



## 2024 HIPAA Final Rule to Support Reproductive Health Care Privacy

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This issue brief provides an analysis of the Department of Health and Human Services' (HHS) 2024 final rule to modify the regulations implementing the Standards for Privacy of Individually Identifiable Health Information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act).<sup>1</sup> The final 2024 *HIPAA Privacy Rule to Support Reproductive Health Care Privacy* (hereinafter "2024 HIPAA Privacy Rule") was published in the Federal Register on Friday, April 26, 2024, and has an effective date of June 25, 2024.<sup>2</sup> The 2024 HIPAA Privacy Rule applies to covered entities and their business associates. Entities subject to this regulation must comply with the requirements of the final rule by December 23, 2024.

Broadly, the 2024 HIPAA Privacy Rule:

- prohibits covered entities and their business associates from using or disclosing [protected health information](#) (PHI) for the purpose of imposing or conducting an investigation to impose liability (civil, criminal, or administrative) for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care;
- prohibits covered entities and their business associates from disclosing PHI that may be used to identify any individual for the purpose of imposing liability for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care;

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<sup>1</sup> See Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191; see also Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and 164.

<sup>2</sup> See Dep't of Health and Human Servs., *HIPAA Privacy Rule To Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024), <https://www.federalregister.gov/documents/2024/04/26/2024-08503/hipaa-privacy-rule-to-support-reproductive-health-care-privacy>.

- creates a presumption that reproductive health care was provided lawfully unless certain circumstances exist;
- defines reproductive health care and provides a non-exhaustive list for what can be considered reproductive health care; and
- requires covered entities and their business associates to obtain a valid attestation before they can disclose PHI potentially related to reproductive health care for a use described below.<sup>3</sup>

This issue brief will provide background information on the original HIPAA rule and describe the circumstances that led to the finalization of the 2024 HIPAA Privacy Rule. It will then summarize relevant information from the 2024 HIPAA Privacy Rule and provide a brief conclusion.

## 1. Background

On August 21, 1996, the Health Insurance Portability and Accountability Act (HIPAA) was enacted.<sup>4</sup> This Act aimed to increase the efficiency of health care delivery services including the use of electronic data. The Act included an administrative simplification provision that required the HHS Secretary and the Attorney General to create regulations that would safeguard patients' electronic health information.<sup>5</sup> The Secretary was required to develop a national standard for the management and confidentiality of patients' health information. This action was prompted by the growing use of interconnected electronic health care data and the recognition that patient health care was being compromised because patients were unwilling to trust their health care provider unless they were assured that their health information would remain private.<sup>6</sup>

Therefore, to foster better relations between health care providers and patients, the HHS Office for Civil Rights finalized the original *Standards for Privacy of Individually Identifiable*

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<sup>3</sup> *Id.*

<sup>4</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. 104- 191.

<sup>5</sup> *Id.*

<sup>6</sup> Dep't of Health and Human Servs., *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 32976 (Dec. 28, 2000), <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/prdecember2000all8parts.pdf>.

*Health Information* (hereinafter “Privacy Rule” and more commonly known as the HIPAA Privacy Rule) on December 28, 2000.<sup>7</sup> The Privacy Rule is enforced by the HHS Office for Civil Rights.<sup>8</sup> The Office for Civil Rights reviews complaints of potential Privacy Rule violations, conducts investigations into violations, and issues penalties.<sup>9</sup> The Privacy Rule does not include a private right of action.

The Privacy Rule created guidelines for the protection of PHI and limited the circumstances in which covered entities and their business associates could use or disclose PHI.<sup>10</sup> In the time since its initial promulgation, the Privacy Rule has undergone multiple modifications:

- 2002: in response to comments on the original rule<sup>11</sup>;
- 2013: after the enactment of the HITECH ACT, which required covered entities to notify individuals of data breaches;<sup>12</sup>
- 2014: to allow individuals access to their lab tests<sup>13</sup>;

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<sup>7</sup> *Id.* at 82463.

<sup>8</sup> If a person believes their rights have been violated by a covered entity under HIPAA, the person can file a complaint with the Department of Health and Human Services Office for Civil Rights at: <https://www.hhs.gov/hipaa/filing-a-complaint/index.html>.

<sup>9</sup> HHS, HIPAA What to Expect, <https://www.hhs.gov/hipaa/filing-a-complaint/what-to-expect/index.html#:~:text=You%20may%20file%20a%20health,Security%20or%20Breach%20Notification%20Rules>. (last visited Mar. 6, 2024).

<sup>10</sup> See 42 U.S. Code § 1320d–3(b)(1).

<sup>11</sup> See Dept. of Health and Human Servs., *Standards for Privacy of Individually Identifiable Health Information, Final Rule*, 67 Fed. Reg. 53182 (Dec. 28, 2002), <https://www.govinfo.gov/content/pkg/FR-2002-08-14/pdf/02-20554.pdf#page=2>; see also 45 C.F.R. Part 160 and 164.

<sup>12</sup> See Dept. of Health and Human Servs., *Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Generic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, Final Rule*, 78 Fed. Reg. 5566 (Jan. 25, 2013), <https://www.govinfo.gov/content/pkg/FR-2013-01-25/pdf/2013-01073.pdf#page=3>; see also 45 C.F.R. Part 160 and 164.

<sup>13</sup> See Dept. of Health and Human Servs., *CLIA Program and HIPAA Privacy Rule; Patients Access to Test Reports*, 79 Fed. Reg. 7290 (Feb. 6, 2014), <https://www.govinfo.gov/content/pkg/FR-2014-02-06/pdf/2014-02280.pdf>; see also 45 C.F.R. Part 164.

- 2016: to allow disclosure of PHI to the National Instant Criminal Background Check System.<sup>14</sup>

On June 24, 2022, the Supreme Court released its opinion in *Dobbs v. Jackson Women's Health Organization*.<sup>15</sup> This decision overturned both *Roe v. Wade* and *Planned Parenthood v. Casey*, and held that no constitutional right to abortion exists.<sup>16</sup> This immediately resulted in states enacting and enforcing total or near total abortion bans.<sup>17</sup> Some of these bans threaten revocation of medical licensure for professionals who provided certain types of reproductive health care like abortions, as well as felony charges, fines, and other penalties for those that assist a pregnant person in obtaining reproductive health care. Some states also enacted laws that punish individuals who assist someone traveling out of state for reproductive health care, although they are currently not being enforced.<sup>18</sup>

The *Dobbs* decision fundamentally changed the legal landscape of reproductive health care in the United States and created an inherent mistrust between health care providers and patients in states where there are legal limits to seeking certain sexual and reproductive health services, primarily abortion. Some patients who sought reproductive health care or who had already obtained reproductive health care grew afraid of revealing this information to their providers for fear of being reported to authorities for violation of state law.<sup>19</sup>

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<sup>14</sup> See Dept. of Health and Human Servs., *Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and National Instant Criminal Background Check Systems (NICS)*, 81 Fed. Reg. 382 (Jan. 6, 2016), <https://www.govinfo.gov/content/pkg/FR-2014-02-06/pdf/2014-02280.pdf>; see also 45 C.F.R. Part 164.

<sup>15</sup> *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 302 (2022).

<sup>16</sup> See *Roe v. Wade*, 410 U.S. 113, 164 (1973); see also *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 869 (1992).

<sup>17</sup> See Guttmacher Inst., *Interactive Map: US Abortion Policies and Access After Roe*, [https://states.guttmacher.org/policies/?gad\\_source=1&qclid=Cj0KCQjwir2xBhC\\_ARIsAMTXk86HqGa-DSckazaPYpJqF9zLI9C-Xbqe0F-0mBCeBrFf1BIjismj8vsaAnqFEALw\\_wcb](https://states.guttmacher.org/policies/?gad_source=1&qclid=Cj0KCQjwir2xBhC_ARIsAMTXk86HqGa-DSckazaPYpJqF9zLI9C-Xbqe0F-0mBCeBrFf1BIjismj8vsaAnqFEALw_wcb) (last visited Apr. 30, 2024).

<sup>18</sup> ACLU, *Federal Court Blocks Enforcement of Idaho Attorney General's Prohibition on Out-of-State Abortion Referrals*, <https://www.aclu.org/press-releases/federal-court-blocks-enforcement-of-idaho-attorney-generals-prohibition-on-out-of-state-abortion-referrals> (last visited Apr. 30, 2024).

<sup>19</sup> Dept. of Health and Human Servs., *Notice of Proposed Rulemaking: HIPAA Privacy Rule to Support Reproductive Health Care*, 88 Fed. Reg. 23506 (Apr. 17, 2023), <https://www.govinfo.gov/content/pkg/FR-2023-04-17/pdf/2023-07517.pdf>; see also Brittany

In 2023, HHS issued a Notice of Proposed Rulemaking (NPRM) to modify the original Privacy Rule to protect reproductive health care after the *Dobbs* decision.<sup>20</sup> As described by HHS in the preamble to the 2024 HIPAA Privacy Rule, Black, Indigenous, and other people of color and LGBTQI+ individuals are more likely to be distrusting of their providers if they do not believe that information that they disclose to their providers will remain private.<sup>21</sup> This is due to historical oppression and discrimination that these groups face from the medical community.<sup>22</sup> The 2024 HIPAA Privacy Rule seeks to mend the fractured relationship between providers and patients due to post-*Dobbs* criminalization of reproductive health care and assure patients that information regarding their lawful reproductive health care will be safeguarded.

## 2. Summary of 2024 HIPAA Rule to Support Reproductive Health Care Privacy

### i. What Entities Are Subject to the 2024 HIPAA Privacy Rule?

The 2024 HIPAA Privacy Rule only applies to covered entities and their business associates. Covered entities under HIPAA include: health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form related to complete health care transactions.<sup>23</sup> Business associates (*e.g.*, medical transcriptionists, third party

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*Watts, Ohio Women Charged with Felony After Miscarriage at Home, Describes Shock of her Arrest*, CBS NEWS (Jan. 26, 2024), <https://www.cbsnews.com/news/brittany-watts-the-ohio-woman-charged-with-a-felony-after-a-miscarriage-talks-shock-of-her-arrest/>.

<sup>20</sup> See Dept. of Health and Human Servs., *HIPAA Rule to Support Reproductive Health Care Privacy*, 88 Fed. Reg. 23506 (Apr. 17, 2023), <https://www.govinfo.gov/content/pkg/FR-2023-04-17/pdf/2023-07517.pdf>.

<sup>21</sup> 89 Fed. Reg. at 32985.

<sup>22</sup> See *id.* at 32989 (HHS provides data on the amount of BIPOC and LGBTQI+ groups that have mistrust in their health care provider, believe they will experience discrimination from their health care provider, or have had a negative experience with their health care provider.)

<sup>23</sup> See 45 C.F.R. 160 § 160.102; see also Center for Medicaid & Medicare Servs., *Are You a Covered Entity?*, <https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa/covered-entities#:~:text=HIPAA%2C%20or%20the%20Health%20Insurance,Health%20Plans> (last visited Apr. 30, 2024).

administrators) assist covered entities with their health care functions.<sup>24</sup> The 2024 HIPAA Privacy Rule does not regulate consumer health applications (*e.g.*, menstruation tracking applications).<sup>25</sup> HHS has previously released guidance titled, "Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet," to inform the public on how to protect their health information on mobile devices.<sup>26</sup>

## ii. Applicability to Minors

Under the Privacy Rule finalized in 2000, the parents or guardians of unemancipated minors are treated as the minors' personal representatives as long as they have the authority to make decisions regarding the minors' health care.<sup>27</sup> The 2024 HIPAA Privacy Rule does not change this standard. Therefore, parents or guardians can use or disclose the PHI of their minor child, and have access to the PHI of their child. There are three exceptions to the general principle of parents as personal representatives to their minor children, and additional exceptions for cases of abuse or neglect.<sup>28</sup> Generally parents are not considered personal representatives when:

- the consent of the parent or guardian is not required for a procedure and the minor consents to the procedure;
- someone other than the parent or guardian is authorized to consent to medical procedures for the child (*e.g.*, medical power of attorney); or
- the parent agrees to a relationship of confidentiality between a minor and a provider.<sup>29</sup>
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If an unemancipated minor received lawful reproductive health care and none of the above exceptions apply, the minor's parent or guardian would still have access to that information

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<sup>24</sup> 45 C.F.R. 160 § 160.102.

<sup>25</sup> 89 Fed. Reg. at 33007.

<sup>26</sup> HHS, Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html> (last visited May 6, 2024).

<sup>27</sup> 45 C.F.R. § 164.502.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

unless it conflicts with state law. The provider would not be prohibited from disclosing this information under the Rule.

### iii. Prohibition on Using or Disclosing Protected Health Information (PHI)

The 2024 HIPAA Privacy Rule prohibits covered entities and their business associates from using or disclosing PHI for the purpose of imposing liability (*e.g.*, criminal, civil, or administrative) or conducting an investigation (*e.g.*, criminal, civil, or administrative) on any person, “for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, that was lawful under the circumstances it was provided.”<sup>30</sup> The 2024 HIPAA Privacy Rule further prohibits covered entities and their business associates from using or disclosing PHI for the purpose of identifying a person to impose liability in the aforementioned circumstances (*e.g.*, imposing criminal, civil, or administrative investigation for merely seeking lawful reproductive health care).<sup>31</sup>

HHS defines reproductive health care broadly as health care “that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.”<sup>32</sup> In the preamble, HHS also includes a non-exhaustive list of services that could be considered reproductive health care (reproduced below).<sup>33</sup>

HHS explicitly mentions termination of pregnancy in the non-exhaustive list of services that would be considered reproductive health care.<sup>34</sup> The Department also states in the preamble that the main purpose of promulgating the regulation was the changed legal landscape after the release of the *Dobbs* decision, and a renewed need to ensure PHI is safeguarded after new state laws restricting reproductive health care were enacted.<sup>35</sup> Therefore, abortion and other reproductive health services performed under lawful circumstances would be protected by the rule.

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<sup>30</sup> 89 Fed. Reg. at 32978.

<sup>31</sup> *Id.* at 32989.

<sup>32</sup> *Id.* at 33063.

<sup>33</sup> *Id.* at 33006.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 32978.

**Non-Exhaustive List of Reproductive Health Services Covered Under the Rule<sup>36</sup>**

<b>General Category</b>	<b>Reproductive Health Service</b>
Contraception and Preconception	Emergency contraception, and Preconception screening and counseling
Management of Pregnancy and Pregnancy-related Conditions	Pregnancy screening, Prenatal care, Miscarriage management, Molar pregnancy, Ectopic Pregnancy, Pregnancy Termination (Abortion), Treatments for Preeclampsia, Gestational Diabetes, or Hypertension during Pregnancy
Fertility and Infertility Diagnosis and Treatment	Assisted Reproductive Technology ( <i>e.g.</i> , in vitro fertilization (IVF))
Diagnosis and Treatment of Conditions that Affect the Reproductive System	Diagnosis of Perimenopause, Menopause, Endometriosis, Adenomyosis)
Other Types of Care, Services, and Supplies used for the Diagnosis and Treatment of Conditions Related to the Reproductive System	Mammography, Pregnancy-related Nutrition Services, Postpartum Care Products

The 2024 HIPAA Privacy Rule states that reproductive healthcare is lawful when:

- the reproductive healthcare was lawful under the law of the state it was performed in and under the circumstance it was provided;
- the reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution; or
- when the presumption present in the rule applies.<sup>37</sup>

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<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 32996.



In the 2024 HIPAA Privacy Rule HHS creates a presumption for circumstances in which reproductive health care will be considered lawful. The presumption states that reproductive health care provided by someone other than the covered entity was lawful unless: (1) the covered entity has actual knowledge that the reproductive health care provided was unlawful; or (2) the person requesting the PHI demonstrates a “substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.”<sup>38</sup>

In the preamble discussion, HHS states that for a substantial factual basis to exist:

the regulated entity must obtain from the person making the request sufficient threshold factual evidence that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.<sup>39</sup>

HHS mentions that a substantial factual basis would exist if the person requesting the PHI submitted documentation such as affidavits to support their claim that the reproductive health care was not lawful under the circumstances it was provided.<sup>40</sup> HHS further clarifies that a substantial factual basis would not exist if the person requesting the PHI merely provided an anonymous report that the reproductive health care was unlawful.<sup>41</sup> The presumption of legality in the 2024 HIPAA Privacy Rule ensures that providers are not responsible for investigating the lawfulness of reproductive health care they did not provide.

#### iv. Case Examples

In the preamble HHS provides helpful examples of how the 2024 HIPAA Privacy Rule would be applied in practice.<sup>42</sup> One example is the following: a law enforcement agency in State A requests PHI from a provider in State B for the purpose of prosecuting a patient named Patient C for receiving reproductive health care (*e.g.*, obtaining an abortion) that is lawful in State B but unlawful in State A. Under the 2024 HIPAA Privacy Rule, the provider would be

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<sup>38</sup> *Id.* at 33014.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 33015.

prohibited from providing this information to the State A law enforcement because the purpose for obtaining this information is for imposing criminal liability on Patient C for the mere act of obtaining reproductive health care.<sup>43</sup> After the release of the 2024 HIPAA Privacy Rule HHS also published a fact sheet with other helpful examples of how the rule would operate in practice.<sup>44</sup>

#### v. Attestation Requirement

The 2024 HIPAA Privacy Rule requires an attestation from a person requesting PHI potentially related to reproductive health if the use or disclosure of the PHI is for:

- health care oversight activities;
- judicial or administrative proceedings;
- law enforcement purposes; or
- disclosures about decedents (*e.g.*, coroners).<sup>45</sup>

The attestation must include:

- the name of the patient or class of persons whose PHI is being sought;
- the name of the person requesting the PHI;
- the name of the covered entity disclosing the PHI;
- a statement that the use or disclosure of the PHI is not for a prohibited purpose (*e.g.*, to impose liability for seeking lawful reproductive health care);
- a statement acknowledging that penalties apply if they knowingly obtain PHI in violation of HIPAA or redisclose the PHI to another individual; and
- the signature of the person requesting the PHI.<sup>46</sup>

The attestation must be written in plain language and HHS stated that a model attestation will be available before the compliance date of the 2024 HIPAA Privacy Rule to demonstrate the

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<sup>43</sup> *Id.*

<sup>44</sup> HHS, *HIPAA Privacy Rule Final Rule to Support Reproductive Health Care Privacy: Fact Sheet*, <https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/final-rule-fact-sheet/index.html> (last visited May 7, 2024).

<sup>45</sup> 45 C.F.R. § 164.512(d)—(g)(1).

<sup>46</sup> 89 Fed. Reg. at 33064.

requirements.<sup>47</sup> In comments to the NPRM, NHeLP and other organizations requested the final rule strengthen the attestation requirement by requesting that the attestation include a signed declaration made under penalty of perjury.<sup>48</sup> In the preamble, HHS addresses these comments by: (1) adding a requirement that the attestation include a statement that acknowledging HIPAA penalties apply; and (2) stating that an declaration signed up penalties of perjury is unnecessary given the penalties already attached to violations of HIPAA.<sup>49</sup>

Regarding the attestation requirement, HHS does not expect covered entities to conduct detailed factual inquiries into the validity of an attestation but instead, wants covered entities to look at the totality of the circumstances of which the attestation has been submitted and whether it would be reasonable to rely on the attestation.<sup>50</sup> According to HHS, some factors covered entities should consider when determining whether it would be reasonable to rely on an attestation are:

- who is requesting the PHI;
- the permission upon which the person making the request is relying;
- the permission provided to satisfy other conditions of the relevant permission;
- the PHI requested and its relationship to the purpose of the request (*i.e.*, does the request meet the minimum necessary standard in relation to the purpose of the request); and
- information provided by the person requesting the use or disclosure of PHI to overcome the presumption of reproductive care being lawful (discussed earlier in the brief).<sup>51</sup>

HHS provides examples in the preamble of the circumstances in which it would not be reasonable to rely on the attestation.<sup>52</sup> For example, if a prosecutor, who has openly spoken about wanting to initiate criminal proceedings against people seeking reproductive health care, requests PHI related to reproductive health care and submits an attestation to a covered

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<sup>47</sup> *Id.* at 33030.

<sup>48</sup> *Comment from Coalition of 125 Reproductive Rights and Allied Organizations*, HHS-OCR-2023-0006, HHS-OCR-2023-0006-0001, 2023-07517 (July 31, 2023), <https://www.regulations.gov/comment/HHS-OCR-2023-0006-8970>.

<sup>49</sup> 89 Fed. Reg. at 33038.

<sup>50</sup> *Id.* at 33037.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 33037-38.

entity, it might not be reasonable for the covered entity to believe that the request for PHI is not for a prohibited purpose under the rule.<sup>53</sup> Therefore, under the totality of circumstances it may not be reasonable to rely on the attestation the prosecutor who would then have to submit additional documentation to prove that the request was not for a prohibited purpose.<sup>54</sup>

### 3. Conclusion

Given the Supreme Court's decision in *Dobbs*, and the growing concerns individuals have in assessing reproductive health care due to its increased criminalization, the 2024 HIPAA Privacy Rule is important in reinforcing vital health privacy protections and establishing new accountability for those that request PHI through the attestation requirement. We see this rule as an important step and we look forward to its full implementation and enforcement.

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<sup>53</sup> *Id.* at 33033.

<sup>54</sup> *Id.*