

2017 DRAFTING REQUEST

Bill

For: **Amy Loudenbeck (608) 266-9967** Drafter: **tdodge**
 By: **Mike** Secondary Drafters:
 Date: **1/31/2017** May Contact:
 Same as LRB: **-2072**

Submit via email: **YES**
 Requester's email: **Rep.Loudenbeck@legis.wisconsin.gov**
 Carbon copy (CC) to: **tamara.dodge@legis.wisconsin.gov**
sarah.walkenhorstbarber@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

Topic:

Sale, use and final disposition of fetal body parts; regulating research with fetal body parts; conscience; umbilical cord blood banks

Instructions:

See attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	tdodge 1/31/2017				
/P1	tdodge 2/1/2017	kmochal 1/31/2017	mbarman 1/31/2017		
/P2	tdodge 2/2/2017	eweiss 2/2/2017	mbarman 2/1/2017		
/P3	tdodge 2/6/2017	wjackson 2/6/2017	rmilford 2/2/2017		

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/P4	tdodge 2/7/2017	aernstr 2/7/2017	mbarman 2/6/2017		
/1	chanaman 2/7/2017		chanaman 2/7/2017	mbarman 2/8/2017	

FE Sent For:

<END>

Not
Needed

T/C w/ Mike from Rep. Loudenbeck's office

Ban sale of fetal body parts and research for valuable consideration

Exempt from "fetal body parts" cultured cells and existing cells, cell lines, tissue or organs

Ban research if fetal body part obtained from for-profit entity or abortion clinic, or entity that obtains fetal tissue for sale

Research:

certify - no valuable consideration (keep 7 yrs.)

IRB - informed consent obtained, consent for abortion was before consent for donation, abortion was not altered to obtain fetal body part, attending physician not involved in research

Exceptions

Diagnostic or remedial tests... for sole purpose of providing health info to mom or to preserve life of unborn child or mom

Developing pharmaceuticals or purchasing existing product
No restriction on access to care, meds
Acting exclusively for final disposition

Final disposition

Require abortion physician to arrange for final disposition

Penalty

imprisonment 9 mo or \$50,000 fine.

Liability exemption

no civil, criminal, unprofessional conduct

conscientiously objecting to destructive embryo research
or medical research harmful to human life

if violates moral or religious belief

Cord Blood Bank

Request in Feb from at least one umbilical cord blood bank

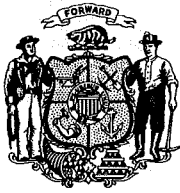
regarding establishment of public collection operation

- One or more sites to collect specific amount
- Collect racially & ethnically diverse blood
- can operate w/in 6 months of contract
- National Cord Blood Coordinating Center or similar agency to maximize use
- national accreditation - HRSA

Information → DHS 1/1/18

Summary to gov. & standing committee → 4/1/18

FJD



State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-1927/P1
TJD: klm

In: 1131

Due Now

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

Generate catalog

1 AN ACT . . . relating to: sale of and research on fetal body parts, final disposition
2 of fetal body parts, cord blood banks, and providing a criminal penalty.

Analysis by the Legislative Reference Bureau

Generally, this bill bans the sale of fetal body parts, regulates certain research on fetal body parts, and requires the final disposition of fetal body parts. This bill also requires the Department of Health Services to request information from umbilical cord blood banks on creating a public cord blood collection operation. Under the bill, fetal body parts are cells, tissue, organs, or other parts of an unborn child aborted by an elective, induced abortion, except for cultured cells and except for cells, cell lines, tissue, or organs from an aborted fetus if the induced abortion occurred before the effective date of the bill.

Current law prohibits a person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a human organ. Current federal law prohibits a person from knowingly acquiring, receiving, or otherwise transferring, in interstate commerce, any fetal tissue for valuable consideration. The bill prohibits any person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a fetal body part and from knowingly providing, receiving, or using, for research, a fetal body part for valuable consideration. "Valuable consideration" does not include any reasonable payment associated with the transportation or storage of a fetal body part. The bill prohibits knowingly acquiring or receiving any fetal body part for research from a for-profit entity, an abortion clinic, or an entity that has as its primary function obtaining fetal tissue for sale.

★
part

A person who uses or receives a fetal body part for research is required by the bill to obtain documentation that the entity that provided the fetal body part did not

obtain the fetal body part for valuable consideration and to maintain that written documentation for seven years. Before using a fetal body part in research, an institutional review board must review the certification from the entity that provided the fetal body part to determine that informed consent was obtained from the woman who donated the fetal body part and that other requirements specified in the bill are met. The bill also exempts from criminal or civil liability or charges of unprofessional conduct a health care provider who conscientiously objects to participation in destructive embryo research or other forms of medical research that is harmful to human life, which violate that health care provider's moral or religious beliefs.

The bill requires that a physician who performs or induces an induced abortion in this state arrange for the final disposition of the fetal body parts. Final disposition, under the bill, means the disposition of fetal body parts by burial, interment, entombment, cremation, or incineration.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 146.343 (1) (e) of the statutes is created to read:

2 146.343 (1) (e) "Principal prenatal health care provider" means a nurse,
3 nurse-midwife, or physician who is the primary prenatal health care provider.

4 **SECTION 2.** 146.346 of the statutes is created to read:

5 **146.346 Fetal body parts; research. (1) DEFINITIONS.** In this section:

6 (a) "Fetal body part" means a cell, tissue, organ, or other part of an unborn
7 child, as defined in s. 939.75 (1), who is aborted by an elective, induced abortion, as
8 defined in s. 69.01 (13m). "Fetal body part" does not include any of the following:

9 1. Cultured cells.

10 2. Cells, cell lines, tissue, or organs from an aborted fetus if the induced
11 abortion, as defined in s. 69.01 (13m), occurred before the effective date of this
12 subdivision ... [LRB inserts date].

13 (b) "Final disposition" means the disposition of fetal body parts by burial,
14 interment, entombment, cremation, or incineration.

1 (c) "Research" means a systematic investigation, including research,
2 development, testing, and evaluation, designed to develop or contribute to
3 generalizable knowledge.

4 (d) "Valuable consideration" does not include any reasonable payment
5 associated with the transportation or storage of a fetal body part.

6 **(2) PROHIBITIONS; RESEARCH REQUIREMENTS.** (a) No person may knowingly and
7 for valuable consideration acquire, receive, or otherwise transfer a fetal body part.

8 (b) No person may knowingly provide, receive, or use, for research, a fetal body
9 part for valuable consideration.

10 (c) No person may knowingly acquire or receive any fetal body part for research
11 from a for-profit entity, an abortion clinic, or an entity that has as its primary
12 function obtaining fetal tissue for sale.

13 (d) Any person who uses or receives any fetal body part for research shall obtain
14 written documentation from the entity that provided the fetal body part that certifies
15 that the entity did not obtain the fetal body part for valuable consideration. The
16 person who uses or receives the fetal body part for research shall maintain that
17 written documentation from the entity for at least 7 years.

18 (e) Before the use of any fetal body part for research, an institutional review
19 board shall review the certification from the entity that provided the fetal body part
20 to determine that informed consent for research using the fetal body part was
21 obtained from the woman who donated the fetal body part and that all of the
22 following requirements are met:

23 1. The consent of the woman for the induced abortion, as defined in s. 69.01
24 (13m), ^{is} was obtained before requesting or obtaining her consent for donation of the
25 fetal body part for research.

SECTION 2

1 2. No alteration of the timing, method, or procedures used to terminate a
2 woman's pregnancy is made solely for the purpose of obtaining a fetal body part for
3 research.

4 3. The woman's attending physician who obtains the fetal body part may not
5 also be involved in performing the research.

6 4. The woman donating the fetal body part is informed of any known medical
7 risks to her or any risks to her privacy that might be associated with the donation
8 of a fetal body part and of any similar risks that are associated with her medical care.

9 (f) This subsection does not apply to use of a fetal body part for diagnostic or
10 remedial tests, procedures, or observations that have the sole purpose of determining
11 the life or health of the unborn child in order to provide that information to the
12 mother or preserving the life or health of the child, unborn child, or the child's
13 mother. Notwithstanding pars. (a) to (c), a person is not guilty of violating this
14 section if the person is developing pharmaceutical products or paying or receiving a
15 payment for an existing pharmaceutical product. Nothing in this section may be
16 construed as restricting access to health care, to prescription drugs or devices, or to
17 other pharmaceutical products.

18 **(3) FINAL DISPOSITION.** (a) Notwithstanding sub. (2) (a) to (c), a physician who
19 performs or induces an induced abortion, as defined in s. 69.01 (13m), in this state
20 shall arrange for the final disposition of fetal body parts resulting from the induced
21 abortion.

22 (b) Notwithstanding sub. (2) (a) to (c), a person is not guilty of violating this
23 section if the person is acting exclusively in furtherance of final disposition of a fetal
24 body part.

1 (4) CONSCIENCE. No health care provider may be held criminally or civilly liable
2 or charged with unprofessional conduct for conscientiously objecting to participation
3 in destructive embryo research or other forms of medical research that is harmful to
4 human life, ^{that} which violate a provider's moral or religious belief.

5 (5) PENALTY. Any person who violates this section is subject to a fine not to
6 exceed \$50,000 or imprisonment not to exceed 9 months, or both.

7 **SECTION 3. Nonstatutory provisions.**

8 (1) INFORMATION ON ESTABLISHING PUBLIC CORD BLOOD COLLECTION OPERATION.

9 (a) Before January 1, 2018, the department of health services shall request
10 information from at least one umbilical cord blood bank regarding the establishment
11 of a public cord blood collection operation within the state to collect, transport,
12 process, and store cord blood from residents of the state for therapeutic and research
13 purposes. The department of health services shall include in the request for
14 information questions eliciting the umbilical cord blood bank's ability to do all of the
15 following:

16 1. Establish and operate one or more collection sites within the state to collect
17 a specified target number of cord blood units.

18 2. Implement collection procedures designed to collect cord blood units that
19 reflect the state's racial and ethnic diversity.

20 3. Establish public cord blood collection operations no later than 6 months after
21 executing a contract with the department of health services unless the umbilical cord
22 blood bank is unable to negotiate any necessary contracts related to the collection
23 sites within that time.

WISCONSIN LEGISLATIVE REFERENCE BUREAU

Information Services 608-266-0341—Legal Services 608-266-3561



2/1

T/C w/ mike - Rep. Lowdenbeck's

My suggestion 69.01(13m) → 253.10(2)(a)

"that is obtained after & as a result of an elective abortion"

x-ref federal definition of "valuable consideration"

FID



State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-1927/P1

TJD:klm

ep2
tamm

In: 211

ASAP

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SA

Regen.

- 1 AN ACT to create 146.343 (1) (e) and 146.346 of the statutes; relating to: sale
- 2 of and research on fetal body parts, final disposition of fetal body parts, cord
- 3 blood banks, and providing a criminal penalty.

Analysis by the Legislative Reference Bureau

that are
obtained after
and as
a result
of

Generally, this bill bans the sale of fetal body parts, regulates certain research on fetal body parts, and requires the final disposition of fetal body parts. This bill also requires the Department of Health Services to request information from umbilical cord blood banks on creating a public cord blood collection operation. Under the bill, fetal body parts are cells, tissue, organs, or other parts of an unborn child aborted by an elective, induced abortion, except for cultured cells and except for cells, cell lines, tissue, or organs from an aborted fetus if the induced abortion occurred before the effective date of the bill.

Current law prohibits a person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a human organ. Current federal law prohibits a person from knowingly acquiring, receiving, or otherwise transferring, in interstate commerce, any fetal tissue for valuable consideration. The bill prohibits any person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a fetal body part and from knowingly providing, receiving, or using, for research, a fetal body part for valuable consideration. "Valuable consideration" does not include any reasonable payment associated with the transportation or storage of a fetal body part. The bill prohibits knowingly acquiring or receiving any fetal body part for research from a for-profit entity, an abortion clinic, or an entity that has as its primary function obtaining fetal tissue for sale.

A person who uses or receives a fetal body part for research is required by the bill to obtain documentation that the entity that provided the fetal body part did not obtain the fetal body part for valuable consideration and to maintain that written documentation for seven years. Before using a fetal body part in research, an institutional review board must review the certification from the entity that provided the fetal body part to determine that informed consent was obtained from the woman who donated the fetal body part and that other requirements specified in the bill are met. The bill also exempts from criminal or civil liability or charges of unprofessional conduct a health care provider who conscientiously objects to participation in destructive embryo research or other forms of medical research that is harmful to human life, ^{and that} which violate that health care provider's moral or religious beliefs.

The bill requires that a physician who performs or induces an ^{induced} induced abortion in this state arrange for the final disposition of the fetal body parts. Final disposition, under the bill, means the disposition of fetal body parts by burial, interment, entombment, cremation, or incineration.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 146.343 (1) (e) of the statutes is created to read:

2 146.343 (1) (e) "Principal prenatal health care provider" means a nurse,
3 nurse-midwife, or physician who is the primary prenatal health care provider.

4 **SECTION 2.** 146.346 of the statutes is created to read:

5 **146.346 Fetal body parts; research. (1) DEFINITIONS.** In this section:

6 (a) "Fetal body part" means a cell, tissue, organ, or other part of an unborn
7 child, as defined in s. 939.75 (1), ^{that is obtained} who is aborted by ^{after and as a} an elective, ^{result} induced abortion, as
8 defined in s. ^{of} 69.01 (13m). "Fetal body part" does not include any of the following:

9 1. Cultured cells. ^{253.10(2)(a)}

10 2. Cells, cell lines, tissue, or organs from an aborted fetus if the ^{induced} induced
11 abortion, as defined in s. ^{253.10(2)(a)} 69.01 (13m), occurred before the effective date of this
12 subdivision [LRB inserts date].

1 (b) "Final disposition" means the disposition of fetal body parts by burial,
2 interment, entombment, cremation, or incineration.

3 (c) "Research" means a systematic investigation, including research,
4 development, testing, and evaluation, designed to develop or contribute to
5 generalizable knowledge.

has the meaning given in
42 USC 289g-2(e)(3) as amended to
January 1, 2017

6 (d) "Valuable consideration" does not include any reasonable payment
7 associated with the transportation or storage of a fetal body part.

8 (2) PROHIBITIONS; RESEARCH REQUIREMENTS. (a) No person may knowingly and
9 for valuable consideration acquire, receive, or otherwise transfer a fetal body part.

10 (b) No person may knowingly provide, receive, or use, for research, a fetal body
11 part for valuable consideration.

12 (c) No person may knowingly acquire or receive any fetal body part for research
13 from a for-profit entity, an abortion clinic, or an entity that has as its primary
14 function obtaining fetal tissue for sale.

15 (d) Any person who uses or receives any fetal body part for research shall obtain
16 written documentation from the entity that provided the fetal body part that certifies
17 that the entity did not obtain the fetal body part for valuable consideration. The
18 person who uses or receives the fetal body part for research shall maintain that
19 written documentation from the entity for at least 7 years.

20 (e) Before the use of any fetal body part for research, an institutional review
21 board shall review the certification from the entity that provided the fetal body part
22 to determine that informed consent for research using the fetal body part was
23 obtained from the woman who donated the fetal body part and that all of the
24 following requirements are met:

253.10,
(2)(a)

1 1. The consent of the woman for the induced abortion, as defined in s. 69.01
2 (13m), is obtained before requesting or obtaining her consent for donation of the fetal
3 body part for research.

4 2. No alteration of the timing, method, or procedures used to terminate a
5 woman's pregnancy is made solely for the purpose of obtaining a fetal body part for
6 research.

7 3. The woman's attending physician who obtains the fetal body part may not
8 also be involved in performing the research.

9 4. The woman donating the fetal body part is informed of any known medical
10 risks to her or any risks to her privacy that might be associated with the donation
11 of a fetal body part and of any similar risks that are associated with her medical care.

12 (f) This subsection does not apply to use of a fetal body part for diagnostic or
13 remedial tests, procedures, or observations that have the sole purpose of determining
14 the life or health of the unborn child in order to provide that information to the
15 mother or preserving the life or health of the child, unborn child, or the child's
16 mother. Notwithstanding pars. (a) to (c), a person is not guilty of violating this
17 section if the person is developing pharmaceutical products or paying or receiving a
18 payment for an existing pharmaceutical product. Nothing in this section may be
19 construed as restricting access to health care, to prescription drugs or devices, or to
20 other pharmaceutical products.

21 (3) FINAL DISPOSITION. (a) Notwithstanding sub. (2) (a) to (c), a physician who
22 performs or induces an induced abortion, as defined in s. 69.01 (13m), in this state
23 shall arrange for the final disposition of fetal body parts resulting from the induced
24 abortion.

253.10 (2)(a)

1 (b) Notwithstanding sub. (2) (a) to (c), a person is not guilty of violating this
2 section if the person is acting exclusively in furtherance of final disposition of a fetal
3 body part.

4 (4) CONSCIENCE. No health care provider may be held criminally or civilly liable
5 or charged with unprofessional conduct for conscientiously objecting to participation
6 in destructive embryo research or other forms of medical research that is harmful to
7 human life that violate a provider's moral or religious belief.

8 (5) PENALTY. Any person who violates this section is subject to a fine not to
9 exceed \$50,000 or imprisonment not to exceed 9 months, or both.

10 **SECTION 3. Nonstatutory provisions.**

11 (1) INFORMATION ON ESTABLISHING PUBLIC CORD BLOOD COLLECTION OPERATION.

12 (a) Before January 1, 2018, the department of health services shall request
13 information from at least one umbilical cord blood bank regarding the establishment
14 of a public cord blood collection operation within the state to collect, transport,
15 process, and store cord blood from residents of the state for therapeutic and research
16 purposes. The department of health services shall include in the request for
17 information questions eliciting the umbilical cord blood bank's ability to do all of the
18 following:

19 1. Establish and operate one or more collection sites within the state to collect
20 a specified target number of cord blood units.

21 2. Implement collection procedures designed to collect cord blood units that
22 reflect the state's racial and ethnic diversity.

23 3. Establish public cord blood collection operations no later than 6 months after
24 executing a contract with the department of health services unless the umbilical cord

1 blood bank is unable to negotiate any necessary contracts related to the collection
2 sites within that time.

3 4. Participate in the National Cord Blood Coordinating Center or a similar
4 national cord blood inventory that lists cord blood units in a manner that assures
5 maximum opportunity for use.

6 5. Establish and operate a program that provides cord blood units for research
7 and agree to provide cord blood units that are unsuitable for therapeutic use to
8 researchers located within the state at no cost to the researcher.

9 6. Maintain national accreditation with an accrediting organization that is
10 recognized by the federal health resources and services administration.

11 (b) Before April 1, 2018, the department of health services shall submit a
12 summary of the responses to the request for information under paragraph (a) and
13 any recommendations developed from the responses to the governor and to the
14 appropriate standing committees of the legislature under section 13.172 (3) of the
15 statutes.

16 (END)

WISCONSIN LEGISLATIVE REFERENCE BUREAU

Information Services 608-266-0341—Legal Services 608-266-3561



2/2

T/C w/mike

Remove "cell lines" from p 2, line 11

Conscience

provider → person

"in research utilizing fetal body parts ~~is~~ that violates
a person's moral or religious belief."

IRB

Informed consent } in accordance w/ 42 USC 289g-1

1, 2, & 4.

old-move to 3,



State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-1927(P2)
TJD:klm&amn

In. 2/2

Dw ASAP

1 P3
EMW

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

1 **AN ACT to create** 146.343 (1) (e) and 146.346 of the statutes; **relating to:** sale
2 of and research on fetal body parts, final disposition of fetal body parts, cord
3 blood banks, and providing a criminal penalty.

Analysis by the Legislative Reference Bureau

Generally, this bill bans the sale of fetal body parts, regulates certain research on fetal body parts, and requires the final disposition of fetal body parts. This bill also requires the Department of Health Services to request information from umbilical cord blood banks on creating a public cord blood collection operation. Under the bill, fetal body parts are cells, tissue, organs, or other parts of an unborn child that are obtained after and as the result of an elective abortion, except for cultured cells and except for cells, cell lines, tissue, or organs from an aborted fetus if the abortion occurred before the effective date of the bill.

Current law prohibits a person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a human organ. Current federal law prohibits a person from knowingly acquiring, receiving, or otherwise transferring, in interstate commerce, any fetal tissue for valuable consideration. The bill prohibits any person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a fetal body part and from knowingly providing, receiving, or using, for research, a fetal body part for valuable consideration. The bill prohibits knowingly acquiring or receiving any fetal body part for research from a for-profit entity, an abortion clinic, or an entity that has as its primary function obtaining fetal tissue for sale.

A person who uses or receives a fetal body part for research is required by the bill to obtain documentation that the entity that provided the fetal body part did not

obtain the fetal body part for valuable consideration and to maintain that written documentation for seven years. Before using a fetal body part in research, an institutional review board must review the certification from the entity that provided the fetal body part to determine that informed consent was obtained from the woman who donated the fetal body part and that other requirements specified in the bill are met. The bill also exempts from criminal or civil liability or charges of unprofessional conduct a health care provider ^{person} who conscientiously objects to participation in destructive embryo research or other forms of medical research that is harmful to human life that ^s violate that health care provider's ^{person} moral or religious beliefs. ^{utilizing a fetal body part}

in accordance with federal law

The bill requires that a physician who performs or induces an abortion in this state arrange for the final disposition of the fetal body parts. Final disposition, under the bill, means the disposition of fetal body parts by burial, interment, entombment, cremation, or incineration.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 146.343 (1) (e) of the statutes is created to read:

2 146.343 (1) (e) "Principal prenatal health care provider" means a nurse,
3 nurse-midwife, or physician who is the primary prenatal health care provider.

4 **SECTION 2.** 146.346 of the statutes is created to read:

5 **146.346 Fetal body parts; research.** (1) DEFINITIONS. In this section:

6 (a) "Fetal body part" means a cell, tissue, organ, or other part of an unborn
7 child, as defined in s. 939.75 (1), that is obtained after and as a result of an elective
8 abortion, as defined in s. 253.10 (2) (a). "Fetal body part" does not include any of the
9 following:

10 1. Cultured cells.

11 2. Cells, cell lines, tissue, or organs from an aborted fetus if the abortion, as
12 defined in s. 253.10 (2) (a), occurred before the effective date of this subdivision

13 [LRB inserts date].

1 (b) "Final disposition" means the disposition of fetal body parts by burial,
2 interment, entombment, cremation, or incineration.

3 (c) "Research" means a systematic investigation, including research,
4 development, testing, and evaluation, designed to develop or contribute to
5 generalizable knowledge.

6 (d) "Valuable consideration" has the meaning given in 42 USC 289g-2 (e) (3)
7 as amended to January 1, 2017.

8 **(2) PROHIBITIONS; RESEARCH REQUIREMENTS.** (a) No person may knowingly and
9 for valuable consideration acquire, receive, or otherwise transfer a fetal body part.

10 (b) No person may knowingly provide, receive, or use, for research, a fetal body
11 part for valuable consideration.

12 (c) No person may knowingly acquire or receive any fetal body part for research
13 from a for-profit entity, an abortion clinic, or an entity that has as its primary
14 function obtaining fetal tissue for sale.

15 (d) Any person who uses or receives any fetal body part for research shall obtain
16 written documentation from the entity that provided the fetal body part that certifies
17 that the entity did not obtain the fetal body part for valuable consideration. The
18 person who uses or receives the fetal body part for research shall maintain that
19 written documentation from the entity for at least 7 years.

20 (e) Before the use of any fetal body part for research, an institutional review
21 board shall review the certification from the entity that provided the fetal body part
22 to determine that informed consent for research using the fetal body part was
23 obtained from the woman who donated the fetal body part and that all of the
24 following requirements are met:

in accordance with 42 USC 289g-1

1 1. The consent of the woman for the abortion, as defined in s. 253.10 (2) (a), is
2 obtained before requesting or obtaining her consent for donation of the fetal body
3 part for research.

4 2. ^{In accordance with 42 USC 289g-1} ~~No~~ alteration of the timing, method, or procedures used to terminate a
5 woman's pregnancy is made solely for the purpose of obtaining a fetal body part for
6 research.

7 ⁴ 3. The woman's attending physician who obtains the fetal body part is not also
8 involved in performing the research.

9 ³ 4. The woman donating the fetal body part is informed ^{in accordance with} of any known medical ^{42 USC}
10 risks to her or any risks to her privacy that might be associated with the donation ^{289g-1}
11 of a fetal body part and of any similar risks that are associated with her medical care.

12 (f) This subsection does not apply to use of a fetal body part for diagnostic or
13 remedial tests, procedures, or observations that have the sole purpose of determining
14 the life or health of the unborn child in order to provide that information to the
15 mother or preserving the life or health of the child, unborn child, or the child's
16 mother. Notwithstanding pars. (a) to (c), a person is not guilty of violating this
17 section if the person is developing pharmaceutical products or paying or receiving a
18 payment for an existing pharmaceutical product. Nothing in this section may be
19 construed as restricting access to health care, to prescription drugs or devices, or to
20 other pharmaceutical products.

21 (3) FINAL DISPOSITION. (a) Notwithstanding sub. (2) (a) to (c), a physician who
22 performs or induces an abortion, as defined in s. 253.10 (2) (a), in this state shall
23 arrange for the final disposition of fetal body parts resulting from the abortion.

move

1 (b) Notwithstanding sub. (2) (a) to (c), a person is not guilty of violating this
2 section if the person is acting exclusively in furtherance of final disposition of a fetal
3 body part.

4 (4) CONSCIENCE. No health care provider ^{person} may be held criminally or civilly liable
5 or charged with unprofessional conduct for conscientiously objecting to participation
6 in destructive embryo research or other forms of medical research ^{utilizing a fetal body part} that is harmful to
7 human life that ^s violate a provider's ^{person} moral or religious belief.

8 (5) PENALTY. Any person who violates this section is subject to a fine not to
9 exceed \$50,000 or imprisonment not to exceed 9 months, or both.

10 SECTION 3. Nonstatutory provisions.

11 (1) INFORMATION ON ESTABLISHING PUBLIC CORD BLOOD COLLECTION OPERATION.

12 (a) Before January 1, 2018, the department of health services shall request
13 information from at least one umbilical cord blood bank regarding the establishment
14 of a public cord blood collection operation within the state to collect, transport,
15 process, and store cord blood from residents of the state for therapeutic and research
16 purposes. The department of health services shall include in the request for
17 information questions eliciting the umbilical cord blood bank's ability to do all of the
18 following:

19 1. Establish and operate one or more collection sites within the state to collect
20 a specified target number of cord blood units.

21 2. Implement collection procedures designed to collect cord blood units that
22 reflect the state's racial and ethnic diversity.

23 3. Establish public cord blood collection operations no later than 6 months after
24 executing a contract with the department of health services unless the umbilical cord

SECTION 3

1 blood bank is unable to negotiate any necessary contracts related to the collection
2 sites within that time.

3 4. Participate in the National Cord Blood Coordinating Center or a similar
4 national cord blood inventory that lists cord blood units in a manner that assures
5 maximum opportunity for use.

6 5. Establish and operate a program that provides cord blood units for research
7 and agree to provide cord blood units that are unsuitable for therapeutic use to
8 researchers located within the state at no cost to the researcher.

9 6. Maintain national accreditation with an accrediting organization that is
10 recognized by the federal health resources and services administration.

11 (b) Before April 1, 2018, the department of health services shall submit a
12 summary of the responses to the request for information under paragraph (a) and
13 any recommendations developed from the responses to the governor and to the
14 appropriate standing committees of the legislature under section 13.172 (3) of the
15 statutes.

16 (END)

WISCONSIN LEGISLATIVE REFERENCE BUREAU

Information Services 608-266-0341—Legal Services 608-266-3561



2/6

Change (2)(b) to read No person may use, for research, a fetal body part that is provided or received for valuable consideration.

Make (e) 2.6.4. requirements instead of IRB review

word informed consent in accordance w/ 45 CFR

46.116 &, if applicable, 42 USC 289g-1

only some
comply w/ both
depending on type
of research

Change "certification" in 3-19 to "written documentation"

TJD



State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-1927/P3
TJD:klm/amn/emw P4

In: 216

Due Today (H)

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

all

- 1 AN ACT to create 146.343 (1) (e) and 146.346 of the statutes; relating to: sale
- 2 of and research on fetal body parts, final disposition of fetal body parts, cord
- 3 blood banks, and providing a criminal penalty.

Analysis by the Legislative Reference Bureau

Generally, this bill bans the sale of fetal body parts, regulates certain research on fetal body parts, and requires the final disposition of fetal body parts. This bill also requires the Department of Health Services to request information from umbilical cord blood banks on creating a public cord blood collection operation. Under the bill, fetal body parts are cells, tissue, organs, or other parts of an unborn child that are obtained after and as the result of an elective abortion, except for cultured cells and except for cells, tissue, or organs from an aborted fetus if the abortion occurred before the effective date of the bill.

Current law prohibits a person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a human organ. Current federal law prohibits a person from knowingly acquiring, receiving, or otherwise transferring, in interstate commerce, any fetal tissue for valuable consideration. The bill prohibits any person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a fetal body part and from knowingly providing, receiving, or using, for research, a fetal body part for valuable consideration. The bill prohibits knowingly acquiring or receiving any fetal body part for research from a for-profit entity, an abortion clinic, or an entity that has as its primary function obtaining fetal tissue for sale.

A person who uses or receives a fetal body part for research is required by the bill to obtain documentation that the entity that provided the fetal body part did not

written

Insert A (no 9)

that is provided or received

documentation
obtain the fetal body part for valuable consideration and to maintain that written documentation for seven years. Before using a fetal body part in research, an institutional review board must review the certification from the entity that provided the fetal body part to determine that informed consent was obtained in accordance with federal law and that other requirements specified in the bill are met. The bill also exempts from criminal or civil liability or charges of unprofessional conduct a person who conscientiously objects to participation in research utilizing a fetal body part that violates that person's moral or religious beliefs.

The bill requires that a physician who performs or induces an abortion in this state arrange for the final disposition of the fetal body parts. Final disposition, under the bill, means the disposition of fetal body parts by burial, interment, entombment, cremation, or incineration.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 146.343 (1) (e) of the statutes is created to read:

2 146.343 (1) (e) "Principal prenatal health care provider" means a nurse,
3 nurse-midwife, or physician who is the primary prenatal health care provider.

4 **SECTION 2.** 146.346 of the statutes is created to read:

5 **146.346 Fetal body parts; research.** (1) **DEFINITIONS.** In this section:

6 (a) "Fetal body part" means a cell, tissue, organ, or other part of an unborn
7 child, as defined in s. 939.75 (1), that is obtained after and as a result of an elective
8 abortion, as defined in s. 253.10 (2) (a). "Fetal body part" does not include any of the
9 following:

10 1. Cultured cells.

11 2. Cells, tissue, or organs from an aborted fetus if the abortion, as defined in
12 s. 253.10 (2) (a), occurred before the effective date of this subdivision [LRB inserts
13 date].

14 (b) "Final disposition" means the disposition of fetal body parts by burial,
15 interment, entombment, cremation, or incineration.

1 (c) "Research" means a systematic investigation, including research,
2 development, testing, and evaluation, designed to develop or contribute to
3 generalizable knowledge.

4 (d) "Valuable consideration" has the meaning given in 42 USC 289g-2 (e) (3)
5 as amended to January 1, 2017.

6 (2) PROHIBITIONS; RESEARCH REQUIREMENTS. (a) No person may knowingly and
7 for valuable consideration acquire, receive, or otherwise transfer a fetal body part.

8 *Insert 3-8* (b) No person may knowingly provide, receive, or use, for research, a fetal body
9 part for valuable consideration.

10 (c) No person may knowingly acquire or receive any fetal body part for research
11 from a for-profit entity, an abortion clinic, or an entity that has as its primary
12 function obtaining fetal tissue for sale.

13 *Insert 3-13* (f) (d) Any person who uses or receives any fetal body part for research shall obtain
14 written documentation from the entity that provided the fetal body part that certifies
15 that the entity did not obtain the fetal body part for valuable consideration. The
16 person who uses or receives the fetal body part for research shall maintain that
17 written documentation from the entity for at least 7 years.

18 (g) (e) Before the use of any fetal body part for research, an institutional review
19 board shall review the *written documentation* certification from the entity that provided the fetal body part
20 to determine that informed consent for research using the fetal body part was
21 obtained in accordance with 42 USC 289g-1 and that all of the following
22 requirements are met: *45 CFR 46.116 and, if applicable,*

23 1. The consent of the woman for the abortion, as defined in s. 253.10 (2) (a), is
24 obtained before requesting or obtaining her consent for donation of the fetal body
25 part for research in accordance with 42 USC 289g-1.

45 CFR 46.116 and, if applicable,

SECTION 2

1 2. In accordance with 42 USC 289g-1, no alteration of the timing, method, or
2 procedures used to terminate a woman's pregnancy is made solely for the purpose of
3 obtaining a fetal body part for research. 45 CFR 46.116 and, if applicable,

4 2. e ③. The woman donating the fetal body part is informed, in accordance with 42
5 USC 289g-1, of any known medical risks to her or any risks to her privacy that might
6 be associated with the donation of a fetal body part and of any similar risks that are
7 associated with her medical care.

8 4. The woman's attending physician who obtains the fetal body part is not also
9 involved in performing the research.

10 (h) e ①(f) This subsection does not apply to use of a fetal body part for diagnostic or
11 remedial tests, procedures, or observations that have the sole purpose of determining
12 the life or health of the unborn child in order to provide that information to the
13 mother or preserving the life or health of the child, unborn child, or the child's
14 mother. Notwithstanding pars. (a) to (c), a person is not guilty of violating this
15 section if the person is developing pharmaceutical products or paying or receiving a
16 payment for an existing pharmaceutical product. Nothing in this section may be
17 construed as restricting access to health care, to prescription drugs or devices, or to
18 other pharmaceutical products.

19 (3) FINAL DISPOSITION. (a) Notwithstanding sub. (2) (a) to (c), a physician who
20 performs or induces an abortion, as defined in s. 253.10 (2) (a), in this state shall
21 arrange for the final disposition of fetal body parts resulting from the abortion.

22 (b) Notwithstanding sub. (2) (a) to (c), a person is not guilty of violating this
23 section if the person is acting exclusively in furtherance of final disposition of a fetal
24 body part.

1 (4) CONSCIENCE. No person may be held criminally or civilly liable or charged
2 with unprofessional conduct for conscientiously objecting to participation in
3 research utilizing a fetal body part that violates a person's moral or religious belief.

4 (5) PENALTY. Any person who violates this section is subject to a fine not to
5 exceed \$50,000 or imprisonment not to exceed 9 months, or both.

6 **SECTION 3. Nonstatutory provisions.**

7 (1) INFORMATION ON ESTABLISHING PUBLIC CORD BLOOD COLLECTION OPERATION.

8 (a) Before January 1, 2018, the department of health services shall request
9 information from at least one umbilical cord blood bank regarding the establishment
10 of a public cord blood collection operation within the state to collect, transport,
11 process, and store cord blood from residents of the state for therapeutic and research
12 purposes. The department of health services shall include in the request for
13 information questions eliciting the umbilical cord blood bank's ability to do all of the
14 following:

15 1. Establish and operate one or more collection sites within the state to collect
16 a specified target number of cord blood units.

17 2. Implement collection procedures designed to collect cord blood units that
18 reflect the state's racial and ethnic diversity.

19 3. Establish public cord blood collection operations no later than 6 months after
20 executing a contract with the department of health services unless the umbilical cord
21 blood bank is unable to negotiate any necessary contracts related to the collection
22 sites within that time.

23 4. Participate in the National Cord Blood Coordinating Center or a similar
24 national cord blood inventory that lists cord blood units in a manner that assures
25 maximum opportunity for use.

1 5. Establish and operate a program that provides cord blood units for research
2 and agree to provide cord blood units that are unsuitable for therapeutic use to
3 researchers located within the state at no cost to the researcher.

4 6. Maintain national accreditation with an accrediting organization that is
5 recognized by the federal health resources and services administration.

6 (b) Before April 1, 2018, the department of health services shall submit a
7 summary of the responses to the request for information under paragraph (a) and
8 any recommendations developed from the responses to the governor and to the
9 appropriate standing committees of the legislature under section 13.172 (3) of the
10 statutes.

11

(END)

**2017-2018 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-1927/P4ins
TJD:...

1 INSERT A

 The bill prohibits the altering of the timing, method, or ^{ing}procedures used to terminate a woman's pregnancy solely for the purpose of obtain a fetal body part for research. The bill also prohibits a woman's attending physician who obtains a fetal body part from being involved in performing research on the fetal body part.

2 END INSERT A

3 INSERT 3-8

4 (b) No person may knowingly use, for research, a fetal body part that is
5 provided or received for valuable consideration.

6 END INSERT 3-8

7 INSERT 3-13

8 (d) No person may alter the timing, method, or procedures used to terminate
9 a woman's pregnancy solely for the purpose of obtaining a fetal body part for
10 research.

11 (e) A woman's attending physician who obtains a fetal body part may not be
12 involved in performing research on the fetal body part.

13 END INSERT 3-13



State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-1927/P4
TJD:all

In: 2/7

Now

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

I made
no
changes.
15D

- 1 **AN ACT to create** 146.343 (1) (e) and 146.346 of the statutes; **relating to:** sale
2 of and research on fetal body parts, final disposition of fetal body parts, cord
3 blood banks, and providing a criminal penalty.

Analysis by the Legislative Reference Bureau

Generally, this bill bans the sale of fetal body parts, regulates certain research on fetal body parts, and requires the final disposition of fetal body parts. This bill also requires the Department of Health Services to request information from umbilical cord blood banks on creating a public cord blood collection operation. Under the bill, fetal body parts are cells, tissue, organs, or other parts of an unborn child that are obtained after and as the result of an elective abortion, except for cultured cells and except for cells, tissue, or organs from an aborted fetus if the abortion occurred before the effective date of the bill.

Current law prohibits a person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a human organ. Current federal law prohibits a person from knowingly acquiring, receiving, or otherwise transferring, in interstate commerce, any fetal tissue for valuable consideration. The bill prohibits any person from knowingly and for valuable consideration acquiring, receiving, or otherwise transferring a fetal body part and from knowingly using, for research, a fetal body part that is provided or received for valuable consideration. The bill prohibits knowingly acquiring or receiving any fetal body part for research from a for-profit entity, an abortion clinic, or an entity that has as its primary function obtaining fetal tissue for sale. The bill prohibits the altering of the timing, method, or procedures used to terminate a woman's pregnancy solely for the purpose of

obtaining a fetal body part for research. The bill also prohibits a woman's attending physician who obtains a fetal body part from being involved in performing research on the fetal body part.

A person who uses or receives a fetal body part for research is required by the bill to obtain written documentation that the entity that provided the fetal body part did not obtain the fetal body part for valuable consideration and to maintain that written documentation for seven years. Before using a fetal body part in research, an institutional review board must review the documentation from the entity that provided the fetal body part to determine that informed consent was obtained in accordance with federal law and that other requirements specified in the bill are met. The bill also exempts from criminal or civil liability or charges of unprofessional conduct a person who conscientiously objects to participation in research utilizing a fetal body part that violates that person's moral or religious beliefs.

The bill requires that a physician who performs or induces an abortion in this state arrange for the final disposition of the fetal body parts. Final disposition, under the bill, means the disposition of fetal body parts by burial, interment, entombment, cremation, or incineration.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 146.343 (1) (e) of the statutes is created to read:

2 146.343 (1) (e) "Principal prenatal health care provider" means a nurse,
3 nurse-midwife, or physician who is the primary prenatal health care provider.

4 **SECTION 2.** 146.346 of the statutes is created to read:

5 **146.346 Fetal body parts; research. (1) DEFINITIONS.** In this section:

6 (a) "Fetal body part" means a cell, tissue, organ, or other part of an unborn
7 child, as defined in s. 939.75 (1), that is obtained after and as a result of an elective
8 abortion, as defined in s. 253.10 (2) (a). "Fetal body part" does not include any of the
9 following:

10 1. Cultured cells.

11 2. Cells, tissue, or organs from an aborted fetus if the abortion, as defined in
12 s. 253.10 (2) (a), occurred before the effective date of this subdivision ... [LRB inserts
13 date].

1 (b) "Final disposition" means the disposition of fetal body parts by burial,
2 interment, entombment, cremation, or incineration.

3 (c) "Research" means a systematic investigation, including research,
4 development, testing, and evaluation, designed to develop or contribute to
5 generalizable knowledge.

6 (d) "Valuable consideration" has the meaning given in 42 USC 289g-2 (e) (3)
7 as amended to January 1, 2017.

8 **(2) PROHIBITIONS; RESEARCH REQUIREMENTS.** (a) No person may knowingly and
9 for valuable consideration acquire, receive, or otherwise transfer a fetal body part.

10 (b) No person may knowingly use, for research, a fetal body part that is
11 provided or received for valuable consideration.

12 (c) No person may knowingly acquire or receive any fetal body part for research
13 from a for-profit entity, an abortion clinic, or an entity that has as its primary
14 function obtaining fetal tissue for sale.

15 (d) No person may alter the timing, method, or procedures used to terminate
16 a woman's pregnancy solely for the purpose of obtaining a fetal body part for
17 research.

18 (e) A woman's attending physician who obtains a fetal body part may not be
19 involved in performing research on the fetal body part.

20 (f) Any person who uses or receives any fetal body part for research shall obtain
21 written documentation from the entity that provided the fetal body part that certifies
22 that the entity did not obtain the fetal body part for valuable consideration. The
23 person who uses or receives the fetal body part for research shall maintain that
24 written documentation from the entity for at least 7 years.

1 (g) Before the use of any fetal body part for research, an institutional review
2 board shall review the written documentation from the entity that provided the fetal
3 body part to determine that informed consent for research using the fetal body part
4 was obtained in accordance with 45 CFR 46.116 and, if applicable, 42 USC 289g-1
5 and that all of the following requirements are met:

6 1. The consent of the woman for the abortion, as defined in s. 253.10 (2) (a), is
7 obtained before requesting or obtaining her consent for donation of the fetal body
8 part for research in accordance with 45 CFR 46.116 and, if applicable, 42 USC
9 289g-1.

10 2. The woman donating the fetal body part is informed, in accordance with 45
11 CFR 46.116 and, if applicable, 42 USC 289g-1, of any known medical risks to her or
12 any risks to her privacy that might be associated with the donation of a fetal body
13 part and of any similar risks that are associated with her medical care.

14 (h) This subsection does not apply to use of a fetal body part for diagnostic or
15 remedial tests, procedures, or observations that have the sole purpose of determining
16 the life or health of the unborn child in order to provide that information to the
17 mother or preserving the life or health of the child, unborn child, or the child's
18 mother. Notwithstanding pars. (a) to (c), a person is not guilty of violating this
19 section if the person is developing pharmaceutical products or paying or receiving a
20 payment for an existing pharmaceutical product. Nothing in this section may be
21 construed as restricting access to health care, to prescription drugs or devices, or to
22 other pharmaceutical products.

23 **(3) FINAL DISPOSITION.** (a) Notwithstanding sub. (2) (a) to (c), a physician who
24 performs or induces an abortion, as defined in s. 253.10 (2) (a), in this state shall
25 arrange for the final disposition of fetal body parts resulting from the abortion.

1 (b) Notwithstanding sub. (2) (a) to (c), a person is not guilty of violating this
2 section if the person is acting exclusively in furtherance of final disposition of a fetal
3 body part.

4 (4) CONSCIENCE. No person may be held criminally or civilly liable or charged
5 with unprofessional conduct for conscientiously objecting to participation in
6 research utilizing a fetal body part that violates a person's moral or religious belief.

7 (5) PENALTY. Any person who violates this section is subject to a fine not to
8 exceed \$50,000 or imprisonment not to exceed 9 months, or both.

9 **SECTION 3. Nonstatutory provisions.**

10 (1) INFORMATION ON ESTABLISHING PUBLIC CORD BLOOD COLLECTION OPERATION.

11 (a) Before January 1, 2018, the department of health services shall request
12 information from at least one umbilical cord blood bank regarding the establishment
13 of a public cord blood collection operation within the state to collect, transport,
14 process, and store cord blood from residents of the state for therapeutic and research
15 purposes. The department of health services shall include in the request for
16 information questions eliciting the umbilical cord blood bank's ability to do all of the
17 following:

18 1. Establish and operate one or more collection sites within the state to collect
19 a specified target number of cord blood units.

20 2. Implement collection procedures designed to collect cord blood units that
21 reflect the state's racial and ethnic diversity.

22 3. Establish public cord blood collection operations no later than 6 months after
23 executing a contract with the department of health services unless the umbilical cord
24 blood bank is unable to negotiate any necessary contracts related to the collection
25 sites within that time.

1 4. Participate in the National Cord Blood Coordinating Center or a similar
2 national cord blood inventory that lists cord blood units in a manner that assures
3 maximum opportunity for use.

4 5. Establish and operate a program that provides cord blood units for research
5 and agree to provide cord blood units that are unsuitable for therapeutic use to
6 researchers located within the state at no cost to the researcher.

7 6. Maintain national accreditation with an accrediting organization that is
8 recognized by the federal health resources and services administration.

9 (b) Before April 1, 2018, the department of health services shall submit a
10 summary of the responses to the request for information under paragraph (a) and
11 any recommendations developed from the responses to the governor and to the
12 appropriate standing committees of the legislature under section 13.172 (3) of the
13 statutes.

14

(END)

Kohn, Hanna

From: Bruhn, Michael
Sent: Wednesday, February 08, 2017 8:03 AM
To: LRB.Legal
Subject: Draft Review: LRB -1927/1

Please Jacket LRB -1927/1 for the ASSEMBLY.