

June 15th, 2023

Via Electronic Mail

Department of Health and Human Services
Office for Civil Rights
Attention: RIN 0945-AA20
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on NPRM - Health Insurance Portability and Accountability Act Privacy Rule to Support Reproductive Health Care Privacy (RIN 0945-AA20)

Dear Director Fontes Rainer,

On behalf of the Future of Privacy Forum (FPF), we are pleased to provide comments and recommendations to the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) regarding the Notice of Proposed Rulemaking (NPRM) on extending additional protections to reproductive health care data under the Health Insurance Portability and Accountability Act (HIPAA).¹ As recognized by the Biden administration, privacy is particularly important in the context of reproductive health care.² The NPRM presents an opportunity to enhance the protections afforded to sensitive reproductive health care information (RHCI) under HIPAA, and align HHS OCR policy with the practices of other regulatory entities such as the Federal Trade Commission (FTC).

FPF is a non-profit organization focused on advancing responsible data practices and fostering a privacy-conscious environment in the digital era.³ As an organization dedicated to privacy and data protection, we have developed significant expertise in this space. We know that privacy is foundational to trust in patient-provider interactions and ongoing care, and even more so in evolving digital spaces and technologies.⁴

¹ 88 Fed. Reg. 23506 (Apr. 17, 2023),

<https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-to-support-reproductive-health-care-privacy>.

² Joseph R. Biden, “Executive Order on Securing Access to Reproductive and Other Healthcare Services,” The White House (Aug. 23, 2022),

<https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/>; See also, Future of Privacy Forum, “FPF Statement On U.S. Supreme Court’s Decision To Overturn Roe v. Wade” (June 24, 2022),

<https://fpf.org/blog/fpf-statement-on-u-s-supreme-courts-decision-to-overturn-roe-v-wade/>.

³ The views expressed in this comment are those of FPF and do not necessarily represent the opinions of our supporters or Advisory Board.

⁴ Billie Murray & Susan McCrone, *An integrative review of promoting trust in the patient-primary care provider relationship*, 71 J. Adv. Nurs. 3 (2015), <https://pubmed.ncbi.nlm.nih.gov/25113235/>; Paige Nong, et al., *Discrimination, trust, and withholding information from providers: Implications for missing data and*

Accordingly, we recommend that HHS bolster privacy safeguards and support the responsible handling of RHCI by specifically:

- Ensuring that covered entities are aware of and responsible for information that, directly or indirectly, can reveal data about individuals seeking or receiving reproductive health care;
- Providing additional guidance and resources to address the information privacy responsibilities of covered entities for their business associates and vendors;
- Distributing privacy education and guidance materials to covered entities and partners on data privacy transparency;
- Conducting regulatory analysis and providing compliance support for small clinics and rural/remote providers facing increased legal requests for reproductive and related health information;
- Addressing privacy protections for reproductive health care data collected and generated during and as a part of clinical research.

I. **BACKGROUND**

A. **REPRODUCTIVE HEALTH CARE INFORMATION REQUIRES PROTECTION, INCLUDING DIRECTLY OR INDIRECTLY INFERRED INFORMATION**

The Supreme Court's 2021 decision in *Dobbs v. Jackson Women's Health Organization* ("Dobbs")⁵ underscores the importance of providing additional protections for RHCI.⁶ Reproductive choices are among the most impactful life decisions and are recognized as a key aspect of decisional privacy.⁷ The risks of the revelation of reproductive health care seeking, accessing, or provision have increased in the wake of the Supreme Court's decision.

Reproductive health care information can be revealed both directly and indirectly, through inferences from other information that appears to be unrelated to reproductive health on its face. Certain types of information directly reveal a person's reproductive status, such as pregnancy testing and treatment records (including billing records with particular codes related to a procedure or medical condition.) However, other information indirectly reveals reproductive health care information through inferences, especially since reproductive care implicates a range of health care activities and services that may not seem facially applicable.⁸ For example, financial information related to billing data may enable inferences about reproductive medical

inequity, 18 SSM Popul. Health 101092 (2022), <https://pubmed.ncbi.nlm.nih.gov/35479582/>; Matthew Ridd et al., *The patient–doctor relationship: a synthesis of the qualitative literature on patients' perspectives*, 59 Br. J. Gen. Pract. e116 (2009), <https://pubmed.ncbi.nlm.nih.gov/19341547/>.

⁵ *Dobbs v. Jackson Women's Health Organization*, 597 U.S. ____ (2022).

⁶ Reproductive health care encompasses and implicates an extensive range of health care information including but not limited to contraception, fertility treatments, menopause, and gender health care, as well as laboratory results (ex. hormone levels and urine testing) or radiology reports (ex. pelvic ultrasounds) that are often part of diagnostic testing.

⁷ Danielle Keats Citron and Daniel J. Solove, *Privacy Harms*, 102 B.U.L. Rev 793 (2022).

⁸ See Daniel J. Solove, *Data Is What Data Does: Regulating Use, Harm, and Risk Instead of Sensitive Data*, 118 Nw. U. L. Rev. (forthcoming 2024).

procedures.⁹ The potential for reproductive health status to be indirectly inferred typically increases as different data points are combined, such as purchases for menstrual care products with medication purchase patterns.

B. PRIVACY IS FOUNDATIONAL TO TRUST IN PATIENT-PROVIDER RELATIONSHIPS

Patient privacy protections are a key support in provider-patient relationships, ensuring the healthcare system is trusted, and facilitating accurate information about patient health.¹⁰ Trust in data systems facilitates the organization and disclosure of necessary information for continuity of care across covered entities.¹¹ Therefore, guardrails for digital information disclosures are crucial for establishing and maintaining trust in patient-provider relationships, especially reproductive health care in a post-*Dobbs* landscape. In a national study of 3,539 U.S. adults, respondents' willingness to share digital health information was greatest when conducted with key privacy protections, including transparency.¹² In contrast, patients may be less likely to disclose health information to providers when they are not aware of privacy protections.¹³

C. PROVIDERS OF OBSTETRIC SERVICES IN RURAL AREAS FACE GREATER RISKS AND HAVE FEWER RESOURCES TO PROTECT THE PRIVACY OF PATIENTS SEEKING REPRODUCTIVE CARE

In rural and remote areas of the United States, access to adequate reproductive health care options is often limited, posing significant challenges for both patients and providers. Even prior to *Dobbs*, the increasing disruption or loss of obstetric services in rural areas has had a disproportionate impact on individuals residing in these regions. Between 2000-2014, rural

⁹ *Supra* note 4.

¹⁰ See Neil M. Richards and Woodrow Hartzog, *Taking Trust Seriously in Privacy Law*, 19 Stan. Tech. L. Rev. 431 (2016) (noting that privacy can and should be thought of as enabling trust in our essential information relationships); Akhil Shenoy and Jacob M. Appel, *Safeguarding Confidentiality in Electronic Health Records*, Cambridge Quarterly of Healthcare Ethics (Mar. 31, 2017) (noting that “trust and the therapeutic alliance it generates are central to the provider–patient relationship.”).

¹¹ See Supathiratheavy Rasiah, et al., *A study of the nature and level of trust between patients and healthcare providers, its dimensions and determinants: a scoping review protocol*, BMJ Open (2020), <https://bmjopen.bmj.com/content/bmjopen/10/1/e028061.full.pdf>.

¹² Ravi Gupta, et al., “Consumer Views on Privacy Protections and Sharing of Personal Digital Health Information,” 6 JAMA Netw. Open e231305 (2023), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2801917> (noting that, “[researchers determined] the relative importance of specific privacy protections derived from the fair information practice principles and approaches in other nations, including consent, data transparency, regulatory oversight, and ability to delete previously collected personal data in various uses of digital health data.”).

¹³ *Id.*

counties without obstetric care rose above 50%.¹⁴ Individuals in rural counties are disproportionately affected by the disruption or loss of obstetric services.

The *Dobbs* decision has exacerbated this trend in rural areas, forcing providers to send patients to and patient to seek the nearest health provider or clinic that may provide needed care - in the rural Western US these options may be few and geographically distant and under-resourced. The Supreme Court's decision has worsened this situation by forcing providers to refer patients to health facilities or clinics in neighboring states with reproductive health care protections, which may be few.¹⁵ Patients in these areas face limited options for care access and an increased risk of identification and covered entities will have an increased risk of prohibited disclosures of RHCI, necessitating additional privacy protections. The same clinics and providers may face growing pressure due to requests for reproductive health care information from both law enforcement and private citizens who are motivated to prosecute patients and providers.¹⁶ Smaller and less-resourced clinics also have fewer resources to dedicate to resisting inappropriate law enforcement requests, a fact that exposes their patients to greater privacy risks. Additionally, while some major employers have offered to cover travel costs for employees seeking abortion care outside states with abortion restrictions, this arrangement may create privacy risks for employees who receive health insurance through their employers.¹⁷

D. CLINICAL TRIALS AND RESEARCH COLLECT SUBSTANTIAL REPRODUCTIVE INFORMATION THAT IS AT RISK OF DISCLOSURE, NECESSITATING EXPLICIT PRIVACY SAFEGUARDS

Researchers and support staff for clinical trials collect significant reproductive health data from participants. Even in trials unrelated to reproductive health, participants often disclose their medical histories and undergo pregnancy testing. Although clinical trial information is typically de-identified, there is a possibility of re-identification during emergencies or in cases of

¹⁴ Committee Opinion No. 586, "Health Disparities in Rural Women," Committee on Health Care for Underserved Women, The American College of Obstetricians and Gynecologists (Feb 2014), <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/02/health-disparities-in-rural-women>.

¹⁵ For example, the State of Idaho severely restricts abortion and seeks to restrict travel for reproductive treatment. Idaho residents are most likely to seek treatment in the neighboring states of Washington or Oregon, which have passed protections for reproductive health care. However, reproductive treatment centers, clinics, and providers are few in nearby eastern Oregon and Washington, increasing the potential pressure and high volumes of law enforcement and private citizen requests.

¹⁶ See "Location and Hours," Planned Parenthood of Greater Washington and North Idaho, Accessed June 14, 2023, <https://www.plannedparenthood.org/planned-parenthood-greater-washington-north-idaho/get-care/location-and-hours> (noting that for a substantial portion of the Idaho mid-panhandle region there is only one abortion clinic within a 1-2 hour drive, in a region that includes multiple Idaho colleges and universities with large out-of-state populations where it is likely the clinic will see a large volume of RHCI requests from law enforcement and incentivized private citizens.).

¹⁷ Jheel Gosain, et al., *Dobbs In A Technologized World: Implications For US Data Privacy*, Data Sharing in Health Sciences and Law (Springer, forthcoming 2023).

significant adverse events.¹⁸ Non-covered entities involved in trial recruitment may retain reproductive health information protected by HIPAA.¹⁹

Certificates of Confidentiality (CoCs), which are standard in many studies and particularly those funded by the National Institutes of Health (NIH), provide some protection for researchers and participants. CoCs have been subject only to limited legal scrutiny, however, and their efficacy as privacy-preserving devices could be tested in future proceedings.²⁰ The erosion of trust in privacy during research would be particularly harmful to women and uterine or ovarian reproductive health research, which is still emerging as a focus in clinical trial research since the 1970s and officially when Congress wrote the NIH inclusion policy into federal law through a section in the NIH Revitalization Act of 1993.²¹ Without adequate privacy protections, representation in clinical research may stagnate or decrease.²²

II. **RECOMMENDATIONS**

A. ENSURE THAT COVERED ENTITIES ARE AWARE OF AND RESPONSIBLE FOR INFORMATION THAT, DIRECTLY OR INDIRECTLY, CAN REVEAL SEEKING OR RECEIVING REPRODUCTIVE HEALTH CARE

To adequately protect individuals and provide clarity for healthcare entities, HHS should ensure that covered entities are fully aware of and responsible for both direct and indirect information that reveals reproductive health care information. This can be achieved by interpreting the

¹⁸ *Recommendations for pregnancy testing in clinical trials*, Clinical Trials Transformation Initiative (Aug. 2017), https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Pregnancy_Testing_Recs.pdf.

¹⁹ See, e.g., “Walgreens Launches Clinical Trial Business to Address Industrywide Access and Diversity Challenges and Redefine Patient Experience,” Walgreens (June 16, 2022), <https://news.walgreens.com/press-center/walgreens-launches-clinical-trial-business-to-address-industrywide-access-and-diversity-challenges-and-redefine-patient-experience.htm>;

“Walmart’s Healthcare Research Institute Launches with Mission to Improve Care for Underserved Communities through Research,” Walmart (Oct. 11, 2022), <https://corporate.walmart.com/newsroom/2022/10/11/walmarts-healthcare-research-institute-launches-with-mission-to-improve-care-for-underserved-communities-through-research>;

Amazon Web Services, “Modernizing Clinical Trials: Digital Technologies and the Cloud,” FiercePharma, Accessed June 12, 2023, https://d1.awsstatic.com/Industries/HCLS/AWS_ClinicalTrials_Whitepaper_Final.pdf.

²⁰ See *People v. Newman*, N.Y.2d 379 (N.Y. 1973) (noting that “judicial control over the confidentiality of patients’ records in the program is established.”).

²¹ NIH Revitalization Act, Pub. L. No. 103-43, 107 Stat. 122 (1993)(noting that even today, underrepresentation of women in clinical trials remains a serious obstacle for medical research.).

²² For more information on the impact of confidentiality on participation in clinical trials, see, e.g., Michelle M. Mello, et al., “Clinical Trial Participants’ Views of the Risks and Benefits of Data Sharing,” *N. Eng. J. Med.* (June 7, 2018), <https://pubmed.ncbi.nlm.nih.gov/29874542/>; Research!America, “Poll: Majority of Americans would participate in clinical trials if recommended by doctor,” Elsevier Connect (July 31, 2013), <https://www.elsevier.com/connect/poll-majority-of-americans-would-participate-in-clinical-trials-if-recommended-by-doctor>.

definition of "reproductive health care" broadly and inclusively, providing a non-exhaustive list of examples of prohibited disclosures, and developing model attestations with key information.

- Define "Reproductive Health Care" Broadly

The rule should define "reproductive health care" inclusively, with the term applying to all reproductive care information held, including data that may only indirectly reveal reproductive status. The proposed definition of "reproductive health care" in the NPRM is "care, services, or supplies related to the reproductive health of the individual."²³ The NPRM further states HHS's intention for reproductive health care to be interpreted "broadly and inclusive of all types of health care related to an individual's reproductive system."²⁴ A broad definition of reproductive healthcare best protects against the disclosure of intimate information.²⁵ Applying this broad definition also safeguards information received through developing and experimental services and treatments, preserving trust in medical research. Furthermore, a broad definition allows providers to assess and reject requests for indirectly related information that could reveal reproductive health, protecting unaware patients.

- Advise Covered Entities on the Scope of Reproductive Health Care Information

FPF recommends that HHS OCR provide a non-exhaustive list of examples of immediately apparent reproductive health care information and indirect information that would be prohibited from disclosure under the proposed rule as revelatory of reproductive care.²⁶ This clarity will assist covered entities in identifying and protecting RHCI effectively. In particular, greater clarity will empower small, rural, and under-resourced health providers to more efficiently counter requests from law enforcement.

- Publish Model Attestations that Include Specific Information

As part of the NPRM, HHS OCR is considering creating a model template for reproductive health care information requests.²⁷ We support the publication of model attestation(s), which align with existing PHI request and disclosure systems and would help bring greater clarity and guidance for covered entities, particularly smaller and rural health care providers. Such attestations would

²³ *Supra* note 1 at 23527.

²⁴ *Id.*

²⁵ *Supra* note 7.

²⁶ Examples for this list include: International Classification of Diseases (ICD) codes related to reproductive health, ABO blood type and Rh factor (indicative of ABO fetus incompatibility, which could provide evidence of spontaneous abortion or miscarriage), dates, times, and places of treatments (patient and provider visit metadata), and the type of injury (also potentially indicative of spontaneous abortion or miscarriage); See also Erica Remer, "The Medicine and ICD-10 Coding of Abortion," MedLearn Publishing (May 23, 2022), <https://medlearn.com/the-medicine-and-icd-10-coding-of-abortion/>; J. Glenn Lauritsen, et al., *Materno-fetal ABO incompatibility as a cause of spontaneous abortion*, *Clinical Genetics* (1975), 7 (4): 308-316, available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1399-0004.1975.tb00334.x?sid=nlm%3Apubmed>.

²⁷ *Supra* note 1 at 23536.

help to restrict “the use and disclosure of PHI that could harm HIPAA’s overall goals of increasing trust in the health care system.”²⁸

As part of a model attestation, there should be an acknowledgment of variations in specificity between requestors (ex. law enforcement versus private requests) as well as the jurisdictional origin of the request. HHS OCR should also specify key information to be included in attestations that may help covered entities more easily identify investigations of reproductive health care, including the offense or criminal code for the underlying charge and offense or criminal code category of the charge. A reference to specific criminal codes can help a covered entity avoid undesired disclosures at scale, especially because not all investigations may appear to be related to pregnancy or reproductive health on their face. Examples of investigations that may lead to unintended prohibited disclosures may include but are not limited to, missing person cases, negligence, and improper disposal of remains.²⁹

B. PROVIDE ADDITIONAL GUIDANCE AND RESOURCES TO ADDRESS THE INFORMATION PRIVACY RESPONSIBILITIES OF COVERED ENTITIES FOR THEIR BUSINESS ASSOCIATES AND VENDORS

FPF recommends that HHS OCR provide additional guidance and resources to address the responsibilities of covered entities regarding business associates (BAs) and other vendors that collect, manage, and use patient data.³⁰ Today, HIPAA-covered entities process a large volume of digital patient data due to the increasing use of healthcare-supportive technologies. In most cases, technology vendors supporting care would also be considered covered entities as Business Associates (BAs) and enter into Business Associate Agreements (BAAs) that provide contractual obligations for the management and use of collected patient data. However, not all technology vendors that support care are BAs, as they may not collect, handle, or process data that falls under the definition of PHI.³¹ Nonetheless, this information, whether directly reported by a patient via care support technologies (ex. to receive beneficial discounts) or indirectly inferred from unobvious PHI (ex. website tracking technologies) may indicate reproductive health seeking,

²⁸ *Supra* note 1 at 23522.

²⁹ See Sara O’Brien and Clare Duffy, “Nebraska teen and mother facing charges in abortion-related case that involved obtaining their Facebook messages,” CNN Business (Aug. 10, 2022), <https://www.cnn.com/2022/08/10/tech/teen-charged-abortion-facebook-messages/index.html> (noting that in an investigation of improper disposal of remains, a Nebraska teen and her mother’s digital messages were requested by law enforcement in an investigation of the Nebraska teen’s delivery of a stillborn fetus. Based on the reproductive health information revealed in Facebook messages, the teen and mother were later also charged with abortion and aiding abortion, as well as improper disposal of remains.).

³⁰ See 42 U.S.C. § 17934 (2009).

³¹ 45 CFR § 160.103.

access, or provision.³² Greater guidance and clarity from HHS OCR will help ensure that reproductive health privacy protections extend throughout the entire ecosystem of care support technologies and services.

C. DISTRIBUTE PRIVACY EDUCATION AND GUIDANCE MATERIALS TO COVERED ENTITIES AND PARTNERS ON DATA PRIVACY TRANSPARENCY

FPF recommends HHS OCR collaborate with other agencies to generate and distribute privacy guidance materials to covered entities and partners, focusing on best practices for managing technology partnerships that require sharing of reproductive health information to support continuity and transparency of care. Collaborative efforts with agencies like the FTC and the FDA should be pursued and structured to continue the facilitation of information portability for reproductive care. These collaborations should focus on producing guidance materials for both HIPAA-covered entities and non-HIPAA health technology vendors who may partner with covered entities.

For example, best practices for incorporating RHCI privacy requirements into contracts and data use agreements will aid covered entities and technology vendors in ensuring comprehensive privacy protections throughout the ecosystem of care support technologies and services. By providing clear guidance and reinforcing privacy safeguards, trust can be fostered and individuals' autonomy over their reproductive health choices can be respected.

D. CONDUCT REGULATORY ANALYSIS AND PROVIDE COMPLIANCE SUPPORT FOR SMALL CLINICS AND RURAL/REMOTE PROVIDERS FACING INCREASED LEGAL REQUESTS FOR REPRODUCTIVE AND RELATED HEALTH INFORMATION

HHS OCR should conduct additional regulatory analysis to fully understand the regulatory impacts on rural or remote clinics and provide targeted guidance and compliance support. In addition to small providers having fewer resources (as explored in the NPRM), rural and remote clinics in abortion-protective states may experience higher volumes of patients and requests. By conducting further analysis, the HHS OCR can provide targeted guidance and support to these clinics, providers, and associated covered entities, helping them navigate compliance challenges and mitigate the increased risk of prohibited disclosures and breaches under the proposed rule.

In addition to the compliance support and clarity discussed above (Parts II.A-B), additional compliance support for rural and remote clinics could include tailored training for clinical staff, a

³² See Ari B. Friedman, et al., *Widespread Third-Party Tracking On Hospital Websites Poses Privacy Risks For Patients And Legal Liability For Hospitals*, Health Affairs (Apr. 2023), <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.01205?journalCode=hlthaff>; Stephanie O'Neill, "As Insurers Offer Discounts For Fitness Trackers, Wearers Should Step With Caution," NPR (Nov. 19, 2018), <https://www.npr.org/sections/health-shots/2018/11/19/668266197/as-insurers-offer-discounts-for-fitness-trackers-wearers-should-step-with-caution>; Bernard Marr, "This Health Insurance Company Tracks Customers' Exercise and Eating Habits Using Big Data and IoT," Forbes (May 27, 2019), <https://www.forbes.com/sites/bernardmarr/2019/05/27/this-health-insurance-company-tracks-customers-exercise-and-eating-habits-using-big-data-and-iot/?sh=7424014a6ef3>.

dedicated series of webpages for rural covered entities, and a collection of references for further information provided by the HHS OCR.³³

E. ADDRESS PRIVACY PROTECTIONS FOR REPRODUCTIVE HEALTH CARE DATA COLLECTED AND GENERATED DURING AND AS PART OF CLINICAL RESEARCH

Finally, we urge the HHS OCR to clarify and update the privacy protections afforded to reproductive health data obtained in clinical research settings. This encompasses data pertaining to pregnancy, fertility, contraception, and other RHCI collected by researchers as part of standard safety procedures. Additional guidance should emphasize the significance of obtaining informed consent specifically for the collection and use of RHCI, ensuring that participants have a complete understanding of how their data will be utilized and the risks of re-identification. Additionally, HHS OCR should outline best practices for data anonymization and de-identification to minimize the risk of re-identification and uphold participant privacy.

To the extent this information is held by HIPAA-covered entities or the information retains HIPAA protections HHS should clarify that that information is covered by this rulemaking. In other cases, HHS may need to re-coordinate with other agencies, including NIH and the FDA on if and to what extent the scope of COCs needs to be revisited. By extending enhanced safeguards to clinical trials, HHS can foster clinical research by ensuring privacy protections for researchers and participants.

III. CONCLUSION

We support HHS's efforts to enhance protections for reproductive health care data under HIPAA. Our recommendations would provide clarity, guidance, and support to covered entities to effectively safeguard sensitive information while delivering quality care. Privacy in patient-provider relationships is crucial, and our recommendations align with the proposed rule's objective of strengthening safeguards for reproductive health care information.

We look forward to answering any questions and to working with HHS on these important issues and look forward to the final rule that prioritizes privacy and fosters trust in reproductive health care. If you have any questions regarding these comments please contact Jordan Wrigley at jwrigley@fpf.org (cc: info@fpf.org).

Sincerely,

Jordan Wrigley
Lead and Researcher for Health & Wellness, Future of Privacy Forum

³³ OCR, "When does the Privacy Rule allow covered entities to disclose protected health information to law enforcement officials?," HHS (Dec. 28, 2022), <https://www.hhs.gov/hipaa/for-professionals/faq/505/what-does-the-privacy-rule-allow-covered-entities-to-disclose-to-law-enforcement-officials/index.html>.



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