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December 14, 2021

IDOH Guidance for Implementation of Abortion Complication Reporting Requirements from Senate Enrolled Act (SEA) 340 and House Enrolled Act (HEA) 1211

Dear Partners:

As a result of a recent 7th Circuit Court of Appeals decision, an injunction preventing the enforcement of certain provisions of Senate Enrolled Act 340-2018 and House Enrolled Act 1211-2019, including Indiana Code section 16-34-2-4.7 (the "Reporting Requirement"), was lifted October 28, 2021, and these provisions are now enforceable.

This law sets forth the requirements in Indiana for licensed physicians, hospitals, and abortion clinics to report certain abortion complications to the state. The complete list of complications is attached to this letter.

Currently, Indiana Department of Health (IDOH) has a paper form that will need to be emailed to IDOH as of October 28, 2021. The required form can be found on the website at https://www.in.gov/health/vital-records/vital-record-registration/terminated-pregnancy-reporting/ Completed forms should be emailed to TPComplications@health.in.gov.

In addition, the IDOH provides the following guidance:

- The form should be filed within 30 days of the onset of treatment of the abortion complication.
- Providers should use their reasonable medical judgment in determining whether a specific health complaint or medical issue is a reportable abortion complication.
- The form should be submitted for the patient's initial visit and for any follow-up visits where a new complication is diagnosed and treated.
- Only the physician or the facility needs to submit the form, not both.
- The abortion complications reporting form is separate from the terminated pregnancy report that must be filed for each abortion.
- Providers should ensure that no identifying information of the patient shall be in the report.

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Abortion Complications Required to be Reported

- (1) Uterine perforation.
- (2) Cervical laceration.
- (3) Infection.

(4) Vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events (CTCAE).

- (5) Pulmonary embolism.
- (6) Deep vein thrombosis.
- (7) Failure to terminate the pregnancy.
- (8) Incomplete abortion (retained tissue).
- (9) Pelvic inflammatory disease.
- (10) Missed ectopic pregnancy.
- (11) Cardiac arrest.
- (12) Respiratory arrest.
- (13) Renal failure.
- (14) Shock.
- (15) Amniotic fluid embolism.
- (16) Coma.
- (17) Placenta previa in subsequent pregnancies.
- (18) Pre-term delivery in subsequent pregnancies.
- (19) Free fluid in the abdomen.

(20) Hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(21) Hypoglycemia occurring while the patient is being treated at the abortion facility.

(22) Allergic reaction to anesthesia or abortion-inducing drugs.

(23) Psychological complications, including depression, suicidal ideation, anxiety, and sleeping disorders.

(24) Death.

(25) Any other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program.