



An Association of Research Institutions

January 23, 2023

Submitted via Email to <http://www.regulations.gov>

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Response to Notice of Proposed Rulemaking “Confidentiality of Substance Abuse Disorder Patient Records” (Docket Number HHS-OCR-0945-AA16)

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is the conduct of research involving human participants, and the regulations governing various aspects of that research, including those regarding participation privacy and confidentiality. We write today to submit comments in response to the notice of proposed rulemaking “Confidentiality of Substance Abuse Disorder Patient Records” published on December 2, 2022¹ (“NPRM”) concerning proposed changes to the regulations at Title 42, Part 2 of the Code of Federal Regulations² (“Part 2 Regulations”).

As the NPRM notes, the Coronavirus Aid, Relief and Economic Security (CARES) Act³ calls for the Department of Health and Human Services (DHHS) to issue regulations that better align the Part 2 Regulations with the Health Insurance Privacy and Affordability Act regulations⁴ (“HIPAA Regulations”). COGR fully supports DHHS’ efforts to bring about this alignment and concurs with the NPRM’s assessment that the current Part 2 and HIPAA Regulations “create dual obligations and compliance challenges for HIPAA covered entities and business associates” that maintain records subject to both sets of regulations. As many COGR members engage in research directed to understanding the causes and public health implications of substance abuse disorders and identifying effective treatments, ensuring consistent regulations regarding the collection and

¹ [87 Fed. Reg. 74216](#)

² Confidentiality of Substance Abuse Disorder Patient Records, [42 C.F.R. Part 2](#).

³ [Pub. L. 116-136](#), 134 Stat. 281 (Mar. 27, 2020) at § 3221.

⁴ [45 CFR Parts 160 & 164](#).

use of data for research for this patient population is of particular concern to our membership. Overlapping and sometimes inconsistent requirements make it difficult for institutions to develop and implement applicable policies, processes, and training and for individuals working with both types of records to understand and carry out their compliance responsibilities and may limit the opportunities for research to gain insight into substance abuse disorders.

With respect to the research use of Part 2 data, we note that there are already robust regulatory protections in place for human subjects in this area even beyond the HIPAA provisions (e.g., human subjects protection regulations and Food and Drug Administration (FDA) regulations) and that the intent of Congress to avoid unnecessary overlapping or conflicting requirements is particularly acute in the research area. Many COGR institutions conduct clinical and public health research on substance use disorders, and facilitating this research is essential to understanding and treating these conditions. Consistent with this expertise, our comments and recommendations focus on the NPRM provisions that affect research and are aimed at promoting institutions' ability to carry out this vital work, while providing strong protections for research participants' privacy and confidentiality. Our specific comments and recommendations follow.

1. Conformance with HIPAA Regulations

In aligning the two sets of regulations, both §3221 of the CARES Act and Part 2's authorizing legislation⁵ call for ensuring that Part 2 Regulations conform with HIPAA Regulations to the maximum extent possible. COGR supports such full alignment, and several of our specific comments note areas where this could be improved.

2. Section 2.31, Consent Requirements

In research, particularly clinical research subject to FDA regulations, data collected pursuant to informed consent and/or HIPAA authorization that is later withdrawn may need to be used by regulators or study sponsors for safety monitoring and required regulatory reporting.⁶ COGR recommends that the proposed Part 2 regulations specifically address this situation, and we suggest the following modification (shown in ***bold italicized typeface***) to §2.31(a)(6) to make clear that it encompasses research uses taken in reliance on the consent before withdrawal, as well as any applicable FDA reporting requirement as permitted under HIPAA Regulation [45 CFR §164.512\(b\)\(1\)\(iii\)](#):

The patient's right to revoke the consent in writing, except to the extent that the part 2 program, or other lawful holder of patient identifying information that is permitted to make the disclosure (***including disclosures for research purposes***), has already acted in reliance on it, and how the patient may revoke consent. ***Further, in the case of such identifying information being used for research, the disclosures to the FDA permitted under 45 CFR §164.512(b)(1)(iii) also shall be permitted.***

3. Section 2.52, Scientific Research

⁵ [42 U.S.C. §290dd-2\(g\)](#).

⁶ See, e.g., [21 CFR §312.32](#), IND Safety Reporting.

- a. **Creation of De-identified Data and Limited Data Sets:** Both the HIPAA and Part 2 Regulations recognize the importance of facilitating scientific research in cases where obtaining prospective research subject consent is not practical, and they contain provisions specifying how such research should be conducted. Two data use avenues recognized by HIPAA Regulations, but not explicitly addressed in the proposed amendments to the Part 2 Regulations, are the use of identifiable Part 2 data to create (a) de-identified data; and (b) limited data sets, as each of those data categories are defined at [45 CFR §164.514](#). Each of these avenues facilitates the conduct of research using other than fully identifiable data and protecting the confidentiality of the persons whose data is used.

In the NPRM's discussion of the Patient Notice under §2.22 of the Part 2 Regulations, DHHS recognized the advantage to patient confidentiality of not requiring consent for de-identification when it states:

[R]equiring patient consent for de-identification activities would be inconsistent with the new permission to disclose de-identified information for public health purposes as provided in section 3221(c) of the CARES Act. *Such a requirement also would create a barrier to de-identification that may negatively affect patient privacy by increasing permissible but unnecessary uses and disclosures of identifiable Part 2 records in circumstances when de-identified records would serve the intended purpose.* As noted above, the Department believes uses and disclosures for fundraising warrant this added privacy protection, consistent with congressional intent as expressed in the Sense of Congress. [*Emphasis added.*]

The same logic applies to use of identifiable Part 2 data solely for the creation of de-identified data and limited data sets for research and other HIPAA-permitted purposes. Thus, COGR urges DHHS to expressly recognize in §2.52(a), the right of Part 2 program or responsible party conducting scientific research to use identifiable Part 2 data for making de-identified or limited data sets without the need for obtaining individual consent in the same manner as is permitted under 45 CFR §164.514.

- b. **Use of De-identified Data:** Along the same lines, the proposed amendments place far greater restrictions on the use of Part 2 data de-identified in accordance with the HIPAA standards at 45 CFR §164.514 than do the HIPAA Regulations. Under the HIPAA Regulations, information that is de-identified in accordance with any of the methods detailed in 45 CFR §164.514 is no longer considered Protected Health Information that is subject to the HIPAA Regulations.⁷ Under the proposed amendments, however, §2.52(b)(3) limits the use of de-identified Part 2 data in "research reports" to data presented in "aggregate form." Given that de-identified health information is information "that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual,"⁸ the requirement to present such data only in aggregate form in research reports unnecessarily restricts research, without

⁷ [45 CFR §164.514\(a\)](#).

⁸ *Id.*

any corresponding benefit to data subjects. Further, this aggregation requirement defeats the CARES Act objective of bringing Part 2 Regulations into alignment with HIPAA Regulations.

The proposed amendments to §2.52(b)(3) refer to the HIPAA de-identification methods set forth in 45 CFR §164.514(b). Noting nothing to the contrary elsewhere in the NPRM, we presume that any of the HIPAA de-identification methods detailed in that section are appropriate for use in de-identifying Part 2 records. Nevertheless, to avoid confusion, COGR recommends that this fact be expressly stated in the final rule.

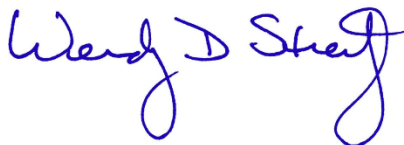
To address each of the foregoing concerns, COGR recommends that DHHS conform the Part 2 Regulations with the HIPAA Regulations by deleting the current text of §2.52(b)(3) and replacing it with the following text:

May, use Part 2 data in research if the patient identifying information (a) has been de-identified in accordance with any of the standards of the HIPAA Privacy Rule at 45 CFR §164.514(b); or (b) is in the format of a limited data set as defined in 45 CFR §164.514(e), which limited data set is used in accordance with all requirements of §164.514(e), including the requirement for a data use agreement.

Conclusion

COGR appreciates DHHS work through the NPRM to better align the Part 2 and HIPAA Regulations and these efforts will make it easier for research institutions, researchers, and care providers to comply and to continue to conduct research to address this special population's health needs. We believe that our comments and recommendations here will aid these efforts, and we appreciate the opportunity to provide them. Should you have any questions regarding this transmittal, please feel free to contact Kris West, COGR's Research Ethics and Compliance Director at kwest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is written in a cursive style with a large, looped initial "W".

Wendy D. Streit
President