Benjamin Rioja Paris
Policy Analyst, Regulatory Policy
Thomas A. Roe Institute for Economic Policy Studies
The Heritage Foundation

Jonathan Abbamonte
Senior Research Associate
Center for Data Analysis
The Heritage Foundation

214 Massachusetts Ave., NE
Washington, D.C., 20002
June 16, 2023

Hon. Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Attention: HIPAA Privacy Rule To Support Reproductive Health Care Privacy (RIN 0945-AA20, Docket ID HHS-OCR-2023-0006).

Dear Secretary Becerra:

We write to comment on the U.S. Department of Health and Human Services' NPRM "HIPAA Privacy Rule To Support Reproductive Health Care Privacy" (RIN 0945-AA20), pursuant to the notice-and-comment process outlined in and protected by 5 U.S.C. § 553(c). The proposed rule is arbitrary and capricious, and the Department cannot go through with it. First, the rule as written is unclear and open to wild misinterpretation. Further, the rule would impose a far greater cost than the Department claims, with a discrepancy of over $1.6 billion in five-year costs resulting from irrational underestimation and neglect of key cost factors on the part of the Department. Additionally, the rule would create barriers and chilling effects with respect to the swift execution of justice with respect to sensitive criminal cases, such as sexual assault, and does not take into account several disadvantages. Finally, the claimed benefits of the proposed rule are unreasonably inflated: most egregiously, the Department suggests that this rule would benefit 74 million individuals, whereas a reasonable estimate mindful of relevant data suggests it would only benefit 50,400. For these reasons, the Department should not and cannot go forward with this rule. Our full comment follows. Thank you for your consideration of this pressing matter.

TABLE OF CONTENTS

I. The Department Appears to Put Forth Two Standards of Interpretation on Prohibited Disclosures.

The proposed rule would prevent covered health care providers from disclosing protected health information to law enforcement and the courts in cooperation with a criminal investigation or judicial proceedings pursuant 45 CFR §164.512(e)-(f) when such protected health information (PHI) has any "connection with seeking, obtaining, providing, or facilitating reproductive health care."[1] The Department's proposed §164.509 would permit covered health care providers to provide PHI related to reproductive health care for the purposes of health oversight, law enforcement, or judicial or administrative proceedings if requestors file a strictly defined, narrowly constructed attestation that PHI will not be used "for a purpose prohibited under §164.502(a)(5)(iii)."[2] The language of the proposed §164.502(a)(5)(iii), however, is confusing as it puts forth two standards for the Department's prohibition on the disclosure of reproductive health care PHI for the purposes of law enforcement or judicial proceedings. At §164.502(a)(5)(iii)(A)(1), the proposed rule prohibits the provision of PHI when "the use or disclosure is for a criminal, civil, or administrative investigation into or proceeding against *any person in connection with* seeking, obtaining, providing, or facilitating reproductive health care" (emphasis added) whereas at §164.502(a)(5)(iii)(D), the proposed rule states that "[n]othing in this section shall be construed to prohibit a use or disclosure of protected health information otherwise permitted by this subpart unless such use or disclosure *is primarily for the purpose of* investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care" (emphasis added). At §164.502(a)(5)(iii)(A)(1), the Department states that its prohibition of disclosure applies to any person in any way connected or involved with to reproductive health services, regardless of what sorts of charges are being pursued in a criminal investigation where reproductive health care PHI is requested. But at §164.502(a)(5)(iii)(D), the Department appears to be imposing a stricter standard by saying that its prohibition on reproductive health care PHI only applies to criminal investigations primarily pursuing charges "for the mere act" of engaging in reproductive health care services, though the language of this paragraph is unclear. The proposed §164.502(a)(5)(iii)(D) could be interpreted as pertaining only to non-reproductive health care PHI or reproductive health care PHI for non-judicial or investigatory purposes as it states that nothing in §164.502 should be construed to prohibit the disclosure of PHI "otherwise permitted by this subpart [45 CFR Part 164, Subpart E]," i.e., all other disclosures of PHI that are permitted under 45 CFR Part 164, Subpart E and are not prohibited under §164.502(a)(5)(iii)(A)-(C).

If the Department intends to limit its prohibition on the disclosure of reproductive health care PHI to only investigations and judicial proceedings which primarily seek to prosecute health

[1] 88 FR 23552.
[2] 88 FR 23553.

care providers and individuals "for the mere act" of engaging in reproductive health care services, then the Department should make this clear at §164.502(a)(5)(iii)(A). There is no reason why the Department cannot make this point clear within a single paragraph at §164.502(a)(5)(iii)(A). Breaking up its interpretation of prohibited PHI disclosures over §164.502(a)(5)(iii)(A) and §164.502(a)(5)(iii)(D) appears to put forth two standards of interpretation on the prohibition of reproductive health care PHI. The proposed rule, as it is currently written, is unnecessarily confusing and unclear, particularly to health care providers who may not be well-versed in law.

II. The Department Does Not Reasonably Evaluate the Quantifiable Cost of the Rule

A. The Department Ignores Costs for Health Care Entities Reviewing Attestations.

The Department does not account for the cost on the part of regulated health care entities to determine the lawfulness of PHI requests. While attestations are intended to ensure that PHI is only given out for non-prohibited purposes, attestations must accurately reflect the nature of the PHI request in question. The primary cost of an attestation is not found in a regulated entity requesting it, but rather, in verifying the information attested-to in the attestation. The Department recognizes the existence of this cost, but makes no attempt to quantify or qualify it:

> "The Department believes that the regulated entity would likely need to determine whether the requested PHI includes PHI potentially related to reproductive health care. However, the Department lacks sufficient information to estimate the amount such a burden would vary from the burden of processing requests for PHI with an authorization. Additionally, the Department believes that regulated entities may need to evaluate whether the reproductive health care encompassed within the scope of a request under 45 CFR 164.512(d) through (f) and (g)(1) was lawful under the circumstances in which it was provided, and solicits comments on data about the associated costs of such reviews."[3]

First, the Department cannot claim that this is a reasonable evaluation of this particular cost of the proposed rule. Simply mentioning the potential existence of a cost does not mean that the agency has evaluated or weighed that cost in its decision-making.[4] It is notable that the Department's documented cost to regulated entities dealing with attestations is only derived from the burden "associated with the requirement to keep records of the attestations received."[5] Thus,

---

[3] 88 FR 23544.
[4] See, e.g., *Parhat v. Gates*, quoting Lewis Carroll, The Hunting of the Snark 3 (1876): "the fact that the government has 'said it thrice' does not make [it] true." *Parhat v. Gates*, 532 F.3d 834, 848 (D.C. Cir. 2008).
[5] 88 FR 23544.

the Department's estimate cannot be said to have included the cost of review of attestations, despite recognizing that regulated entities will have burden from reviewing the nature of PHI requests and evaluating the veracity of attestations. There is no evidence that these costs were seriously considered.

This is especially egregious because the Department could have easily considered these costs. For example, a reasonable estimate would be that each regulated entity would use an hour of the time of a lawyer on retainer in consultation with a qualified health care professional to determine the veracity and appropriateness of an attestation. This reflects the labor of each party reviewing the attestation (10 minutes); investigating the relevant laws cited as the origin of the civil, criminal, or administrative proceeding (10 minutes); discussing with one another the nature of the PHI requested (10 minutes); determining together the relevance of this and other HIPAA regulations (10 minutes); evaluating the veracity and legitimacy of the attestation (10 minutes); and determining the necessary course of action (10 minutes). Taking the rest of the Department's cost estimate as it is, this would be calculated by the equation:

$$(\$142.34/hr \ * 1\ hr + \$87.60/hr * 1\ hr) * 774{,}331\ attestations = \$178{,}049{,}670.14$$

Thus, the Department has failed to account for over $178 million in annual cost, or an additional undiscounted 5-year cost of over $890 million. The fact that this cost was totally absent from the proposed rule's considerations is enough to show that the Department failed to consider cost; the fact that it alone exceeds several of the Department's other cost calculations and the threshold for economic significance set by EO 12866 makes it especially egregious and, as another cost toward regulated entities, should tip the scales against proceeding with the proposal. Failing to account for such a large cost, whose estimation was easy and reasonable, means that the Department has "entirely failed to consider an important aspect of the problem."[6] This, in turn, is evidence that the Department has failed to "pay[] attention to the advantages *and* the disadvantages of agency decisions" in general, an act required of reasonable regulation.[7] The proposed rule, therefore, is arbitrary and capricious, and the Department cannot go forward with it.

B. The Department Does Not Justify Its Estimate of the Number of Attestations

The Department's estimate of the number of attestations it will receive under the proposed rule is not justified, and indeed, is unreasonable. The Department estimates this number by "adopt[ing] the cost estimates already approved for documenting disclosures based on an authorization because those estimates provide an established baseline," namely, per its ICR

[6] *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).
[7] *Michigan v. Envtl. Prot. Agency*, 576 U.S. 743, 752-53 (2015).

for 45 CFR 164.508, "one burden hour per covered entity" representing "the requirement to keep records of the attestations received."[8] It is notable that the ICR claimed that there would be one burden, i.e., one disclosure under 45 CFR 164.508, per regulated entity, and that this one burden would impose a time-burden of one hour (the Department focuses only on the burden-hour, but the ICR anticipates one burden which will take one burden-hour).[9] If the Department believes that the number of attestations will differ from the number of disclosures, then it must provide reasoning to support the notion that the number of burden-hours per attestation will be less than the number per disclosure (i.e., since the Department claims that both will impose an overall burden of one hour per year, if it believes that there will be $X > 1$ attestations per year, then the Department must believe that each attestation will impose a time-cost of $1/X$ hours). It provides no such explanation, and indeed, no such explanation exists. Thus, the Department can only contend, based on the (lack of) justification provided, that the number of attestations will equal the number of disclosures, i.e., one per year.

Elsewhere in the rule, however, the Department recognizes that "approximately 26 states" would make requests for exemptions because of the "fast-developing" legal environment surrounding abortion and related deeds.[10] This assumption correctly reflects the fact that both state laws and the proposed rule seek to navigate uncharted territory with respect to these health matters, especially in light of *Dobbs v. Jackson Women's Health Organization*. Given that the Department recognized the developing legal environment surrounding these health matters before, however, it is unclear why the Department declined to include this factor in its analysis of the number of attestations that entities will receive. That is, it is unreasonable to think that the number of attestations that will be received will mirror the number of disclosures estimated under current law according to the 2023 ICR.

A better estimate of the number of attestations that will be received is to add onto the number of disclosures to account for the special cases that will newly require attestations because of the rule. For example, attestations will be required to obtain medical records as evidence in cases of rape and sexual assault. These attestations will necessarily add to the number of disclosures because they do not address the same kind of PHI that disclosures would. Attestations would be needed to confirm the mere fact of someone having received healthcare after an assault or rape, for example, and then again if the court needed to know data about the procedure itself. Considering just reported rape cases, this would mean an estimated 144,300 extra attestations per year.[11] Thus the number of attestations would be increased by at least this amount to 918,631.

---

[8] 88 FR 23544.
[9] See 88 FR 3998. We note that the Department fails to actually provide explicit citation of this ICR request, creating a burden to public comment by obscuring the origin of its data.
[10] 88 FR 23544.
[11] Statista, "Number of Reported Forcible Rape Cases in the United States from 1990 to 2021," 2023. https://www.statista.com/statistics/191137/reported-forcible-rape-cases-in-the-usa-since-1990/.

Using the Department's estimate for cost-per-attestation, this would make the cost of attestations increase from $67,831,396 to:

$$918{,}631\ attestations * 1\ hour/attestation * \$87.60/hour = \$80{,}472{,}075.60.$$[12]

However, as we demonstrated in I.A, the Department's cost estimate lacks a major component of cost, namely, verification. Therefore the cost of attestations to recipients would also have to add:

$$918{,}631\ attestations * (\$142.34/hr\ * 1\ hr + \$87.60/hr * 1\ hr) = \$211{,}230{,}012.14.$$

This would bring the total cost to the sum of these two numbers:

$$\$80{,}472{,}075.60 + \$211{,}230{,}012.14 = \$291{,}702{,}087.74.$$

This sum is over 430% of the estimate given by the Department and would represent a multi-billion dollar undiscounted cost over a five-year period. Neglect of a cost of this size, $223.87 million dollars greater than the Department's estimate, is a clear sign of a failure to sufficiently consider cost in the proposed rule.

C. The Department Grossly Underestimates the Cost of Mailing Updates.

The Department claims that the labor for an administrative support staff member to complete NPP mailings will be 0.25/60 hours, that is, 0.25 minutes or 15 seconds.[13] This estimate is nowhere justified in the proposal, and indeed, the Department does not even explain the math for the public simply saying that it will be "62,500 hours" of labor performed on behalf of 15,000,000 mailers.[14] We do not know how the Department came to this number or why it should be considered reasonable. This alone makes the Department's estimate arbitrary and capricious, but, even worse, the estimate itself is wholly unreasonable.

First of all, the Department does not include any additional time to write letters accompanying these mailers, which (presumably) should at least explain the NPP in plain language, lest the rule seem either to contradict overall state-based abortion bans or restrictions or otherwise problematically confuse recipients. Outside of the context of a website, the updated NPP will not be obviously an expansion of privacy, and therefore will require a letter explaining the changes. Thus, the Department should add onto its time another half-hour of work for a health care professional and a lawyer for each entity, with a cost of:

$$774{,}331 * (\$142.34/hr\ * 1/2\ hr + \$87.60/hr * 1/2\ hr) = \$89{,}024{,}835.07$$

Thus, nearly $90 million in likely costs is completely unaccounted for.

---

[12] 88 FR 23544.
[13] 88 FR 23545, Table 6.
[14] 88 FR 23545, "D. Costs Arising From Changes to the Notice of Privacy Practices."

On the time of mailing itself, the Department provides no justification for a 15-second time for each one. Indeed, printing the documents would have as much as 90 seconds of fixed time costs (10 seconds to open each document in a word processor, 5 seconds to initiate each print job, 15 seconds to verify the printer settings, 15 seconds to verify the number of copies needed for each document and print each document, and 15 seconds to authorize the print job) for just one copy, and 10 seconds for each additional copy (assuming averages for an inkjet printer of 5 seconds per document for two documents, based on a document length of one and three pages, respectively, plus half a second total to staple the three pages). Based on the fact that we have 774,331 regulated entities printing 15,000,000 mailers, a reasonable assumption is 20 copies per entity ($15{,}000{,}000/774{,}331 = 20$ rounded to the nearest mailer), i.e., $90 + 20 * 10.5 = 300$ seconds or five minutes to print the average number of mailers per regulated entity, or an average per-mailer time cost of 15 seconds. Thus, the simple time for printing has already accounted for the entirety of the Department's estimate. This is not reasonable; the Department must also include additional mailing costs since these mailers are not included in annual mailings (per the Department's own RIA). The mailers could require a larger envelope or even be necessarily separate from the normal mailers, such that they must be paid for by a credit card or mailed from a post office facility. In all, each regulated entity would likely have to spend an additional 15 minutes for its set of 20 mailers: 5 seconds to fold each document (100 seconds for a single set of documents, 200 seconds total), 5 seconds to place both in an envelope (100 seconds), 5 seconds to seal each (100 seconds), 10 seconds to calculate and apply proper postage (200 seconds), and a total of 5 minutes to walk to and drop off in an appropriate business services venue. This means that, per mailer, this cost is 45 seconds ($15\ minutes * 60\ seconds\ per\ minute\ /\ 20\ mailers = 45\ seconds\ per\ mailer$) plus the 15 seconds for printing, i.e., one full minute per mailer. The total cost, between printing and mailing, for each entity, on average, would be 20 minutes. Thus the total hours spent by each of the 774,331 entities to mail their 20 mailers would be:

$$\frac{20}{60} hours\ per\ entity * 774{,}331\ entities = 258{,}110.33\ hours.$$

This would in turn lead to a dollar-denominated cost of:

$$258{,}110.33\ hours * \$41.76/hour = \$10{,}778{,}687.52,$$

which, when added to the amount to write the accompanying letter, is:

$$\$89{,}024{,}835.07 + \$10{,}778{,}687.52 = \$99{,}803{,}522.59$$

An amount thirty-eight times more than the $2.61 million that the Department originally estimated for the mailing cost. This far more reasonable estimate reflects the potentially high and arduous costs that the rule would impose, and likewise shows the extent to which the Department's estimate was arbitrary and capricious. In particular, having provided no substantive explanation for the 15-second time-cost, the Department does not give the public any reason to believe that it took seriously its obligation to fully consider the costs of rulemaking.

In all, considering all of the costs described above, we estimate that these particular costs of the proposed rule will impose a cost of $391,505,610.33, compared to the $70,441,396 that the Department offers. Thus, the Department underestimates the cost of the proposed rule by $321,064,214.33. Our reasonable and justified estimate yields an undiscounted 5-year cost of $1,957,528,051.65: a difference from the Department's of over $1.6 billion dollars. These costs were easily quantifiable and would necessarily arise by the very nature of the rule; by ignoring them, the Department has shown no serious attempt to pay attention to the downsides of its regulation, in violation of the binding precedents and principles of administrative law and natural justice.

D. The Department Unlawfully Ignores the Costs Imposed on the Health of Women Due to Increased Access to Abortion.

The Department's proposed rule, by design, would increase women's access to abortion. As a result, the number of abortions per annum will be higher if the Department's proposed rule is adopted and enforced. For the analysis derived in this section, we assume that if the proposed rule is adopted no significant decline in services (where legal) will occur.

Joyce (2012) estimated that the number of abortions in the United States could decline by 14.9% if 31 states ban abortion.[15] The Department estimates that 26 states could potentially develop exception requests to submit to the Secretary if this proposed rule were to be adopted.[16] In our analysis we assume a 14.9% decline in abortion nationally due to these same 26 states[17] banning abortion post *Dobbs v. Jackson Women's Health Organization* as a baseline for the number of abortions that would occur if the Department's proposed rule were adopted and no significant decline in services (where legal) would occur.

Many observational studies have found associations between women who have had an abortion and poor mental health outcomes and increase substance abuse. Several studies have found that women with a history of induced abortion are statistically significantly more likely to suffer an episode of Major Depressive Disorder (MDD) than women with no history of induced abortion. Coleman (2011) performed a meta-analysis of the literature on the impact of abortion on women's mental health outcomes and substance abuse and found a pooled odds ratio of 1.37 for MDD for women with history of an abortion.[18]

---

[15] Joyce TJ, Tan R, Zhang Y. Back to the future? Abortion before & after Roe. National Bureau of Economic Research; 2012 Aug 23.
[16] 88 FR 23544.
[17] *See* Elizabeth Nash, Lauren Cross, ''26 States Are Certain or Likely to Ban Abortion Without Roe: Here's Which Ones and Why,'' Guttmacher Institute (published Oct. 28, 2021; updated Apr. 19, 2022; an updated analysis was published on Jan. 10, 2023), https://www.guttmacher.org/article/2021/10/26-states-are-certain-or-likely-ban-abortion-without-roe-heres-which-ones-and-why.
[18] Coleman PK. Abortion and mental health: quantitative synthesis and analysis of research published 1995–2009. The British Journal of Psychiatry. 2011 Sep;199(3):180-6.

The population prevalence of major depressive episodes by age and sex were estimated using summary statistics from the Substance Abuse and Mental Health Services Administration (SAMHSA)[19] and population projections from the United Nations Department of Economic and Social Affairs, Population Division.[20] We estimated the number of women with a history of abortion from age-specific population rates provided in Jones (2017),[21] using population projection data from the U.N. Population Division to compute population-level estimates. Effect sizes due to abortion bans from the 26 states were approximated using American Community Survey (2021, 1-year estimates) microdata for the resident population by state, age, and sex.

If we assume that the proposed rule, if adopted, would successfully prevent all out-of-state effects on legal access to abortion then the number of women who suffer from at least one major depressive episode as a direct result of the Department's proposed rule due to a higher level of abortion access over the next 10 years (2024-2034) is shown in Table 1 (below). Over the next 10 years, the Department's proposed rule could cause 23,046 women to suffer a major depressive episode who otherwise would not if the proposed rule were not adopted.

Using the estimated average incremental direct cost of a case of MDD as found by Greenberg (2021), we can estimate the economic costs that would be incurred as a result of an increase in the prevalence of MDD due to abortion as a result of the Department's proposed rule as shown in Table 2. We estimate that the Department's proposed rule would add approximately $150 million (in constant 2020 US$) in direct costs associated with increases in MDD prevalence over the next 10 years (2024-2034).

Studies have similarly found that women with history of an induced abortion are significantly associated with greater alcohol abuse, higher prevalence of anxiety, and have a greater risk of attempting suicide or suffering from self-inflicted harm.[22] The Department could and should perform similar evaluation of costs to assess the toll on women's health and the economic costs the Department's proposed rule would have a result of more secure access to abortion.

[19] National Institute of Mental Health (citing data from Substance Abuse and Mental Health Services Administration). Major depression [Internet]. [last updated 2022 Jan]. Available from: https://www.nimh.nih.gov/health/statistics/major-depression.
[20] United Nations, Department of Economic and Social Affairs, Population Division (2022). World Population Prospects 2022, Online Edition.
[21] Jones RK, Jerman J. Population group abortion rates and lifetime incidence of abortion: United States, 2008–2014. American journal of public health. 2022 Sep;112(9):1284-96.
[22] Coleman PK. Abortion and mental health: quantitative synthesis and analysis of research published 1995–2009. The British Journal of Psychiatry. 2011 Sep;199(3):180-6.

Table 1. Impact of the Proposed Rule: The Number of Additional Women that Would Suffer from a Major Depressive Episode as a Result of a Previous Abortion

Year	Prevalence of Major Depressive Episodes
2024	377
2025	737
2026	1,085
2027	1,425
2028	1,762
2029	2,102
2030	2,444
2031	2,781
2032	3,115
2033	3,446
2034	3,772
Total	23,046

Table 2. Impact of the Proposed Rule: Economic Cost Due to the Increased Number of Women that Would Suffer from a Major Depressive Episode as a Result of Previous Abortion

Year	Direct Costs Related to Major Depressive Disorder due to Proposed Rule (in constant 2020 US$)
2024	$2,459,548
2025	$4,808,188
2026	$7,078,540
2027	$9,296,700
2028	$11,495,288
2029	$13,713,448
2030	$15,944,656
2031	$18,143,244
2032	$20,322,260
2033	$22,481,704
2034	$24,608,528
Total	$150,352,104

Thus, the Department's total ignored costs for the five-year window can be raised by the $23,642,976 in costs through 2027, to a total of $1,981,171,027.65.

III. The Department Ignores Several Non-Quantifiable Costs of the Proposed Rule

A. The Proposed Rule Would Impose a Chilling Effect on Covered Health Care Providers' Disclosure of Information for the Purposes of Criminal, Civil, and Administrative Investigations and Proceedings.

It appears that the Department is seeking to prohibit the disclosure of PHI for reproductive health care for the purposes of criminal, civil, and administrative investigations and proceedings primarily aimed at "investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care."[23] However, the proposed rule, as it is currently written, would impose a chilling effect on covered health care providers' willingness to cooperate with criminal investigations and judicial proceedings seeking

[23] 88 FR 23553.

to bring justice to victims of rape, incest, sex trafficking, domestic violence, abuse, and neglect if such victims in any way seek, express interest in, obtain, use, or pay for reproductive health care services.

For one, the lack of clarity in the Department's standard of interpretation for prohibited reproductive health care PHI disclosures in the proposed §164.502(a)(5)(iii)(A) and §164.502(a)(5)(iii)(D) as described above in Section I of this part of this written comment would inevitably impose a chilling effect on covered health care providers. Indeed, §164.502(a)(5)(iii)(A) appears to prohibit health care providers from providing any PHI for any criminal investigation or judicial proceedings that are connected to reproductive health services in any way. If health care providers do not have clarity in what reproductive health care PHI they can provide and in what contexts they are permitted to provide them, health care providers may simply choose the course of action which is least likely to impose a liability on them—namely, they would likely choose not to provide any PHI that pertains to reproductive health care for the purposes of any criminal investigation or judicial proceeding, regardless of the matter being adjudicated.

Furthermore, the proposed rule, as it is currently written, gives the impression that the Department is significantly limiting the disclosure of reproductive health care PHI for the purposes of conducting criminal investigations and judicial proceedings concerning victims of abuse, neglect, or domestic violence.

For one, the Department's proposed preamble to 45 CFR § 164.512 explicitly excludes reproductive health care PHI per § 164.502(a)(5)(iii) from the permitted disclosures for which authorization is not required, including for the purposes of law enforcement and judicial and administrative proceedings. At § 164.512(c), the Department is proposing to explicitly prohibit reproductive health care PHI disclosures for the purposes of conducting criminal investigations and judicial proceedings concerning victims of abuse, neglect, or domestic violence "when the report of abuse, neglect, or domestic violence is based primarily on the provision of reproductive health care."[24]

Secondly, the Department is proposing to amend § 164.502(g)(5) which permits health care providers to not treat a person as the personal representative of a patient if the health care provider has reason to believe that the patient may be subjected to domestic violence, neglect, or abuse by that person or if treated that person as the patient's personal representative could endanger the patient.[25] In the proposed rule, the Department is proposing to remove this privilege for health care providers if "the primary basis for the covered entity's belief is the facilitation or provision of reproductive health care."[26]

---

[24] 88 FR 23553.
[25] 45 CFR § 164.502(g)(5)
[26] 88 FR 23553.

Both of these changes to the current regulations governing PHI disclosures (neither of which are particularly clear in their definition or scope) subject disclosure of reproductive PHI to a higher level of scrutiny than non-reproductive health care PHI. This inevitably imposes a chilling effect on covered health care providers' willingness to cooperate with investigations and judicial proceedings concerning patients who may have utilized reproductive health services, regardless of the matter being adjudicated.

Furthermore, under the Department's proposed §164.509, covered health care providers would only be permitted to disclose protected health information in cooperation with a criminal investigation or judicial proceedings if they receive from the requestor a strictly constructed attestation that such disclosure is not "primarily for the purpose of investigating or imposing liability on any person for…seeking, obtaining, providing, or facilitating reproductive health care."[27] It is worth noting that the attestation procedure the Department is seeking to introduce at §164.509 would only apply to reproductive health care PHI, not to any other PHI. Thus, the Department's proposed rule would introduce special heightened restrictions on the disclosure of reproductive health care PHI not required for any other kind of PHI. Under §164.509, law enforcement and judicial and administrative requestors of reproductive health PHI would be required to file a strictly constructed, narrowly defined attestation that affirms that PHI will not be used "for a purpose prohibited under §164.502(a)(5)(iii)."[28] Such an attestation is required to include the required elements list in §164.509(c). And such attestation would become invalid if the attestation "contains an element or statement not required by [§164.509(c)],"[29] or if the attestation is combined with any other document.[30] This overly and unnecessarily strict protocol for obtaining PHI disclosures for purposes of law enforcement investigations or judicial and administrative proceedings that are not required for obtaining any other kind of PHI for the same purposes would impose a chilling effect on procuring and obtaining necessary fact-finding evidence in the course of criminal, civil, and administrative investigations and proceedings for which reproductive health care PHI could be helpful, particularly in investigations and proceedings pursuing justice for victims of rape, incest, sex trafficking, domestic violence, abuse, and neglect.

B. The Department Unlawfully Ignores Costs to Women Coerced into Procuring an Abortion.

The Department's proposed rule would make it significantly more difficult for law enforcement and the court system to investigate and prosecute criminals who perpetrate sex crimes and other criminal activity such as (but not limited to), rape, incest, sex trafficking, domestic violence against women, abuse, neglect, and violence with the intent of causing a

[27] 88 FR 23553.
[28] 88 FR 23553.
[29] 88 FR 23553.
[30] Proposed 45 CFR § 164.502(b)(3).

woman to miscarry a pregnancy. Victims of these crimes often are forced or coerced into seeking what the Department is defining as reproductive health care. It is not uncommon for victims of rape or incest to seek out abortion in circumstances where the perpetrator of the crime has decision power over the victim. There are reports in the United States that victims of sex trafficking have been forced into seeking abortion from covered health care providers whilst being coerced into hiding their status as victims of sex trafficking.[31]

The Department's proposed rule would, by design, set up barriers to the procurement of public health information necessary to conduct criminal investigations if such public health information has any "connection with seeking, obtaining, providing, or facilitating reproductive health care."[32] Such barriers, as described in Section I.E of this comment, could impose a chilling effect on the health care providers' willingness to cooperate in a criminal, civil, or administrative investigation or judicial proceeding where reproductive health care PHI is requested to aid in the investigation or proceeding of crimes such as those described in the preceding paragraph.

IV. The Department Unreasonably Overestimates the Benefits of the Proposed Rule

A. The Department's Estimate of the Number of Individuals Affected Is Unreasonable.

The Department claims that the number of individuals "potentially affected by the proposed rule" is 74 million.[33] It derives this number from a simple sum of the number of females aged 10-44 in the United States. First of all, this number is not even a reasonable evaluation of the number affected by the Department's own logic. In this very section of the NPRM, the Department notes that "78 percent of sexually active females" either obtained abortion or accessed reproductive health care in a given period of time.[34] Given this figure, it is not clear why the Department believes that all women benefit rather than the proportion who are sexually active and access the relevant procedures and services. At the very least, the Department should by its own logic reduce this number by 78 percent to calculate the number impacted, to arrive at 57.72 million.

---

[31] Micaiah Bilger. "Sex Trafficking Victims Often Forced by Their Abusers to Have Multiple Abortions, One Had 17," LifeNews (May 23, 2016), https://www.lifenews.com/2016/05/23/sex-trafficking-victims-often-forced-by-their-abusers-to-have-multiple-abortions-one-had-17/.
[32] 88 FR 23552.
[33] 88 FR 23543-23544.
[34] Ibid.

Even this number, however, is an overestimate. HIPAA protections on the whole may be considered a benefit to all people who access health care in the United States. However, this proposal cannot claim to obtain all of the benefits of HIPAA; that is, the proposed rule in reality affects only those who are subject to certain laws, legal investigations, and possible invasions of privacy. As it stands, that number is incredibly small: the Texas law, for example, has had very few examples, with only two cases being seriously considered in high courts.[35] Thus, a reasonable estimate of the number of people benefitted by this rule could be in the hundreds.

A generous estimate would be of the number of women in Texas, South Carolina, and Oklahoma (the only states with laws preempted by this rule) who have or will access abortion or abortifacients after the *Dobbs* case. Or, to be even more generous to the Department, the number who might reasonably be affected by such laws in the future. According to The New York Times, the number of women from the 13 states with abortion bans who traveled across state lines to have an abortion after *Dobbs* was, at most, 2,100 per month.[36] Thus, a reasonable estimate would be to double this number to account for the fact that the Department believes that at most 26 states will attempt to affect such rules. Per year, this means that the rule would affect 50,400 women per year. This, then, is a much more reasonable estimate of the number of individuals the rule would benefit: a number over 1,400 times smaller than the number given by the Department at just 0.068 percent of 74,000,000. Even if we assume that every single one of these women obtains an abortion exactly once, such that the 50,400 are different women each year, this would still be 1,713,600 women over the course of the relevant age range—just 2.3 percent of the 74 million (over 43 times smaller than said number).[37] To overestimate the potential number of women affected by the rule to this large an extent once again shows that the Department did not reasonably consider the costs and benefits of the proposed rule.

B: The Department's List of Benefits Is Not Reasonable

The Department claims that the proposed rule would result in several non-quantifiable benefits which, in reality, either will not materialize or will occur only to a paltry extent.

The Department claims, for example, that the proposed rule would "contribute to increased access to prenatal health care at the critical early stages of pregnancy by affording individuals the assurance that they may obtain reproductive health care without fearing that

---

[35] See Eleanor Klibanoff, "Texas state court throws out lawsuit against doctor who violated abortion law," The Texas Tribune, Dec. 8, 2022, https://www.texastribune.org/2022/12/08/texas-abortion-provider-lawsuit/, and "Three Texas women are sued for wrongful death after allegedly helping friend obtain abortion medication," The Texas Tribune, March 10, 2023, https://www.texastribune.org/2023/03/10/texas-abortion-lawsuit/.

[36] Margot Sanger-Katz and Claire Cain-Miller, "Legal Abortions Fell By Six Percent in the Six Months After Dobbs, New Data Shows," https://www.nytimes.com/2023/04/12/upshot/legal-abortions-fell-dobbs.html.

[37] Of course, this would not be a sensible way of calculating the number, since some women get abortions more than once, and since as a general rule rules should not project the number of people affected indefinitely, but instead consider the number of people expected to be affected in a given year as opposed to those over a lifetime.

records related to that care would be subject to disclosure."[38] This claim is ridiculous: there is no form of "prenatal care" targeted by any of the state laws in question or by any foreseeable law of the sort addressed by the proposed rule. The only procedure practically affected by the proposed rule is abortion, which can in no reasonable way be said to benefit "prenatal health," since its entire purpose is the termination of pregnancy, i.e., prenatal death.

Further, the Department also claims that the proposed rule would benefit health care continuity, because:

> "If a health care provider believes that the patient's PHI is likely to be disclosed without the patient's or the health care provider's knowledge or consent, possibly to initiate or be used in criminal or civil proceedings against the patient, their health care provider, or others, the health care provider is more likely to omit information about a patient's medical history or condition, or leave gaps or include inaccuracies, when preparing patient medical records."[39]

First, this "benefit" comes with a massive associated cost, namely, tacitly blessing medical misconduct. Medical professionals are required to do their jobs for the sake of the health of the patients; it is a violation of basic medical ethics for doctors to attempt to hide patient medical information in order to try to skirt the law. There is thus no benefit to doctors who practice medicine according to ethical and lawful conduct. The fact that the Department even mentions this as if it were normal or understandable behavior is unreasonable and morally hazardous. Regulations should not be designed to cater to the behavior of lawbreakers. And, contrary to the principles of administrative law, at no point does the Department suggest an alternative method of achieving this benefit, such as penalties for falsification or personal censorship of medical records by doctors or other health care workers.

Even more importantly, however, it is not clear that this rule will result in the claimed benefit. The Department does not cite any sources that there is such discontinuity occurring at any appreciable scale. This benefit, taken as a concrete material betterment of recipients or their patients, will only accrue if there is significant lack of continuity occurring; the psychological well-being of doctors and health care workers is not the same thing as the material benefit of continuity, which will only exist if there is widespread discontinuity currently. We have no evidence of this, and so the benefit is not reasonably expected in our estimation.

Overstating these benefits of the proposal calls into question the Department's claim that the rule's costs are outweighed by its benefits. Ultimately, the Department has not shown that the benefits listed outweigh the true costs of the proposed rule. It has certainly not shown that the greatly reduced benefits as described in this section of our comment can justify such costs. More importantly, however, the unreasonable inflation of benefits and unreasonable underestimation or neglect of several costs—in the amount of billions of dollars over the forecast

[38] 88 FR 23546.
[39] 88 FR 23547.

window—shows that the Department did not undertake the consideration of "the advantages *and* the disadvantages of agency decisions" required by administrative law.[40] The Department has not shown that it is interested in taking the costs and benefits of its regulation seriously, acting in an arbitrary and capricious manner.

For all of the reasons detailed above, we urge the U.S. Department of Health and Human Services not to go forward with the proposed rule.

Respectfully submitted,

Benjamin Rioja Paris
Policy Analyst, Regulatory Policy
Thomas A. Roe Institute for Economic Policy Studies
The Heritage Foundation

Jonathan Abbamonte
Senior Research Associate
Center for Data Analysis
The Heritage Foundation.[41]

[40] *Michigan v. EPA*, 752-53.
[41] Affiliation and titles provided for identification purposes only. We submit this comment in our personal capacities only and not as employees of The Heritage Foundation.