

FINAL DISPOSITION OF FETAL REMAINS

PRINCIPLE: Pursuant to HEA 1337 implementation, the following protocols have been established by the South Bend Medical Foundation for final disposition of fetal remains received for pathology examination.

- A. Products of conception and fetal remain tissues should **ONLY** be submitted to South Bend Medical Foundation for the purposes of histologic and pathologic examination.
- B. All fetal remain specimens submitted to South Bend Medical Foundation are to have a **green** "HEA 1337" label affixed onto the anatomic pathology requisition and specimen container. This will allow the Histology Department to easily identify fetal remains upon receipt.
- C. The **Surgical Pathology Requisition** is required and is to be completed and submitted with the specimen(s).
- D. The **Provisional Notification of Death — Burial Transit Permit** is provided as a resource and should be used by the client for proper documentation once the sample is returned.
- E. Any fetal remain tissue will be returned to the client with a **blue** "HEA 1337 return to client" label. If there is no sample left after testing, a letter stating this will be returned to the client.
- F. Packets are available to providers, upon request, with inclusion of the above listed forms.
- G. Client specific fetal remain programs are to adhere to their internal policy.

Updated September 6, 2019

To: Chief Executive Officers, Chief Medical Officers, Chief Nursing Officers, Risk-Management

From: Trent Fox, IHA Senior Director of Public Policy and Legislative Relations
Andy VanZee, IHA Vice President of Regulatory Affairs

Re: **New Requirements for the Disposition of Fetal Remains**

Executive Summary

The Indiana Attorney General's Office filed a motion on August 30 with the District Court to lift the injunction as it pertains to House Enrolled Act (HEA) 1337. The Indiana State Department of Health notified IHA that on September 3 the injunction was lifted and portions of HEA 1337 as it relates to disposition of fetal remains are now enforceable. Please see the attached guidance from the Indiana State Department of Health as well as IHA's previous communications on HEA 1337.

Previously on May 28, the U.S. Supreme Court ruled to uphold a portion of a 2016 Indiana law requiring new procedures to be followed by health care facilities in the disposition of both miscarried and aborted fetal remains. The American Civil Liberties Union of Indiana on behalf of Planned Parenthood of Indiana and Kentucky filed a lawsuit on April 7, 2016 asking the Court to grant a preliminary injunction and block the enforcement of House Enrolled Act ("HEA") 1337. The case challenged the constitutionality of the requirements related to fetal disposition, as well as the law's restrictions on the ability of pregnant women to obtain abortions in certain circumstances. As a result, the law's effective date was delayed until the Supreme Court's ruling to uphold provisions of the law related to the disposition of fetal remains.

The memorandum below summarizes the obligations of a hospital to provide for the final disposition of a fetus that is either miscarried or aborted in the hospital's facilities.

Before that time, hospitals should review current policies and practices related to the handling, storage, and disposition of miscarried and aborted fetuses at any developmental stage, both before and after twenty (20) weeks of gestational age. The crux of the legislation, which has now been upheld by the court, is the reference to Indiana's chapter on "infectious waste" which involves the following facilities:

- (1) Hospitals.
- (2) Ambulatory surgical facilities.
- (3) Medical laboratories.
- (4) Diagnostic laboratories.
- (5) Blood centers.

- (6) Pharmaceutical companies.
- (7) Academic research laboratories.
- (8) Industrial research laboratories.
- (9) Health facilities.
- (10) Offices of health care providers.
- (11) Diet or health care clinics.
- (12) Offices of veterinarians.
- (13) Veterinary hospitals.
- (14) Emergency medical services providers.
- (15) Mortuaries.
- (16) Abortion clinics.

All of these facilities must provide for the final disposition of any fetal remains in their possession through either internment or cremation, irrespective of the gestational age of the fetus. See I.C. 16-34-3 and I.C. 16-21-11. Hospitals may need to revise current agreements with medical waste disposal services and/or establish new arrangements with funeral homes or crematories to ensure that fetal remains are appropriately separated from medical waste materials and disposed of in accordance with the new law.

Summary of HEA 1337: Disposition of Fetal Remains

With the recent court ruling, hospitals will now be subject to new requirements related to the disposition of the remains of a miscarried fetus¹ and an aborted fetus² (hereinafter together referred to as “fetal remains”). Under HEA 1337, hospitals along with a list of facilities are implicated through the infectious waste statute (I.C. 16-41-16-1) and now must provide for the final disposition of any fetal remains in its possession through either internment or cremation, irrespective of the gestational age of the fetus. See I.C. 16-34-3 and 16-21-11. Hospitals will have ten (10) business days after a miscarriage occurs in its facilities, or an abortion is performed in its facilities, to either: 1) conduct final disposition of the fetal remains; or 2) ensure that the fetal remains are preserved until final disposition may occur. See I.C. 16-41-16-7.6. For a violation of these new disposition requirements, the Indiana State Department of Health (ISDH) may commence a licensure action against a facility where a violation occurs or, alternatively, the ISDH may impose a civil penalty not to exceed \$1,000 per violation per day against an individual who violates the requirements. An individual who recklessly violates or fails to comply with the disposition requirements commits a Class B misdemeanor.

Disposition under current law. Under current law, the parent(s) of a fetus, which has been miscarried within a hospital, has the right to choose the means by which

¹ A miscarried fetus means “an unborn child, irrespective of gestational age, who has died from a spontaneous or accidental death before expulsion or extraction from the unborn child’s mother, irrespective of the duration of the pregnancy.” See I.C. 16-21-11-2.

² An aborted fetus refers to “an unborn child, irrespective of gestational age or the duration of the pregnancy” in which the pregnancy is terminated by surgical procedure or by an abortion-inducing drug “with an intention other than to produce a live birth or to remove a dead fetus.” See I.C. 16-18-2-128.7 and I.C. 16-18-2-1.

the hospital will conduct final disposition, regardless of the gestational age of the miscarried fetus.³ A parent(s) may select disposition by interment or cremation for a miscarried fetus of any gestational age; however, in the absence of such direction, Indiana law does not specify how a hospital must dispose of a miscarried fetus with a gestational age of *less than twenty (20) weeks*.⁴ A hospital may dispose of such remains through interment or cremation, or the hospital may treat a miscarried fetus with a gestational age of less than 20 weeks as "infectious waste" or "pathological waste" under I.C. 16-14-16 and 410 I.A.C. 1-3.⁵

Current law directs that aborted fetal remains of any gestational age be disposed of either: (1) through interment "in the earth" in an established cemetery; or (2) by cremation, which includes both "incineration by a crematory" and "incineration as authorized for infectious and pathological waste".⁶

Disposition under HEA 1337. In accordance with the new law, a hospital may only dispose of fetal remains of any gestational age through cremation conducted by a crematory or through interment⁷.

Under HEA 1337, a miscarried fetus or an aborted fetus with a gestational age of less than twenty (20) weeks may no longer be considered, or treated in the same manner as, "infectious waste" or "pathological waste" for the purposes of disposition. See I.C. 16-41-16-1. The use of incineration by onsite or offsite medical waste disposal services cannot be used for fetal remains, as such means of disposition no longer constitutes "cremation" under the new law.

Consequently, hospital personnel must ensure that fetal remains are separated from medical waste products, so that the hospital may either dispose of, or arrange for the disposition of, the fetal remains through cremation or burial within the time limits prescribed by HEA 1337. This would include remains from ectopic pregnancies.

It is not a requirement that each individual miscarried fetus or aborted fetus be interred or cremated separately. HEA 1337 expressly permits simultaneous cremation, whereby more than one (1) miscarried or aborted fetus may be cremated within the same cremation chamber. See I.C. 16-34-3-4 and I.C. 16-21-11-6. This permits hospitals to store fetal remains and periodically provide for communal cremations and burials.

³ See I.C.16-21-11-5 et seq., Treatment of Miscarried Fetal Remains (enacted by P.L. 127-2014).

⁴ HEA 1337 does not alter the disposition procedures required under current law for stillbirths, or miscarried fetuses with a gestational age of *more than twenty (20) weeks*.

⁵ The treatment and disposal methods authorized for infectious waste and pathological waste under I.C. 16-41-16 and 410 I.A.C. 1-3 includes, among other methods, disposal through onsite or offsite incineration services and discharge in a sanitary sewer or septic system.

⁶ See I.C. 16-34-3 et seq. and 410 I.A.C. 35-2-1, Treatment of Aborted Fetal Remains (enacted by P.L. 113-2015).

⁷ HEA 1337 does not define "interment". Indiana Cemetery Law defines the term as burial "in the earth". Presumably, disposition of fetal remains by "interment" also includes burial by other means in an established cemetery, such through inurnment and entombment under I.C. 23-14-33.

It is also important to note that the obligation of a hospital to provide for the final disposition of fetal remains applies only to fetuses in the hospital's possession. If a parent elects to receive the fetal remains (as is permitted for a miscarried or an aborted fetus with a gestational age of less than twenty (20) weeks), then the hospital is not responsible for the disposition of remains that have been released to the parent or any costs associated with disposal that is undertaken by the parent. Further, the new law does not place the same disposition requirements on a pregnant woman who miscarries outside of the hospital nor does it place obligations on a hospital to provide for final disposition of a fetus that is miscarried or aborted outside of the hospital's facilities. However, if a pregnant woman transports the fetal remains to the hospital, the hospital is strongly encouraged to address the pregnant woman's continuum of care and take possession of the remains for proper disposition. Hospitals may also encounter other providers or entities impacted by this law who seek to bring the fetal remains to the hospital for disposition. Again, a hospital is not required under HEA 1337 to take possession of the fetal remains, but the Indiana State Department of Health (ISDH) is encouraging hospitals and funeral homes to coordinate with entities impacted by the law for the lawful disposition of the fetal remains.

Additionally, the disposition requirements of HEA 1337 do not apply to the products of conception involved in *in vitro* fertilization, because such "fetuses" have been neither miscarried nor aborted.

Hospital procedures following a miscarriage or abortion. Current law requires that the parent(s) of a fetus that is miscarried in a hospital, or a pregnant woman who obtains an abortion in a hospital, receive certain information regarding their rights to determine the final disposition of the fetal remains and inform a hospital of their decision for final disposition, which must be documented in the medical record of the mother. See I.C. 16-34-3-2 and I.C. 16-21-11-5. These requirements, which took effect under P.L. 127-2014 and P.L. 113-2015, remain unchanged under the new law.

A certificate of stillbirth is not required to be obtained for a miscarried or an aborted fetus with a gestational age of less than twenty (20) weeks. However, in order for fetal remains of any gestational age to be transported out of the hospital for burial or cremation, the person in charge of interment (referred to as the "funeral director") is required to obtain a burial transit permit in accordance with I.C.16-37-3. The form of the burial transit permit requires the person or facility having authority to release a dead body to provide certain information regarding the deceased and next of kin.

If a parent elects to receive the fetal remains, then a burial transit permit must be obtained for each individual instance in which the disposition of remains is released to the parent. For the disposition of fetal remains in the hospital's possession, one burial transit permit shall be used for all fetal remains transported out of the hospital for simultaneous cremation and/or burial.

Under HEA 1337, the name of a fetus is not required to be designated on the burial transit permit and the space for a name may remain blank. Any information provided on the permit that may be used to identify the parent(s) or pregnant woman is confidential and must be redacted from any public record of the burial transit permit. See I.C. 16-34-3-4 and I.C. 16-21-11-6.

Costs of final disposition. HEA 1337 requires hospitals having possession of fetal remains to "provide for the final disposition", meaning arranging for and, presumably, paying for any costs related to the disposition of the fetal remains. However, if the parent(s) of a miscarried fetus, or a pregnant woman who obtains an abortion, chooses a location for the final disposition of the fetal remains other than the location that is "usual and customary" for the hospital, the parent(s) or pregnant woman is responsible for the costs of disposition at that chosen location.

Pathological examinations and autopsies of fetal remains. The ability to perform pathological examinations on the remains of, or any tissue from, a miscarried fetus is not affected by HEA 1337. Such examinations may continue under current procedures, so long as the miscarried fetus is disposed of, or preserved for final disposition, within ten (10) business days of the miscarriage.

HEA 1337 clarifies that an autopsy performed on a miscarried fetus under certain circumstances does not violate current law which generally prohibits the *purchase or sale* of a human ovum, zygote, embryo, or fetus. The transfer or receipt of a fetus for the purposes of an autopsy is specifically exempted from this prohibition, if the autopsy has been requested in writing by a biological parent. A parent may request an autopsy of a miscarried fetus only if the fetus was diagnosed with a lethal fetal anomaly⁸ where written medical documentation verifies such diagnosis. See I.C. 35-46-5-3.

No pathological examinations or autopsies should be performed on the remains of, or on any tissue from, a fetus that has been aborted. HEA 1337 specifically prohibits the transfer and receipt of fetal tissue, organs, or any other part of an aborted fetus for any purpose other than the disposition of the aborted remains as required by law. It is a Level 5 felony to intentionally acquire, receive, sell, or transfer aborted fetal tissue, and a person may not alter the timing, method, or procedure used to terminate, or abort, a pregnancy in an attempt to circumvent this prohibition for the purpose of collecting such tissue. See I.C. 35-46-5-1.5.

Conclusion

Now that the injunction has been lifted and the law is enforceable, hospitals should review current policies and practices related to the handling, storage, and

⁸ "Lethal fetal anomaly" means a fetal condition diagnosed before birth that, if the pregnancy results in a live birth, will with reasonable certainty result in the death of the child not more than three (3) months after the child's birth. See I.C. 35-46-5-3.

disposition of fetal remains at all gestational ages to ensure compliance with these new requirements. Hospitals may need to revise current agreements with medical waste disposal services and/or establish new arrangements with funeral homes or crematories to ensure that fetal remains are separated from medical waste materials and appropriately disposed of through burial or cremation.

You can find a copy of the final version of HEA 1337 that passed into law here:
<http://iga.in.gov/static-documents/5/1/b/5/51b52d50/HB1337.05.ENRS.pdf>.

Should you have any questions, please do not hesitate to contact Andy VanZee, IHA Vice President of Regulatory and Hospital Operations at avanzee@ihaconnect.org.

Routing Suggestions: Chief Executive Officer; Chief Medical Officer, Chief Nursing Officers, Risk-Management

ISDH Guidance for Implementation of Fetal Disposition Requirements from House Enrolled Act (HEA) 1337

Dear Partners:

As a result of a recent U.S. Supreme Court decision, an injunction preventing the enforcement of certain provisions of HEA 1337 from 2016 is expected to be lifted soon. This law updated the requirements for the disposition of miscarried remains/aborted remains (“fetal remains”) in Indiana. The Consumer Services and Health Care Regulation Commission provides the following guidance:

Once the injunction is lifted:

- The only legal methods of disposition of miscarried remains/aborted remains (“fetal remains”) for healthcare facilities and providers subject to infectious waste laws are burial or cremation, including simultaneous cremation.
- Fetal remains cannot be disposed of as infectious waste.
- Providers are required to complete the burial/cremation or preserve the remains for burial/cremation within 10 days of the miscarriage/abortion.
- A Burial Transit Permit and Disposition for Fetal Remains form should be used when transporting fetal remains for final disposition. A certificate of stillbirth for fetal remains under 20 weeks gestation is not required for local health departments to issue the permit.
- Only one Burial Transit Permit and Disposition for Fetal Remains form is required for each transport of fetal remains for simultaneous cremation.
- Providers can transport fetal remains to another facility to preserve miscarried or fetal remains at that facility without a Burial Transit Permit.

Some portions of previous fetal remains disposition laws remain unchanged:

- Parents and pregnant women may choose to use either the healthcare facility’s method of final disposition or choose a location that is different than the healthcare facility for final disposition.
- Parents or the pregnant woman are responsible for any costs if they choose a location other than what the healthcare facility uses.
- Healthcare facilities are required to inform the pregnant woman or parents of their right to determine final disposition of fetal remains and to document that decision in the woman’s medical record.
- Certificates of stillbirth are still required for non-live births 20 weeks of gestation or later.

A follow up notification will be sent out once the injunction has been lifted.

Summary Overview of HEA 1337 Implementation

Hospital Responsibilities under HEA 1337	- Under HEA 1337, hospitals along with a list of facilities that are subject to the infectious waste statute (I.C. 16-41-16-1), must provide for the final disposition of any fetal remains in their <u>possession</u> through either internment or cremation, irrespective of the gestational age of the fetus. See I.C. 16-34-3 and 16-21-11. - A hospital will have ten (10) business days after a miscarriage occurs in its facilities, or an abortion is performed in its facilities, to either: 1) conduct final disposition of the fetal remains; or 2) ensure that the fetal remains are preserved until final disposition may occur. See I.C. 16-41-16-7.6. - It is not a requirement that each individual miscarried fetus or aborted fetus be interred or cremated separately. - A hospital must complete the form for a burial transit permit for all fetal remains transported out of the hospital for simultaneous cremation and/or burial. Only one permit per transport is needed in this instance.
Rights of the Patient/Family of the Pregnant Woman	- If the parent(s) of a miscarried fetus, or a pregnant woman who obtains an abortion, chooses a location for the final disposition of the fetal remains other than the location that is "usual and customary" for the hospital, the parent(s) or pregnant woman is responsible for the costs of disposition at that chosen location. - If a parent elects to receive the fetal remains (as is permitted for a miscarried or an aborted fetus with a gestational age of less than twenty (20) weeks), then the hospital is not responsible for the disposition of remains that have been released to the parent or any costs associated with disposal that is undertaken by the parent.
Potential Penalties	For a violation of these new disposition requirements, the Indiana State Department of Health (ISDH) may commence a licensure action against a facility where a violation occurs or, alternatively, the ISDH may impose a civil penalty not to exceed \$1,000 per violation per day against an individual who violates the requirements. An individual who recklessly violates or fails to comply with the disposition requirements commits a Class B misdemeanor.
Effective Date	The Indiana Attorney General's office filed a motion to lift the injunction as it relates to some of the provisions of HEA 1337. The District Court granted the motion to lift the injunction and as of September 3 provisions of the law pertaining to the disposition of fetal remains are enforceable.



PROVISIONAL NOTIFICATION OF DEATH - BURIAL TRANSIT PERMIT

Slate Form 38220 (R2 / 9-06) / SDH 06-093-32

COUNTY HEALTH DEPARTMENT

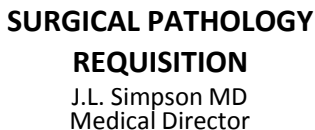
INSTRUCTION : Please type or print clearly.

A REPORT OF DEATH (To be completed by facility where death occurred)			
Name of deceased (First, middle, last)		Date of death (month, day, year)	Time of death (local) ☐ AM ☐ PM
County of death	City of death	Age	Race Sex ☒ Male ☐ Female
Place of death (If not facility such as hospital, nursing home, etc. give street address)			
Name of Medical Certifier (official certifier of cause of death)			Telephone number
Address of Medical Certifier (number and street, city, state, and ZIP code)			
B RELEASE (To be completed by person having authority to release remains)			
Authorization Is hereby granted to release the remains of the above named to:			
Name of funeral home		City	State
Signature of representative of facility releasing remains		Name of next of kin or legal representative authorizing release	
C BURIAL - TRANSIT PERMIT (To be completed by funeral director or representative)			
I, representing _____ name of funeral home city state telephone number			
hereby accept the remains of the above named and agree to secure and file a complete certificate of death within the time limit established by law.			
Signature of funeral director or representative		Printed name of Indiana Licensed Funeral Director	Indiana Funeral Director License number
A certificate of death having been filed or a provisional notification of death received as required by law, permission is hereby given for transportation and disposition of the remains - except for cremation which requires a completed certificate of death.			
Signature of Health Officer		Local number	Date filed (month, day, year)
D RESIDENCE (To be completed by funeral director)			
Last known county of residence	Last known address of deceased (number and street, city, state, and ZIP code)		
Address(es) two (2) years prior to death (number and street, city, state, and ZIP code) (if different) : _____ 1 (number and street, city, state, and ZIP code) _____			
E DISPOSITION (To be signed by sexton of cemetery or representative of crematory)			
Name of cemetery / crematory		Date of disposition (month, day, year)	Date of cremation (month, day, year)
Place of disposition (City, county, state, and ZIP code)			
Method of disposition (check all that apply) ☐ Burial ☒ Cremation ☐ Entombment ☐ Inurnment ☐ Removed from State ☐ Donation ☐ Scattering (location)			
Remains returned to :		Funeral Director	Family Cemetery
Signature of sexton or crematory representative			Date (month, day, year)

DISTRIBUTION: White copy- Health Department copy to accompany the body to its disposition. Must be signed by the sexton of the cemetery or the representative of the crematory, and returned to health department in the county where the death occurred within two (2) days after burial or cremation. Copies may be made for faxing. Contact local health department for out-of-state shipment.

Canary copy- Cemetery/Crematory copy for their records.

Pink copy - To be mailed by the facility where the death occurred to the local health department within twenty four (24) hours following death. Copies of the white form may be made by the facility for its records and for faxing in lieu of mailing.



✓ Dr # Physician's Last Name, First Name

[illegible]

Date _____

FIN MRN Inpatient ☐ outpatient ☐

IF NO BILLING
INFORMATION IS
PROVIDED, AND NO BOX IS CHECKED YOUR
ACCOUNT WILL BE BILLED.

OR Room Number:	Last Name	First Name	Middle Initial
Ordering Physician			
Additional Physician(s)			

PLEASE CHECK: ☐ Routine ☐ Phone report ☐ STAT ☐ Frozen Section

Time placed in formalin: ☐ AM ☐ PM

Stain quality acceptable? ☐ Yes ☐ No

Pathologist Signature:

INSURANCE INFORMATION

Responsible Party Name (required if patient is a minor):

Responsible Party Address:

City State Zip

Responsible Party Phone

() -

☐ Medicare #

☐ Medicaid #

EDD

M/D/Y

☐ Primary Insurance (Complete or attach copy of insurance card.)

INSURANCE COMPANY NAME:		
NETWORK:		
CLAIMS ADDRESS:		
CITY:	STATE:	ZIP:
POLICY HOLDER NAME:		D.O. B.
RELATIONSHIP TO PATIENT: ☐ Self ☐ Spouse ☐ Parent		
POLICY ID #:	GROUP #:	
EMPLOYER:		EFFECTIVE DATE:

☐ Secondary Insurance (Complete or attach copy of insurance card front & back.)

INSURANCE COMPANY NAME:		
NETWORK:		
CLAIMS ADDRESS:		
CITY:	STATE:	ZIP:
POLICY HOLDER NAME:		D.O. B.
RELATIONSHIP TO PATIENT: ☐ Self ☐ Spouse ☐ Parent		
POLICY ID #:	GROUP #:	
EMPLOYER:		EFFECTIVE DATE:

IMPORTANT

A WRITTEN ORDER AND AN APPROPRIATE DIAGNOSIS MUST ACCOMPANY EACH LABORATORY TEST. WHEN ORDERING TESTS FOR WHICH MEDICARE REIMBURSEMENT WILL BE SOUGHT, ONLY TESTS THAT ARE MEDICALLY NECESSARY FOR THE DIAGNOSIS OR TREATMENT OF THE PATIENT SHOULD BE ORDERED.

MICROBIOLOGY PROTOCOL

MICROBIOLOGY CULTURES MAY INCLUDE CHARGES FOR ONE PRIMARY SOURCE SMEAR, ONE PRIMARY CULTURE, ONE CHARGE PER ORGANISM REQUIRING IDENTIFICATION, AND ONE CHARGE PER SENSITIVITY PERFORMED. This is source specific. Refer to the fee schedule for further clarification, or call The Medical Foundation Client Services Department at (574) 236-7263 or (800) 950-7263

ASSIGNMENT OF BENEFITS AND FINANCIAL AGREEMENT

EVERY patient MUST read, sign, and date:

I request that payment of authorized Medicare or insurance benefits be made on my behalf to the South Bend Medical Foundation.

I authorize any holder of medical or other information about me to release to my designated insurance company, Centers for Medicare and Medicaid Services (CMS), and their agents, information to determine payable benefits for related services.

I agree that I am fully responsible for the payment of all the designated laboratory services South Bend Medical Foundation rendered to me or on my behalf. I accept responsibility for charges Medicaid does not cover when I am enrolled in a limited coverage Medicaid program.

I understand that additional testing may be performed based on my physician's request. I agree to be fully responsible for payment if my insurance plan does not cover the cost.

I also agree that if any insurance plan, except Medicaid, determines the tests requested to be medically unnecessary, and/or uncovered procedures, and denies payment to the South Bend Medical Foundation, I accept full responsibility for payment to South Bend Medical Foundation.

Patient Signature

Date