the basis for their medical staff are acted upon the advice and approval and recommendation. The Medical recommendation of the medical director. Director Recommendation shall be placed in the personnel record of the medical staff member. We This rule is not met as evidenced by; will refer to this statement as the Medical Director Recommendation. Based on document review & interview the 2) For any future appointment to or contract with Medical Director failed to provide a medical staff, the Governing Body shall require that recommendation for appointment to the Medical the Medical Director provide a Medical Director Staff for 3 of 5 medical staff files reviewed (MD Recommendation documenting their approval and #3, MD #4 & MD #5) to the Governing Board. recommendation of such appointment or contract and the basis for their approval and Findings include; recommendation. The Medical Director Recommendation shall be placed in the personnel 1. Review of MD #3, MD #4 & MD #5's medical record of the medical staff member. staff files lacked documentation of the Medical The Governing Body Policy shall be revised to Director's recommendation for appointment to the require that a Medical Director Recommendation medical staff. shall be included in medical staff personnel records to document that the Governing Body has ensured that appointments to or contracts with medical staff 2. On 11/06/19 at 1615 hours staff #40 confirmed are acted upon with the Medical Director's advice there was no documentation of the medical and recommendation. director recommending appointment to medical 3) The Governing Body shall be responsible for staff for MD #3, MD #4 & MD #5. numbers 1 and 2 above.

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***410 IAC 26.5-5-2 (d)(3)(A)(F) Appointment and

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410 IAC 26.5-5-2(d)(3)(A) and (F)

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Indiana State Department of Health (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING: C B WING 11/07/2019 014264 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) 410 IAC 26.5-5-1(c)(7)(B) T9999 T9999 Continued From page 3 1/19/20 1) The Governing Body shall revise the Governing ***410 IAC 26.5-5-1(c)(8)(A) Governing Body: Body Policy to provide that facility policies and Powers and Duties: procedures must be reviewed at least triennially. Establish the following: The policy shall be further revised to state that the A policy and procedure for communication with facility's policies and procedures must be reviewed in 2022, and every three years after 2022. The physicians concerning a patient emergency. Governing Body Policy shall set forth the standards for review, the staff responsible, and documentation This rule is not met as evidenced by: of each triennial review. 2) The Governing Body shall ensure that the Based on document review & interview the Governing Body Policy retains the requirement that governing board failed to establish a policy and facility policies and procedures be reviewed at least procedure for communication with physicians triennially. concerning a patient emergency for 1 facility. 3) The Governing Body shall be responsible for numbers 1 and 2 above. Findings include; 410 IAC 26.5-5-1(c)(8)(A) 1. Review of the facility policy & procedures 1/19/20 1) The Governing Body shall establish a policy and lacked documentation of a policy and procedure procedure for communication with physicians for communication with physicians concerning a concerning a patient emergency. Such policy shall be patient emergency. included in the facility policies and procedures. 2) The Governing Body shall ensure that the policy 2. On 11/06/19 at 1550 hours staff #40 confirmed and procedure for communication with physicians there was no policy and procedure for concerning a patient emergency is retained in the communication with physicians concerning a facility policies and procedures. patient emergency. 3) The Governing Body shall be responsible for numbers 1 and 2 above. ***410 IAC 26.5-6-2(c)(1)(B) Required Policies 410 IAC 26.5-6-2(c)(1)(B) 1/19/20 and procedures: 1) The facility shall develop a policy and The clinic shall develop, implement, and maintain procedure concerning criminal history as a the following: health care worker practice problem. The Policies that cover health care worker practice policy shall require the facility to conduct a problems, including, but not limited to, the criminal record background check prior to following: retaining a health care worker, either as an Criminal history. employee or on a contract basis, and to document the results of the background check This rule is not met as evidenced by; in the employee's personnel record. This policy shall be included in the facility policies and Based on document review & interview the facility procedures. failed to ensure a policy & procedure for health

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care worker practice problems addressing

2) The criminal history policy shall set forth the

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Indiana State Department of Health (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING: C B. WING 11/07/2019 014264 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETE (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) T9999 Continued From page 4 T9999 (Continued from page 4) following to ensure the policy is implemented and maintained: 1) criminal history was developed, implemented & person or persons responsible for conducting maintained for 1 facility. the criminal background check; 2) procedures for documenting the criminal background Findings include: check in the employee's personnel record; and 3) procedures for updating the policy. 1. Review of the facility policy & procedures 3) The Governing Body shall be responsible for lacked documentation of a policy and procedure numbers 1 and 2 above. for health care worker practice problems addressing criminal history. 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. ***410 IAC 26.5-10-1(b)(2) Medical staff services 410 IAC 26.5-10-1(b)(2) 1/19/20 1) As set forth above, for each existing appointment, The medical director must do the following: including reappointment, to or contract with Make recommendations to the governing body on medical staff, the Governing Body shall require that the appointment of medical staff. the Medical Director provide a Medical Director Recommendation documenting their approval and This rule is not met as evidenced by: recommendation of the appointment or contract and the basis for the approval and recommendation. Based on document review & interview the The statement shall be placed in the personnel Medical Director failed to provide a record of the medical staff member. recommendation for appointment to the Medical 2) For any future appointment to or contract with Staff for 3 of 5 medical staff files reviewed (MD medical staff, the Governing Body shall require that #3, MD #4 & MD #5) to the Governing Board. the Medical Director provide a Medical Director Recommendation documenting their approval and Findings include; recommendation of the appointment or contract and the basis for the approval or recommendation. 1. Review of MD #3, MD #4 & MD #5's medical The statement shall be placed in the personnel staff files lacked documentation of the Medical record of the medical staff member. Director's recommendation for appointment to the The Governing Body Policy shall be revised to reflect that a Medical Director Recommendation shall be medical staff. added to all medical staff personnel records to 2. On 11/06/19 at 1615 hours staff #40 confirmed document that the Governing Body has ensured that appointments to or contracts with medical staff are there was no documentation of the medical acted upon with the Medical Director's advice and director recommending appointment to medical

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staff for MD #3, MD #4 & MD #5.

recommendation.

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Indiana State Department of Health (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING: C B. WING 11/07/2019 014264 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRÉFIX DATE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) T9999 T9999 Continued From page 5 (Continued from page 5) 3) The Governing Body shall be responsible for numbers 1 and 2 above. ***410 IAC 26.5-10-1(c)(3) Medical staff services 410 IAC 26.5-10-1(c)(3) 1/19/20 The medical director must do the following; 1) The Medical Director shall develop a policy There is a provision for personnel authorized to and procedure concerning personnel take a verbal order. authorized to take verbal orders. The policy shall include the type of medical personnel This rule is not met as evidenced by; authorized to take verbal orders consistent with Indiana law and the medical personnel's Based on document review & interview the scope of practice. The policy shall also medical director failed to ensure a policy & include a process for maintaining the policy, procedure for personnel authorized to take a including periodic review. verbal order was developed & maintained for 1 facility. 2) The Governing Body shall ensure that the verbal order policy is developed and Findings include: maintained consistent with the criteria above. The Governing Body shall ensure that the 1. Review of the facility policy & procedures verbal order policy is retained in the facility lacked documentation of a policy and procedure policies and procedures. for personnel authorized to take a verbal order. 3) The Governing Body shall be responsible for ensuring the Medical Director completes 2. On 11/07/19 at 0945 hours staff #41 confirmed number 1 above. The Governing Body shall there was no policy & procedure for personnel be responsible for ensuring number 2 above. authorized to take a verbal order. ***410 IAC 26.5-12-1(e)(2)(E)(v) Infection control 1/19/20 410 IAC 26.5-12-1(e)(2)(E)(v) administration 1) The Infection Control Program Policy shall The clinic must establish a committee to monitor be revised to provide for a policy on the reuse and guide the infection control program in the of disposables. If the clinic does not reuse any clinic as follows: disposables, the policy shall state that. The infection control committee responsibilities 2) The Infection Control Program's policy on must include, but are not limited to, the following: the reuse of disposables shall include a Reviewing and recommending changes in provision for the Infection Control procedures, policies, and programs that are Committee's review of such policy and a pertinent to infection control. These include, but process for making recommended changes. are not limited to, the following: The Governing Body shall ensure that the Reuse of disposables. policy on reuse of disposables is retained in the

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This rule is not met as evidenced by;

Infection Control Program.

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Indiana State Department of Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING: C B WING 014264 11/07/2019 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PRFFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) (Continued from page 6) T9999 Continued From page 6 T9999 3) The Governing Body shall be responsible for numbers 1 and 2 above. Based on interview the facility failed to have a policy & procedure on the reuse of disposables for 1 facility. Findings include: 1. On 11/07/19 at 1015 hours staff #40 confirmed the facility did not have policy & procedure on the reuse of disposables. 410 IAC 26.5-12-1(e)(2)(E)(viii) 1/19/20 ***410 IAC 26.5-12-1(e)(2)(E)(viii) Infection 1)The Infection Control Program Policy shall be control administration revised to provide for a policy and procedure The clinic must establish a committee to monitor concerning the communicable disease history of new and guide the infection control program in the personnel. The policy shall include standards for clinic as follows: collecting information on new personnel's The infection control committee responsibilities communicable disease history and provisions for must include, but are not limited to, the following: documenting such history. The policy shall be Reviewing and recommending changes in consistent with recommendations and requirements procedures, policies, and programs that are from the Centers for Disease Control and Prevention pertinent to infection control. These include, but and applicable Indiana law. are not limited to, the following: The Infection Control Program Policy shall be An employee health program to determine the further revised to provide for a policy to develop and communicable disease history of new personnel implement an ongoing program addressing as well as an ongoing program for current communicable diseases for current personnel. The policy shall provide standards and timelines for the personnel as required by state and federal program, including a process for documenting agencies. completion of the program. The policy shall be consistent with recommendations and requirements This rule is not met as evidenced by; from the Centers for Disease Control and Prevention and applicable Indiana law. Based on interview the the facility failed to ensure 2) The Infection Control Program's communicable it had developed, implemented & maintained disease policy shall include a provision for the policies addressing the communicable disease Infection Control Committee's review of the policy, a history of new personnel as well as an ongoing process for making recommended changes, and program for current personnel for 1 facility. provisions to ensure that the policy remains consistent with recommendations and requirements Findings include; from the Centers for Disease Control and Prevention

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1. On 11/07/19 at 1020 hours staff #40 confirmed

and applicable Indiana law. The Governing Body

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Indiana State Department of Health (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING: C B. WING 11/07/2019 014264 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3511 LINCOLNWAY WEST WHOLE WOMAN'S HEALTH ALLIANCE, INC SOUTH BEND, IN 46628 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) (Continued from page 7) shall ensure that the T9999 Continued From page 7 T9999 communicable disease policy is retained in the the facility did not have policies that addressed Infection Control Program. the communicable disease history of new 3) The Governing Body shall be responsible for personnel as well as an ongoing program for numbers 1 and 2 above. current personnel. ***410 IAC 26.5-16-1(3)(D) Pharmaceutical 410 IAC 26.5-16-1(3)(D) 1/19/20 services 1) The clinic shall develop a policy to provide The clinic must provide drugs and biologicals in a that instructions to patients on the use of take safe and effective manner in accordance with home medication is the responsibility of the accepted professional practice. The clinic must prescribing physician. The policy shall provide have the following: that the prescribing physician must review any Written policies and procedures developed, written instructions given to patients implemented, maintained, and made available to concerning such medication and personally personnel, including, but not limited to, the provide any verbal instructions concerning following: Reporting of adverse reactions and medication such medication. The policy shall be made available to facility personnel. errors to the: physician responsible for the patient 2) The Governing Body shall ensure that this policy is retained in the clinic's policies and This rule is not met as evidenced by; procedures and remains available to facility personnel. Based on interview the facility failed to have 3) The Governing Body shall be responsible for written policies and procedures developed, numbers 1 and 2 above. 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. 410 IAC 26.5-16-1(3)(B)(i) ***410 IAC 26.5-16-1(3)(B)(i) Pharmaceutical 1/19/20 1) The clinic shall revise its Adverse Events services policy to provide that any facility personnel

Indiana State Department of Health STATE FORM

The clinic must provide drugs and biologicals in a

safe and effective manner in accordance with

TFMV11

must report any adverse reactions and

Case 1:18-cv-01904-SEB-MJD Document 249-1 Filed 01/31/20 Page 10 of 13 Page ID #: 2/20/2019 5836 FORM APPROVED

STATEMEN	State Department o	(X1) PROVIDER/SUPPLIER/CLIA	(X2) MULTIP	LE CONSTRUCTION	(X3) DATE S	
AND PLAN OF CORRECTION IDENTIFICATION NUMBER: 014264		A. BUILDING:		COMPLETED		
		B. WING		C 11/07/2019		
	PROVIDER OR SUPPLIER	ALLIANCE INC 3511 LINC	DRESS, CITY, COLNWAY V END, IN 46		134 133	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULE CROSS-REFERENCED TO THE APPROP DEFICIENCY)	D BE	(X5) COMPLETE DATE
T9999	have the following: Written policies an implemented, main personnel, includir following; Instructions to the home medication in prescribing physic. This rule is not medicated and made available procedures which patients on the use the responsibility of facility. Findings include; 1. On 11/07/19 at the facility did not addressed that instructions are implemented in the second	d procedures developed, ntained, and made available to ag, but not limited to, the patient on the use of take s the responsibility of the ian. It as evidenced by; If the facility failed to ensure the ed, implemented, maintained, e to personnel policy & addressed instructions to e of take home medication is of the prescribing physician for 1	T9999	(Continued from page 8) medication ending the physician responsible for the patient policy shall be made available to facility personnel. 2) The Governing Body shall ensure the policy is retained in the facility's policie procedures and remains available to facility personnel. 3) The Governing Body shall be respond numbers 1 and 2 above.	at this es and cility	
	The clinic must prosafe and effective accepted professionave the following A formulary. This rule is not me	et as evidenced by; w the facility failed to ensure the		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 sur The facility shall establish a process by to revise the formulary on an annual be 3)The Governing Body shall be responsible to the formulary of the responsible to the formulary of the formulary of the responsible to the formulary of the responsible to the formulary of	ly veyors. which pasis.	1/19/20

Indiana State Department of Health STATE FORM

Case 1:18-cv-01904-SEB-MJD Document 249-1 Filed 01/31/20 Page 11 of 13 Page ID #: 5837 FORM APPROVED

Indiana	State Department of	Health			
STATEMEN	NT OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			TE SURVEY MPLETED
		014264	B. WING	1	C /07/2019
	PROVIDER OR SUPPLIER	ALLIANCE INC. 3511 LING	DORESS, CITY, COLNWAY V BEND, IN 46		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC 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 pa	age 9	Т9999		
	requested to provide formulary & none of the formular inspection and appropriate and local regular inspection of the formular inspection of the	itten evidence of regular proval by state and local fire accordance with the following: ulations. It as evidenced by; If the the facility failed to ensure mentation of evidence of and approval by state and local		410 IAC 26.5-17-6(a)(6)(A)-(B) 1)The clinic shall document all evidence of regular inspection and approval by state and local fire agencies. If such inspection is unavailable, the clinic shall document in writing all attempts to secure such an inspection via call logs or by retaining copies of emails containing requests for such inspections. Such written documentation shall be retained in the facility's policies and procedures. 2) The facility shall, on an annual basis, continue to attempt to secure an inspection and approval by a local or state fire agency. The facility shall continue to document all attempts to secure such an inspection in writing in accordance with the standards above. 3) The Governing Body shall be responsible for numbers 1 and 2 above.	1/19/20
	not limited to, the f Emergency and dis	ent program must include, but ollowing: saster preparedness ppropriate community, state, es.		410 IAC 26.5-17-6(a)(7) 1)The facility shall document in its Safety Management Program all evidence of emergency disaster preparedness coordination with appropri community, state, and federal agencies. If such coordination is not possible, the clinic shall document in writing all attempts to coordinate wi an appropriate agency via call logs or by retaining	

This rule is not met as evidenced by; Indiana State Department of Health STATE FORM

Case 1:18-cv-01904-SEB-MJD Document 249-1 Filed 01/31/20 Page 12 of 13-Rage ID 12/20/2019 5838 FORM APPROVED

Indiana State Department of Health STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 014264		(X2) MULTIPLE CONSTRUCTION A. BUILDING:			(X3) DATE SURVEY COMPLETED	
		B. WING		C 11/07/2019		
	PROVIDER OR SUPPLIER	ALLIANCE INC 3511 LINC	DRESS, CITY COLNWAY V END, IN 40			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPRODEFICIENCY)	D BE	(X5) COMPLETE DATE
T9999	that emergency & coordinated with a and federal agencian Findings include; 1. On 11/07/19 at 0 emergency & disast coordinated with a	of the facility failed to ensure the disaster preparedness was an appropriate community, state less for 1 facility. Description of the preparedness that was an appropriate community, state ites was requested from staff	T9999	(Continued from page 10) copies of emails correspondence containing requests for su coordination. Such written documentation retained in the facility's policies and proced 2) The facility shall, on an annual basis, coattempt to coordinate with a community, sfederal agency regarding emergency disast preparedness. In doing so, the facility shall the Indiana State Department of Health En Preparedness Resource Center on an annuand document such attempts to coordinate The facility shall continue to document in accordance with the standards above all att coordinate with a community, state, or fed agency regarding emergency disaster prepared 3) The Governing Body shall be responsible	ch a shall be dures. Intinue to state, or er contact mergency al basis e with it. writing in tempts to eral aredness.	
	Personnel policies The abortion clinic accurate personnel Personnel records data that includes: in job-related educt health records of e offer and subsequ (iii) Immunizations Based on docume facility failed to pro packaging training and S4) who pack and failed to ensure	shall maintain current and el records for all employees. shall: (2) include personal (E) evidence of participation cation and training activities, (F) employees that relate to post ent: (i) physical examinations on the review and interview, the evide take home medication for 2 of 2 staff members (S3 age take home medications re documentation of Post offer unizations for 5 of 5 personnel		numbers 1 and 2 above. 410 IAC 26.5-9-1(a)(2)(E) 1) The facility shall ensure that existing staresponsible for packaging medications are package medications and document such The facility shall ensure that staff member repackage drugs do so consistent with the practice and Indiana State Board of Pharm Documentation of such training shall be pthe staff member's personnel record. 2) The facility shall ensure that any staff hifuture who are responsible for packaging medications are trained to package medications. 3) The Governing Body shall be responsib numbers 1 and 2 above.	e trained to training. s who ir scope of nacy rules. blaced in red in the ations and ensure rugs do so I Indiana tation of tember's	1/19/20
	lacked training on 2. Interview on 11/	onnel files for staff S3 and S4 medication packaging. 706/2019, at approximately 3:11 approximately 3:11		410 IAC 26.5-9-1(a)(2)(F)(i) and (iii) 1)The clinic shall ensure that personnel reexisting employees include the employee's and subsequent health records, including examinations and immunizations. If they	s post-offer physical	1/19/20

Indiana State Department of Health

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Case 1:18-cv-01904-SEB-MJD Document 249-1 Filed 01/31/20 Page 13 of 13 Page ID #: 5839 FORM APPROVED

Indiana	State Department of	Health				
	IT OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIF A. BUILDING	PLE CONSTRUCTION	(X3) DATE S	
		014264	B. WING		11/07	; 7/2019
	PROVIDER OR SUPPLIER	ALLIANCE INC. 3511 LING	DRESS, CITY, COLNWAY \ END, IN 46			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPRODEFICIENCY)	D BE	(X5) COMPLETE DATE
T9999	3. Review of perso S5 lacked docume and Immunizations 4. Interview on 11/6 staff #40 confirmed	ions for patients to take home. nnel files S1, S2, S3, S4 and ntation of Post offer Physical	T9999	(Continued from page 11) already, existing employees shall undergo a physical exam; of such examination shall be documented employee's personnel record. If they have already, existing employees shall undergo immunizations recommended by the Cent Disease Control and Prevention, based on employee's immunization status, and providocumentation of such immunizations an prior immunization status. Such document must be kept in the employee's personnel. The clinic shall ensure existing employees undergone the appropriate physical examinand immunizations and update the person records pursuant to the standards above. 2) The facility shall establish and implement to ensure that personnel records of all empinclude the employee's post-offer and subshealth records, including physical examinations. The policy shall require the personnel undergo a physical exam within the start of their employment; evidence of examination shall be documented in the expersonnel file. The policy shall also require personnel to undergo any immunizations recommended by the Centers on Disease Cand Prevention within 30 days of the start employment, based on the employee's immunization status, and to provide docu of such immunizations and their prior immunization status. Such documentation kept in the employee's personnel record. It shall provide that each employee's health must be updated on an annual basis. 3) The Governing Body shall be responsib numbers 1 and 2 above.	evidence in the not any ters on the vide d their ntation record. have ination nnel out a policy ployees sequent ations and nat all a 30 days of such imployee's e all Control of their mentation in must be The policy records	
	1/5		3 1/1	The State State State		

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 <u>here</u> to review changes to Rule 33.1(g).

AND: Click here for important new guidelines for amicus filings.

Sincerely,

Andy

Andy Cockle
Cockle Legal Briefs
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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

WHOLE WOMAN'S HEALTH ALLIANCE; ALL-OPTIONS, INC.; and JEFFREY GLAZER, M.D., Plaintiffs,) CASE NO. 1:18-cv-1904-SEB-MJD) 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.	
<u>Ol</u>	RDER
The Court has considered Plaintiffs' re	equest for expedited briefing and decision in
connection with their Motion for Leave to Supple	ment the Record and finds that good cause exists
to grant the request.	
Accordingly, it is hereby ORDERED that I	Defendants shall file their response to Plaintiffs'
Motion for Leave to Supplement the Record on o	or before February 7, 2020.

Distribution: All CM/ECF registered counsel of record

Dated: February _____, 2020

HON.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

WHOLE WOMAN'S HEALTH ALLIANCE; ALL-OPTIONS, INC.; and JEFFREY GLAZER, M.D.,) CASE NO. 1:18-cv-1904-SEB-MJD)
Plaintiffs,) CIVIL ACTION
Flamuits,	<i>)</i>)
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.)))))))))))))))))))
OR	<u>DER</u>
The Court has considered Plaintiffs' Motion	n 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