

February 2, 2022

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

Re: Guidance on Substantial Harm and Information Blocking

Dear Secretary Becerra:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to encourage the U.S. Department of Health and Human Services (HHS) to immediately issue guidance to clarify the use of the “Preventing Harm” exception to the Office of the National Coordinator for Health Information Technology’s (ONC) information blocking regulations. **This guidance must make clear to clinicians, patients, health systems, electronic health records (EHR) developers, and health information management professionals that requests by a patient’s personal representative for that patient’s medical information may be denied by clinicians if there is a likelihood of substantial psychological or mental harm, based on an assessment of the circumstances and current professional medical standards of harm.**

The AMA has heard from scores of state and specialty medical societies, as well as individual physician members, that ONC’s failure to provide better guidance to them on the Preventing Harm exception is leading to confusion for clinicians. Moreover, it is causing harm to patients, particularly adolescent patients who may have private medical information inappropriately shared with personal representatives, such as parents and guardians. For example, we have received numerous stories of adolescents confiding in their physician about their evolving or changed sexual orientation or gender identity during encounters, expecting that information to remain confidential. Yet, when an adolescent’s parents request records from those encounters and learn of their child’s sexual orientation or gender identity status, they face significant trauma from their parents’ reaction—at times including physical harm, but most often mental or psychological harm, including being told to leave the family home.

These situations are a result of ONC’s current information blocking regulatory framework. The regulations compel certain “actors,”¹ including clinicians, to provide an individual’s medical information to certain requestors unless a regulatory exception applies. One such exception—Preventing Harm—permits actors to deny a request for information if the release could harm the patient or another individual.² The conditions of the exception are born from Health Insurance Portability and

¹ 45 CFR 171.102 defines “actor” as a “a health care provider, health IT developer of certified health IT, health information network or health information exchange.”

² 45 CFR 171.201.

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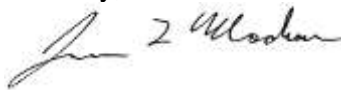
Accountability Act (HIPAA) regulations on records release and harm.³ Usually, the Preventing Harm exception requires that the risk of harm be of a physical (rather than psychological or mental) nature; this is true in both the Preventing Harm exception created by ONC⁴ and in the underlying HIPAA regulations.⁵ ONC has expressed its desire to ensure its policies are aligned with HIPAA. However, HIPAA specifies that when a patient's personal representative requests access to an individual's records—i.e., the request is not coming from the patient themselves, but instead a parent requesting records about their adolescent child—a “substantial harm” standard applies.⁶ This substantial harm standard specifically allows health care providers to consider the likelihood of *substantial psychological or mental harm* to the patient, based on an assessment of the circumstances and current professional medical standards of harm.⁷

Neither ONC nor HHS' Office for Civil Rights (OCR), which created and enforces the underlying HIPAA regulations, have issued the necessary guidance to adequately explain that the Preventing Harm exception may be used when a patient could experience psychological or mental harm as a result of the release of their records to a personal representative. **The lack of guidance around this exception in the face of a historic, paradigm-changing set of regulations compelling data disclosure is unacceptable and stands to harm patients across the country, particularly adolescents.** The AMA has engaged in numerous discussions throughout 2021 with ONC and OCR to elicit clarity on this matter without forward movement. **We are asking HHS to direct ONC to issue FAQs to help rectify this confusion.**

In case it is helpful, please find attached our suggested edits to ONC's current Frequently Asked Questions (FAQs) on this topic, which we provided to ONC and HHS' Office for Civil Rights (OCR) in late 2021. The redline language is pulled almost directly from the preamble text implementing the [2000 HIPAA Regulations](#) explaining the “substantial harm” standard.⁸ Given that this is not new law, and merely a clarifying restatement for the information blocking context, our hope is that these revisions can be published and publicized in the very near future.

Thank you for your attention to this matter. We would be happy to discuss this matter with you further. Please feel free to contact Laura Hoffman, AMA Assistant Director, Federal Affairs, at Laura.Hoffman@ama-assn.org.

Sincerely,



James L. Madara, MD

Attachment

³ The Preventing Harm exception's *type of harm* condition relies on the same types of harm that serve as grounds for reviewable denial of an individual's right of access under the HIPAA Privacy Rule ([45 CFR 164.524](#)). See ONC Cures Act Final Rule preamble [Table 3—Mapping of Circumstances Under § 171.201\(d\) to Applicable Harm Standards](#).

⁴ 45 CFR 171.201(d)(3) and (4).

⁵ 45 CFR 164.524(a)(3)(i).

⁶ 45 CFR 164.524(a)(3)(iii).

⁷ Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000), at 82554-6 and 82733, available at

<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/prdecember2000all8parts.pdf>.

⁸ *Id.*

Where the patient is a minor and to avoid breaching the patient's confidentiality and trust with the provider, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal representative's access, exchange, or use of the minor's EHI? ([IB.FAQ31.1.2021JAN](#))

No. The Preventing Harm Exception was not created to preserve trust between a patient and clinician. The Privacy Exception contains a sub-exception (45 CFR 171.202(e)) that covers practices respecting an individual's request not to share information, subject to certain conditions.

However, if a personal representative requests an individual's record – including in the case of a parent requesting a minor child's record – a provider (such as a physician, physician's assistant, or nurse) may deny a request for access to an individual's EHI if there is a likelihood of substantial psychological or mental harm, based on an assessment of the particular circumstances and current professional medical standards of harm. Unless an actor reasonably believes a practice that interferes with a parent or other legal representative's requested access, exchange, or use of the minor's electronic health information (EHI) will substantially reduce a risk of ~~at least~~ substantial harm to the patient or another person, the [Preventing Harm Exception](#) is not designed to cover that practice.

~~The Privacy Exception contains a sub-exception (45 CFR 171.202(e)) that covers practices respecting an individual's request not to share information, subject to certain conditions.~~

Do the Preventing Harm Exception requirements for the type of harm align with the HIPAA Rules? ([IB.FAQ32.1.2021JAN](#))

Yes. The Preventing Harm Exception's *type of harm* condition relies on the same types of harm that serve as grounds for reviewable denial of an individual's right of access under the Privacy Rule ([45 CFR 164.524](#)). (See [ONC Cures Act Final Rule preamble Table 3—Mapping of Circumstances Under § 171.201\(d\) to Applicable Harm Standards](#).)

In most instances, including where a practice interferes with a patient's own or the patient's other health care providers' legally permissible access, exchange, or use of the patient's electronic health information (EHI), coverage under the Preventing Harm Exception requires that the risk be of physical harm. (See [45 CFR 171.201\(d\)\(3\)](#) and [\(4\)](#).)

However, the Preventing Harm Exception's *type of harm* condition applies a "substantial harm" standard for practices interfering with a patient's *representative's* requested access, exchange, or use of the patient's EHI and to the patient's or their representative's access to other persons' individually identifiable information within the patient's EHI in some circumstances. (See [45 CFR 171.201\(d\)\(1\)](#) and [\(2\)](#)). In such instances, if a personal representative requests an individual's record – including in the case of a parent requesting a minor child's record – a provider (such as a physician, physician's assistant, or nurse) may deny a request for access to an individual's EHI if there is a likelihood of substantial psychological or mental harm, based on an assessment of the particular circumstances and current professional medical standards of harm. This provision applies to personal representatives of minors as well as other individuals. Access may be denied even if the potential harm may be inflicted by someone other than the personal representative.

Where the patient is a minor and to reduce a risk of harm other than physical abuse, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal guardian's access, exchange, or use of the minor's EHI? ([IB.FAQ35.1.2021JAN](#))

Yes, where the *risk of harm* has been determined on an individualized basis and all other conditions of the Preventing Harm Exception are met. For example, the practice must be no broader than necessary and the actor must reasonably believe the practice will substantially reduce the risk of harm. (For all the conditions of the Preventing Harm Exception, please see [45 CFR 171.201](#).)

For purposes of the Preventing Harm Exception, a parent or legal guardian would be considered a patient's legal representative, but the provision applies to personal representatives of other individuals as well. The Preventing Harm Exception's *type of harm* condition applies a "substantial harm" standard for practices interfering with a patient's *representative's* requested access, exchange, or use of the patient's EHI. (See 45 CFR 171.201(d)(1)). In such cases, if a personal representative requests an individual's record, a provider (such as a physician, physician's assistant, or nurse) may deny a request for access to an individual's EHI if there is a likelihood of substantial psychological or mental harm, based on an assessment of the particular circumstances and current professional medical standards of harm. Access may be denied even if the potential harm may be inflicted by someone other than the personal representative.

The *type of harm* conditions for Preventing Harm Exception coverage of practices interfering with patients' and their representatives' access to EHI on the basis of an individualized determination of risk are specifically aligned with the HIPAA Privacy Rule's grounds for reviewable denial of an individual's right of access under the Privacy Rule. (See also [ONC Cures Act Final Rule preamble discussion](#) and [Table 3—Mapping of Circumstances Under § 171.201\(d\) to Applicable Harm Standards](#)).