IPMPC
International Pharmaceutical &
Medical Device Privacy Consortium

February 12, 2019

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: RFI, RIN 0945-AA00
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Re: Department of Health and Human Services, Office for Civil Rights RIN 0945-AA00

Dear Secretary Azar,

The International Pharmaceutical & Medical Device Privacy Consortium ("IPMPC") welcomes the opportunity to respond to the Office for Civil Rights (OCR)'s December 14, 2018 Request for Information ("RFI") on modifying HIPAA rules to improve coordinated care.

The IPMPC is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies and medical device manufacturers.[1] The IPMPC is the leading voice in the global pharmaceutical and medical device industries to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.[2]

We welcome OCR's examination of the HIPAA rules to identify requirements that may impede the transformation to value-based health care or limit or discourage coordinated care among

[1] IPMPC members may also operate related businesses, including CLIA laboratories.

[2] More information about IPMPC is available at https://www.ipmpc.org/. This filing reflects the position of the IPMPC as an organization and should not be construed to reflect the positions of any individual member.

individuals and covered entities without meaningfully contributing to the protection of the privacy or security of individuals. Our comments address the following issues:

1) The need for amendment or clarification of the limitation on "compound authorizations."
2) The need for OCR to further educate covered entities on the right of individuals to direct the covered entity to transmit their PHI to another person or entity.
3) The need for OCR to further educate covered entities on the scope of disclosures of PHI that are permissible for treatment purposes as part of coordination of care.
4) Expansion of the data elements that can be included in a "limited data set."
5) The need for OCR to provide further guidance to covered entities on the scope of PHI that can be provided to pharmaceutical and medical device manufacturers for value-based reimbursement purposes.

I. Limitation on Compound Authorizations

The IPMPC sees no benefit in this limitation on combining a HIPAA authorization with other documents. The Privacy Rule states at 45 CFR 508(b)(3) that "[a]n authorization for use or disclosure of [PHI] may not be combined with any other document to create a compound authorization, except [as expressly enumerated]." This limitation has created significant confusion and uncertainty as to how it may be applied to specific circumstances. For example, is it permissible to combine an authorization for disclosure of PHI with a consent for a non-covered entity recipient of the information to use and further disclose the information? Although one of the exceptions to the prohibition on compound authorizations applies to the combination of "an authorization under this section . . . with any other such authorization under this section," it is unclear how this exception applies (or if it applies) when an individual or entity wishes to combine a HIPAA authorization with a consent required under state law or a consent that is being obtained simply as a matter of good practice.

Pharmaceutical and medical device companies often administer patient support programs that provide assistance to patients in understanding what drugs and devices are covered under their health insurance and determining out-of-pocket costs, in obtaining reimbursement for such drugs/devices, and a variety of other services. To provide these services, it is critical for the pharmaceutical and medical device representatives to communicate and exchange PHI back and forth with the patient, the patient's health care provider(s), and the patient's health insurer. Prohibiting compound authorizations creates additional paperwork that may appear to the patient and their healthcare provider to be largely redundant. Covered entities should be free to combine authorizations with other documents as they see fit, provided they are in compliance with the other HIPAA authorization requirements (e.g., the prohibition on conditioning the provision to an

individual of treatment, payment, enrollment in a health plan, or eligibility for benefits on the individual's provision of an authorization). The IPMPC encourages OCR to amend the Privacy Rule to simplify the process by which patients can enroll for and receive these services, including through the elimination of the prohibition on compound authorizations.

II. Right to Direct the Transmission of PHI to a Third Party

The IPMPC supports the guidance that was provided by OCR in 2016 that clarified that an individual's right of access under HIPAA encompasses a right to have his or her health care provider or health plan send the individual's PHI to a third party. The guidance makes clear that state laws that are contrary to the Privacy Rule's access provisions are preempted by HIPAA. Unfortunately, there appears to remain some confusion over how this guidance applies to state authorization requirements. Therefore, the IPMPC encourages OCR to provide further education to covered entities that emphasizes that state authorization requirements are preempted by HIPAA when an individual exercises his or her right to direct the transmission of PHI to a third party, provided the requirements for such a directed disclosure are met (namely, the direction is given in a writing, signed by the individual (including an electronic signature), and clearly identifies the designated person and where to the send the PHI). OCR should further highlight that it is permissible to combine such a directed disclosure request with a HIPAA authorization or other document.

OCR's directed disclosure guidance provides a potential mechanism for a patient to direct his or her health care provider and health insurer to disclose PHI to a patient support program representative who is providing assistance in understanding coverage, obtaining reimbursement, and other services. OCR should make clear in its education to health care providers that state laws that create additional hurdles for patients to enroll in these services by, e.g., requiring handwritten signatures on authorizations or limiting the duration of a valid authorization, are preempted when an individual directs the disclosure of his or her PHI to a third party.[3]

III. Disclosures of PHI for Care Coordination Purposes

The Privacy Rule permits a health care provider to disclose a patient's PHI for treatment purposes without having to obtain the authorization of the individual. HHS has previously issued guidance emphasizing that "Treatment includes the coordination or management of health care by a

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[3] As HHS has stated in prior guidance, "Unless an exemption exists in the HIPAA Rules, State laws that are contrary to the Privacy Rule access provisions . . . are preempted by HIPAA. See 45 CFR 160.203. Thus, these State laws do not apply when an individual exercises her HIPAA right of access. See 45 CFR Part 160, Subpart B." ("Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524," *available at* https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.)

health care provider with a third party. Health care means care, services, or supplies related to the health of an individual."[4] However, much of this prior guidance has been focused on the disclosure of PHI with other physicians or with social welfare agencies, and covered entities have been cautious about applying this guidance to other types of third parties that are assisting a patient in managing his or her health care.

As noted, pharmaceutical and medical device companies provide a range of patient support services. These may include, for example, assisting a patient in understanding insurance coverage, in obtaining reimbursement for health care, in answering questions the patient has concerning his/her condition and treatment options, in managing health care appointments, and in understanding how to use certain types of drugs and devices (e.g., injection training for patients who will self-administer injections). When a pharmaceutical or medical device company representative provides these services, it is providing "health care" within the meaning of that term under 45 CFR § 160.103, and disclosures to a pharmaceutical or medical device representative for these purposes are permitted as disclosures for treatment purposes. OCR should make this clear in guidance to covered entities.

IV. Expansion of Data Elements in a Limited Data Set

The Privacy Rule allows a covered entity to disclose a limited data set of protected health information for the purposes of research, public health, or health care operations, provided the recipient has entered into a limited data use agreement. (See 45 CFR 164.514(e).) A limited data set excludes not only name and contact information but also a range of "direct identifiers." While this latter information could theoretically be used to re-identify the information, the risks are low where the recipient has agreed to not use or further disclose the information other than as permitted by the data use agreement, use appropriate safeguards to prevent use or disclosure other than as agreed, report to the covered entity any impermissible uses or disclosures, ensure that agents are subject to the same conditions, and not identify the information or contact individuals.

The list of data elements to be removed from a limited data set includes medical record numbers (which OCR has previously commented included prescription numbers), device identifiers

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[4] See "Does HIPAA permit health care providers to share protected health information (PHI) about an individual with mental illness with a third party that is not a health care provider for continuity of care purposes? For example, can a health care provider refer a homeless patient to a social services agency, such as a housing provider, when doing so may reveal that the basis for eligibility is related to mental health?" available at https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html.

and serial numbers, and IP addresses. This information can be useful for research purposes (e.g., to identify duplicate information in research records and to correlate information that relates to a particular device). It makes no sense to restrict the disclosure of this information where a recipient has provided the assurances required in a data use agreement.

V. Disclosure of PHI to Manufacturers for Value-Based Reimbursement Purposes

OCR should provide further guidance to covered entities that makes clear that the Privacy Rule permits health plans and health care providers to disclose PHI to pharmaceutical and medical device manufacturers for purposes of designing and administering value-based reimbursement programs. HHS has previously issued guidance making clear that the Privacy Rule permits a health plan as part of its payment activities to disclose PHI to pharmaceutical manufacturers for purposes of adjudicating claims submitted under a drug rebate contract.[5] The guidance indicates that a business associate agreement is not required to make these disclosures, but the PHI disclosed for payment purposes is subject to the minimum necessary standard (unless the disclosure is required by law as part of a state Medicaid drug rebate program). Because this guidance expressly covers only drug utilization rebate programs, covered entities have been cautious applying the same rationale to the disclosure of PHI needed for value-based reimbursement arrangements.

Pharmaceutical and medical device manufacturers require broad access to PHI in order to design and administer value-based reimbursement programs. PHI is required both on the front-end to design effective value-based reimbursement arrangements and on the back-end to measure performance. IPMPC believes that the rationale behind OCR's drug rebate guidance applies here as well, and, therefore, these disclosures are permitted as part of the covered entity's "payment" activities. This should be made clear to covered entities, including the fact that the minimum necessary standard allows for a broad scope of PHI to be disclosed where such a scope is reasonably necessary for designing and administering these arrangements. In the alternative, if OCR does not agree that the Privacy Rule currently permits these disclosures, then the Privacy Rule should be amended to enable these disclosures.

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[5] See "Does the Privacy Rule permit health plans to disclose protected health information to pharmaceutical manufacturers for the adjudication of drug rebate contracts?" available at https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-health-plans-to-disclose-information-to-pharmaceutical-manufacturers/index.html; see also "Does the Privacy Rule permit state Medicaid agencies to disclose protected health information to pharmaceutical manufacturers and third party data vendors for purposes of validating claims under the Medicaid Drug Rebate program?" available at https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html.

We thank you for the opportunity to provide these comments. We applaud your efforts to reduce HIPAA's regulatory burdens where there are no corresponding benefits to the privacy and security of individuals.

Sincerely,

Peter A. Blenkinsop
IPMPC Secretariat