

SUPPORT HOUSE BILL 1340

Modernizing Indiana's HIV Laws (FAQs Blood Donation)

Authored by Rep. Edward Clere / Co-Authored by: Rep. Brad Barrett, Rep. Rep. Anthony Cook, Rep. Rita Fleming
Senate Sponsors: Sen. Vaneta Becker, Sen. Susan Glick, Sen. Michael Crider, Sen. Jean Breaux, Sen. Shelli Yoder, Sen. J.D. Ford

SUMMARY KEY POINTS – Modernizing IN's HIV-related blood donation criminal laws

- [Current law \(IC 35-45-21-1\)](#) is **outdated**, **ignores scientific facts** around HIV transmission, and **ignores** well-recognized **principles of criminal justice**.
- The US blood supply is the **safest** in the world. There is **no added public health** benefit to punishment in the **rare** event that a person with HIV attempts to donate.
- The **FDA is responsible** for ensuring patients who receive blood products are protected from blood borne viral infections. They do this by **enforcing multiple overlapping safeguards** that include: Donor Screener Questionnaire; Blood antibody and RNA testing; Donor deferral lists; Quarantine; and Investigating Problems and Deficiencies. If any one of these safeguards is breached, the blood component is **destroyed**.
- Only people **who know** their HIV status are subject to criminal penalties; by the time a person **learns they have HIV**, FDA screening for all donated blood, which screens using a questionnaire and tests for several infectious agents using antibody and RNA testing, **will also detect HIV and screen out the donation**; in the case of plasma donations, the person is also added to a national database of unsuitable donors and plasma is heat treated which kills all viruses.
- People with HIV **face unjust exceptionalism** under the criminal law which **violates the ADA**. They are treated differently from people with other infections, such as Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV), who are similarly screened but do not face charges; instead those folks are referred to counseling and testing. People with HIV should be treated the same way under the law.
- Laws that criminalize people with HIV in this regard **are outdated** (enacted in the late 80s), do not reflect advances in science, and are the exception in the US; only 14 states have such laws and all advocates in those states are seeking to repeal these outdated and harmful laws (2 states have already repealed).
- **Leading Public Health Authorities** call for reform and rescinding HIV criminal laws, including the US Dept. of Health and Human Services, and Centers for Disease Control/Prevention.
- The **Indiana Department of Health plan to end the HIV/HCV epidemic** calls for modernizing Indiana's HIV criminal laws to reflect new CDC guidance and scientific truths that have become clear since these laws were enacted.
- The **Indiana Red Cross and Versiti Blood Institute** provided letters for HB1340 that noted it does **“not rely on criminalization to protect the blood supply”** and our repeal efforts would **“not impact their practices to assure blood supply safety”**.
- **Supporting Documents:**
 - 2021 *Blood and Blood Products*, U.S. Food and Drug Administration www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm
 - 2020 *FDA Revised Recommendations for Reducing Risk of HIV Transmission by Blood & Blood Products: Guidance for Industry*. <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>
 - 2018 *Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood* <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/keeping-blood-transfusions-safe-fdas-multi-layered-protections-donated-blood>
 - Indiana Department of Health *Zero Is Possible Indiana 2021-30* (Weblink forthcoming)
 - *National Donor Deferral Registry* (www.pptaglobal.org/safety-quality/national-donor-deferral-registry)
 - 2010. *HIV Transmission Through Transfusion, 2008* <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5941a3.htm>
 - 2020. Risk of HIV from blood transfusion. <https://www.uptodate.com/contents/risk-of-hiv-from-blood-transfusion/print>
 - 2021 HIV criminalisation laws and ending the US HIV epidemic CDC. *Lancet*: Vol 8, ISSUE 1, e4-e6, Jan 01. [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(20\)30333-7/fulltext?s_ci](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(20)30333-7/fulltext?s_ci)
 - 2020 <https://ashpublications.org/blood/article/136/11/1223/463631/ART-and-science-of-keeping-HIV-out-of-the-blood>
 - 2021 US Dept. Health and Human Services. <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>

FAQ Contents

1.	What does HB1340 do in regard to Indiana’s HIV related blood donation laws?	3
2.	Who can be charged under IC35-45-21-1	3
3.	Does the bill change the policy banning use of blood products from people with HIV or at higher risk of having HIV?	3
4.	Why should we remove penalties for people with HIV who attempt to donate blood products?	3
5.	How exactly is the blood supply safe? Do we need to worry about people who know they have HIV attempting to donate blood or plasma?	4
6.	If the blood supply is so safe why are there so many questions on the initial screening?.....	5
7.	What about Undetectable=Utransmittable? Doesn’t that decrease the safety of the blood supply?	5
8.	Has anyone contracted HIV through a blood transfusion or plasma products from someone who KNEW they were HIV+ and it somehow passed through the FDA safety measures?.....	6
9.	Has anyone contracted HIV from the US blood supply in recent years from someone who did not know they had HIV?	6
10.	What about plasma? Can’t people contract HIV through plasma donations?.....	6
11.	What are the odds of contracting Hepatitis versus HIV from a blood transfusion?.....	6
12.	Why would anyone who knows they have HIV attempt to donate blood products in the first place?.....	6
13.	What does the FDA, Red Cross or other Blood Interests Groups have to say about these types of criminal laws?.....	7
14.	But don’t other states impose criminal penalties?.....	10
15.	But if don’t disclose and/or get paid at a plasma center, shouldn’t they still be punished?.....	10

FAQS about modernizing HIV-related blood donation criminal laws.

1. What does HB1340 do in regard to Indiana’s HIV related blood donation laws?

- It removes the criminal penalties for people who know they have HIV from attempting to donate, transfer or sell blood products ([IC35-45-21-1](#)) and the need to notify people who donate of a potential criminal penalty in the required notice section of [IC 16-41-12-15](#)

2. Who can be charged under IC35-45-21-1

- Only people with HIV who know they have HIV.
- People who do not know they have HIV are not charged.
- People who have other infectious diseases (such as HBV or HCV) that bar them from donating, regardless of whether they know they have the disease, are also not charged.

3. Does the bill change the policy banning use of blood products from people with HIV or at higher risk of having HIV?

- No, the policy that bans using blood products from people with HIV stays the same.
- People will still be provided educational HIV material so donors can self-defer.
- They will also be screened using a questionnaire that asks about HIV status, several other diseases, and associated risk factors, that disqualifies them from donating or results in a deferral until they fall out of the risk category.
- All blood will also be tested for HIV, like other infectious diseases, and destroyed if positive.

4. Why should we remove penalties for people with HIV who attempt to donate blood products?

- Current laws **ignore scientific facts** about the routes, risks and current realities of HIV transmission through the blood supply.
- They also **ignore well-recognized principles of criminal justice**, including whether someone intended harm and whether harm is even possible. Punishments are also overly harsh and not proportionate.
- The US blood supply is the safest in the world because the FDA implements several safety measures to protect the blood supply from multiple infectious agents, including HIV, Hepatitis B (HBV), Hepatitis C (HCV), Syphilis, and more. In fact, it’s impossible for a person who knows they have HIV to donate blood products and for it to be used for transfusion or medicine (see next question Q5).
- The FDA does not list criminalization as an effective strategy to keep the blood supply safe from HIV; In fact, it recommends *“donors who have a reactive [HIV] test result should be provided information about the need for medical follow up and counseling”* (pg. 13).¹
- There is no added benefit to public health to criminalize people with HIV in the rare event one might attempt to donate blood products. Rather they should be treated the same as people living with other infectious diseases, like Hepatitis B, who do not face charges, and instead are referred for further counseling and testing services, which is in the interest of public health.
- Treating people differently based on disease status under our blood policies and criminal codes is discriminatory. People with HBV can engage in the same attempted donating behavior as people with HIV, but they do not face charges. Yet, the screening for HIV is more rigorous than HBV. This is a violation of the ADA. People with HIV are singled out for punishment for no justifiable reason.

¹ 2020 Revised Recommendations for Reducing the Risk of HIV Transmission by Blood and Blood Products: Guidance for Industry. <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>

5. How exactly is the blood supply safe?

Do we need to worry about people who know they have HIV attempting to donate blood or plasma?

- If someone knows they have HIV and attempts to donate blood products for whatever reason, please be assured that blood products are safe. This is because:²
- Keeping the US blood supply the world's safest is the ultimate responsibility of the nation's blood establishments that collect and process the units of whole blood donated by volunteers each year. The FDA, however, has the vital role of ensuring that patients who receive a blood transfusion are protected by multiple overlapping safeguards. This FDA blood-safety system includes measures in the following areas:

- **Donor screening:** FDA regulations require that a donor be free from any disease transmissible by blood transfusion, in so far as can be determined by health history and examination. Donors are informed about potential risks and are required to answer questions about factors that may have a bearing on the safety of their blood. For example, donors with a history of intravenous drug abuse are routinely deferred.
In addition to federal regulations, FDA periodically issues guidance documents providing recommendations to decrease the potential for transmission of infectious diseases when new information or testing methodologies becomes available. For example, since November 1999, the FDA has recommended that the blood industry defer potential donors who have lived in the United Kingdom and other European countries to reduce the risk of variant Creutzfeldt-Jakob disease (vCJD), the human form of "mad cow disease."
- **Blood testing:** The FDA reviews and approves all test kits used to detect infectious diseases in donated blood. Plasma is also further heat treated which destroys all viruses. After donation, each unit of donated blood is required to undergo a series of tests for infectious diseases, including:
 - Hepatitis B and C viruses
 - Human Immunodeficiency Virus, Types 1 and 2
 - Human T-Lymphotropic Virus, Types I and II
 - *Treponema pallidum* (Syphilis)
 - Additionally, FDA recommends testing for the following infectious diseases:
 - West Nile Virus
 - *Trypanosoma cruzi* (Chagas disease)
- **Donor deferral lists:** Plasma establishments must keep current a list of deferred donors and use it to make sure that they do not collect blood from anyone on the list. All donors who test reactive for HIV, HBV, and HCV are added to the National Donor Deferral Registry (NDDR) and permanently prohibited from donating plasma in the U.S. and Canada. They are also contacted for further referral testing and counseling³
- **Quarantine:** Donated blood must be quarantined until it is tested and shown to be free of infectious agents
- **Problems and deficiencies:** Blood centers must investigate manufacturing problems, correct all deficiencies, and notify the FDA when product deviations occur in distributed products.

If any one of these safeguards is breached, the blood component is considered unsuitable and destroyed.

What this means is that blood products would be destroyed and never used from a person who knows their HIV status as these rigorous screening processes would readily identify them.*

² 2018 Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/keeping-blood-transfusions-safe-fdas-multi-layered-protections-donated-blood>

³ National Donor Deferral Registry <https://www.pptaglobal.org/safety-quality/national-donor-deferral-registry>

6. If the blood supply is so safe why are there so many questions on the initial screening?

- The questionnaire is used to screen for several items that would lead to either (1) a donation deferral of three months (e.g., they report having sex with someone who is HIV+ or who injects drugs) or a (2) permanent deferral (e.g., they report testing positive for HIV or Hepatitis B).
 - i. Items asked about include:
 1. Questions about traveling outside the US during certain time periods
 2. Questions about IV drug use and sexual risk
 3. Questions about medical procedures
 4. Questions about STDS, Hepatitis and HIV
 5. Questions about current health and how one is feeling.
 6. Several other questions
 - ii. This questionnaire process removes 90% of unsuitable donors.
- The questionnaire also helps screen out people who may have been recently exposed to an infectious disease like HIV or viral hepatitis but they are still within the “*window period*” (i.e., *units from individuals who have been infected but who are in the window during which testing has not yet become positive [about 9 days]*)⁴ In other words policies on donor eligibility reflected into the pre-donation *Donor History Questionnaire* are intended to prevent individuals with high-risk behaviors from donating during the window period; it screens out those with recently acquired HIV but who it is too soon to know they have HIV.
- Essentially, the FDA has the vital role of ensuring that patients who receive a blood transfusion or plasma products are protected by multiple overlapping safeguards⁵ and the donor screener questionnaire is one them:
 - Donor screening questionnaire
 - Blood testing
 - Donor deferral lists
 - Quarantine
 - Reviewing Problems and Deficiencies with Facilities

If any one of these safeguards is breached, the blood component is considered unsuitable for transfusion and is destroyed.

7. What about Undetectable=Untransmittable? Doesn't that decrease the safety of the blood supply?

- No, the safety of the blood supply is not affected if a person is HIV undetectable. The blood supply remains safe. This is because all blood is tested using Anti-HIV Assays which detect antibodies to HIV⁶. So by the time a person learns they have HIV, and is even able to start HIV medicines, FDA blood donor screening and testing will also detect HIV and screen out the donation; the person is then added to a national database of unsuitable donors.
- Ever taken HIV medications is also now part of the medication list in which donors are permanently deferred and not allowed to donate.

****Science Note:** HIV medication can reduce the amount of HIV in one's body (called the viral load) to a very low level (called viral suppression). If one's HIV viral load doesn't show up in a lab blood test from a person, this is called having an undetectable viral load which has prevention benefits. For example, a person with an undetectable viral load cannot pass on HIV sexually; this is known as U=U or Undetectable = Untransmittable. A person will however continue to test positive for HIV for life.⁷

⁴ 2020. Risk of HIV from blood transfusion. <https://www.uptodate.com/contents/risk-of-hiv-from-blood-transfusion/print>

⁵ 2018 Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/keeping-blood-transfusions-safe-fdas-multi-layered-protections-donated-blood>

⁶ Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays <https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays>

⁷ CDC HIV Treatment as Prevention <https://www.cdc.gov/hiv/risk/art/index.html>

8. Has anyone contracted HIV through a blood transfusion or plasma products from someone who KNEW they were HIV+ and it somehow passed through the FDA safety measures?

- No. This is because by the time a person learns they have HIV, FDA screening for all donated blood, which screens using a questionnaire and tests for several infectious agents, will also detect HIV and screen out the donation; the person is then added to a national database of unsuitable donors.

9. Has anyone contracted HIV from the US blood supply in recent years from someone who did not know they had HIV?

- No. There have been no transmission cases of HIV through U.S.-licensed plasma-derived products in well over three decades and the last reported case through a blood transfusion was in 2008 (and only 5 between 2000 and 2008). Transfusion of window period units (i.e., units from individuals who have HIV but who are in the window during which testing has not yet become positive, about 9-11 days, accounts for virtually all of these rare cases of transfusion-transmitted HIV).⁸

10. What about plasma? Can't people contract HIV through plasma donations?

- No. The development of heat treatment viral inactivation procedures for products manufactured from pooled plasma in the 1980s improved the safety of these products by inactivating lipid-enveloped viruses. No transmissions of HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV) have been documented through U.S.-licensed plasma-derived products in well over two decades.⁹

11. What are the odds of contracting Hepatitis versus HIV from a blood transfusion?

There is minimal Residual Risk for HIV, Hepatitis B, and Hepatitis C from Blood (Yet HIV is the only one criminalized).¹⁰ HIV and HCV about 1:2 million / HBV about 1:1.5 million

12. Why would anyone who knows they have HIV attempt to donate blood products in the first place?

- There are no reported cases in IN of anyone attempting to donate after they learned they have HIV.
- There are some rare cases of people attempting to donate plasma after they learned they have HIV.
- Donor questionnaires are used to weed out donors who, in the FDA's view, pose a safety risk to the blood supply. However, because some of these questions are potentially illegal or stigmatized, some people may not disclose information, for example about HIV, having sex with someone with hepatitis, being treated for syphilis, using needles to inject drugs or sex between men. This is why the FDA uses multiple layers of screening to assure blood supply safety (donor questionnaires, blood testing, quarantining donations, etc.).
- Further antidotal evidence from health providers suggest it is often linked to poverty and/or poor literacy. Not everyone understands that plasma is part of blood and therefore believe there is no risk to others and others can't read. Because you get paid a small fee for plasma donations, often people who are poor turn to plasma centers for income. In one case years ago, an Indiana provider reported her client who knew she had HIV, tried to sell her plasma because she was desperate for money to buy diapers for her baby. The women's plasma could not be used and she faced charges instead of being referred for counseling and assistance.

⁸ 2020 FDA Revised Recommendations for Reducing the Risk of HIV by Blood and Blood Products: Guidance for Industry. <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>
Transmission Through Transfusion --- Missouri and Colorado, 2008 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5941a3.htm>
2020. Risk of HIV from blood transfusion. <https://www.uptodate.com/contents/risk-of-hiv-from-blood-transfusion/print>

⁹ 2020 Revised Recommendations for Reducing the Risk of HIV Transmission by Blood and Blood Products: Guidance for Industry. <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>

¹⁰ Screening Blood Donors for HIV, HCV, and HBV at the American Red Cross: 10-Year Trends in Prevalence, Incidence, and Residual Risk, 2007 to 2016 ; *Transfusion Medicine Reviews* Volume 34, Issue 2, April 2020, Pages 81-93
<https://www.sciencedirect.com/science/article/abs/pii/S0887796320300122>

13. **What does the FDA, Red Cross or other Blood Interests Groups have to say about these types of criminal laws?**

- The FDA does not list criminalization as an effective strategy to keep the blood supply safe from HIV; In fact, it recommends

“donors who have a reactive [HIV] test result should be provided information about the need for medical follow up and counseling” (pg. 13).⁸

It’s impossible to have effective medical follow up and counseling, which is in the interest of public health, if one arrested.

- Blood and plasma banks have not opposed ending criminal liability in the rare event that a person with HIV attempts to donate. This is because they follow FDA guidelines; by the time a person learns they have HIV, FDA screening for all donated blood, which tests for several infectious agents, will also detect HIV and screen out the donation; the person is then added to a national database of unsuitable donors, something also done for other blood borne diseases like Hepatitis B and C viruses.
- See letters from the Red Cross and Versiti noting they do not *“rely on criminalization to protect the blood supply.”*

See Next Pages



Indiana Region of The American Red Cross
1510 N. Meridian Street
Indianapolis, IN 46202

April 7, 2021

The Honorable Edward Clere
Indiana House of Representatives Legislative District 72
200 W. Washington Street
Indianapolis, IN 46204

Dear Representative Clere,

I am happy to provide some comments on HB1340 regarding the criminalization of people with HIV who know their status and attempt to donate blood.

- The Red Cross is required to follow the federal FDA guidelines for blood collection and testing.
- The Red Cross operates a national blood collection system, collecting blood from, and providing blood to, individuals in many states in the US.
- There is a patchwork of laws in the US concerning disclosure of HIV status when presenting to donate blood. A small number of states criminalize such behavior, most do not.
- Criminalization is not an FDA recommended measure.
- As these criminalization laws are inconsistent across the states in which we collect and distribute blood products, the Red Cross does not rely on criminalization to protect the blood supply.
- Instead, we carefully follow federal FDA guidelines for blood collection and testing.

Please let me know if there is any other information we can provide.

Sincerely,

A handwritten signature in black ink, appearing to read "Chad Priest", with a stylized flourish at the end.

Chad Priest, JD, MSN, RN, FAAN
Chief Executive Officer – Indiana Region



March 19th, 2021

Dear Representative Clere,

Thank you for reaching out for our input on HB1340, and for specific comments on the item that will remove criminal penalties for people with HIV who attempt to donate blood products in Indiana.

- Versiti is home to the world-renowned Blood Research Institute. We enable lifesaving gifts from our donors, and provide the science behind the medicine through our diagnostic laboratories.
- Versiti is required to follow federal FDA guidelines for blood collection, testing, and safety measures for bloodborne infectious diseases.
- Versiti operates blood collection centers in five midwestern states – Indiana, Ohio, Wisconsin, Illinois and Michigan, and provides blood to individuals in many states in the US.
- There are only about a dozen states that criminalize nondisclosure of HIV status when presenting to donate blood products. Most states do not criminalize such behavior, including two where we operate. Michigan and Wisconsin (the remainder three states currently have introduced reform bills to remove criminal penalties).
- Versiti does not rely on criminalization to protect the blood supply.
- Instead, we carefully follow federal FDA guidelines to protect the blood supply.
- FDA regulations require our donation collection centers to safely dispose of blood products that test positive for any infectious disease, and to provide information about the need for medical care and follow up for those screened as positive.
- We have no official position on this Indiana legislation as it does not impact the safety of the blood supply.

I hope this helps to reassure your colleagues that the presence or absence of criminalization language does not impact Versiti's practices to assure blood supply safety.

Best Regards,

Chris Miskel

Chris Miskel
President and CEO, Versiti

638 N 18th Street / PO Box 2178 / Milwaukee, WI 53201-2178 / versiti.org

14. But don't other states impose criminal penalties?

- Actually, only 16 states ever imposed criminal penalties for attempting to donate blood products while knowingly HIV+ and even less for semen for artificial insemination (see table below).
- All of these laws were enacted in the late 80s or early 90s and are outdated (Indiana's attempted donation law was enacted in 1988); all states ultimately seek repeal of these outdated laws.¹¹

Felony HIV Laws that have ever Criminalized PLHIV for: Attempting to donate, transfer, and/or sell blood products OR semen/gametes.* Highlight Bold Font indicates the law has been successfully repealed or modernized				
<i>STATE</i>	<i>Political Culture</i>	<i>Semen/ Gametes</i>	<i>BLOOD</i>	<i>Notes</i>
1. ARKANSAS	RED		F	
2. CALIFORNIA	BLUE	F	F	Repealed both as part of 2017 reform
3. FLORIDA	RED		F	2021 bill seeks to repeal
4. GEORGIA	RED	F	F	2021 bill seeks repeal
5. IDAHO	RED	F	F	
6. ILLINOIS	BLUE	F	F	2021 bill seeks repeal
7. INDIANA	RED	F	F	Attempted to repeal both in 2019 and 2020 with excellent House support.
8. IOWA	RED	F	F	Repealed as part of 2014 reform
9. KANSAS	PURPLE	F	F	
10. MINNESOTA	PURPLE	F	F	
11. MISSOURI	RED	F	F	2021 bill seeks to repeal both
12. OHIO	RED		F	2021 bill (not yet filed) seeks repeal
13. S. CAROLINA	RED	F	F	
14. S. DAKOTA	RED	F	F	
15. TENNESSEE	RED	F	F	
16. VIRGINIA	BLUE	F	F	2021 bill repeals and was passed three weeks ago; click here for an article
TOTAL		13/10 3 repealed	16/13 3 repealed	

15. But if don't disclose and/or get paid at a plasma center, shouldn't they still be punished?

Other people without HIV who engage in the same behavior (who are also not allowed to donate but do not disclose risk factors) are not charged with a crime. But yes, you certainly could still charge them under Indiana general criminal codes such as fraud or minor theft (in the event they are paid) laws, however rarely that may occur. You do not need an HIV specific crime that is based on someone's HIV status. People with HIV should not be treated differently under the law because of their disease.

Last Updated 4.9.2021

¹¹ HIV Criminalization in the United States: A Sourcebook on State and Federal HIV Criminal Law and Practice, The Center for HIV Law and Policy (updated May 2020) <https://www.hivlawandpolicy.org/sourcebook>