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<http://www.regulations.gov>

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

**Re: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (RIN 0945-AA00)**

Dear Acting Director Frohboese:

The American Geriatrics Society (“AGS”) appreciates the opportunity to comment on the Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (“Proposed Modifications”)<sup>1</sup> issued by the Department of Health and Human Services Office for Civil Rights (“OCR”). Founded in 1942, AGS is a nationwide, not-for-profit society of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of older people. Our nearly 6,000 members include geriatricians, geriatric nurses, social workers, family practitioners, physician assistants, pharmacists, and internists. The AGS provides leadership to healthcare professionals, policymakers, and the public by implementing and advocating for programs in clinical care, research, professional and public education, and public policy.

The AGS has a strong interest in the HIPAA Privacy Rule and its impact on the delivery of (and payment for) health care for older adults. Our comments on the Proposed Modifications focus primarily on OCR’s proposed relaxation of existing restrictions on disclosures of protected health information (“PHI”) to social services agencies, community-based organizations (“CBOs”), home and community-based service (“HCBS”) providers (collectively, “community care organizations” or “CCOs”). CCOs can serve a critical role in preserving and improving the health of older adults. We therefore support OCR’s initiative to improve communication between HIPAA covered entities and these types of organizations. At the same time, as discussed further below, we believe an individual’s right to be aware of and in favor of the involvement of a CCO in his or her health care is critical, and that the Privacy Rule should not be amended in a way that would undermine that right or the privacy of an individual’s PHI.

Our comments also address the minimum necessary standard and the proposed “good faith belief” standard as they would affect the older adults whose health is at the center of AGS’s mission.

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<sup>1</sup> 86 Fed. Reg. 6,446 (Jan. 21, 2021).

**I. Amending the Definition of Health Care Operations to Clarify the Scope of Care Coordination and Case Management (45 C.F.R. § 164.501)**

We support OCR's proposed amendment to the definition of "health care operations," clarifying that the term includes care coordination and case management for individuals, rather than just population-based activities. We do not believe this modest change will result in inappropriate disclosures of PHI. Care coordination and case management at the individual level can be key to providing an older adult with the full support he or she needs, which may include communications among the individual's health care provider, Medicare or other health plan, and one or more CCOs. The proposed amendment will eliminate the existing ambiguity regarding OCR's intent in referring to "population-based activities" in the definition.

**II. Creating An Exception to the Minimum Necessary Standard for Disclosures for Individual-Level Care Coordination and Case Management**

We appreciate OCR's careful attention to the question of how the minimum necessary standard may have unduly limited sharing of PHI, but we feel strongly that the principle underlying the minimum necessary standard should underlie all uses and disclosures of PHI, in any context. Removal of the standard where it currently applies could risk uses and disclosures of PHI beyond what is needed to accomplish a legitimate purpose. In particular, in response to OCR's request for comment on exempting from the minimum necessary standard disclosures for payment purposes, we oppose any such exemption, including for payment purposes related to individual care coordination or case management. We see no reason why more than the minimum amount of PHI needed to determine or adjudicate payments for health care would ever need to be disclosed for payment purposes.

In short, we oppose any change to current 45 C.F.R. § 164.502(b). To the extent that the minimum necessary standard may have hindered covered entities' willingness to share PHI for care coordination or case management purposes, we believe clarification of what constitutes the minimum necessary amount of PHI to achieve a given purpose is the appropriate way to provide covered entities with assurance that appropriate uses and disclosures will not violate the standard. We urge OCR to do this through formal guidance, providing specific indications of the types of PHI that OCR would deem necessary to be disclosed for purposes of care coordination or case management, taking into account various types of circumstances and forms of care coordination and case management. We believe this would serve the goal of care coordination and case management, in the interest of the individual seeking care, far better than limiting the scope of the minimum necessary standard as proposed by OCR.

**III. Clarifying the Scope of Covered Entities' Abilities to Disclose PHI to Certain Third Parties for Individual-Level Care Coordination That Constitutes Treatment or Health Care Operations**

As noted, the AGS strongly supports facilitating care coordination and case management to enhance the health and well-being of older adults, as indicated above. We understand that OCR's intent is that the Privacy Rule not impede care coordination and case management as part of treatment or health care operations and that the Privacy Rule already permits disclosures of PHI without individual authorizations for these purposes in many if not most situations. The modifications proposed by OCR therefore are largely proposed clarifications; however, the terms of the clarifications have great significance for patient privacy and patient care.

**Treatment Disclosures.** With respect to disclosures of PHI for treatment purposes, we do not believe any change in the Privacy Rule is needed, given that the Modifications currently permits disclosures of PHI to *any person* by a covered health care provider for its own treatment purposes, and permits disclosures of PHI by any covered entity to a health care provider (whether covered by HIPAA or not) for such provider's treatment purposes. We consider these permissions sufficient particularly because, as OCR noted in the preamble to the Proposed Modifications, "treatment" includes "the coordination or management of health care by a health care provider *with a third party*."<sup>2</sup> Thus, the Privacy Rule currently permits a covered health care provider to share a patient's PHI with an CCO (not just a health care provider CCO) to the extent such sharing is in furtherance of (i) the covered health care provider's own treatment of the patient, or (ii) the patient's treatment by another health care provider (whether a covered entity or not). And, as OCR noted, these disclosures to a third party are subject to the minimum necessary standard: "For example, a health care provider may disclose the minimum necessary PHI to a senior center or adult day care provider to help coordinate necessary health-related services for an individual, such as arranging for a home aide, to help the older adult or disabled person with their prescribed at-home or post-discharge treatment protocol."<sup>3</sup>

**Health Care Operations Disclosures.** With respect to disclosures of PHI for health care operations purposes, the Privacy Rule also permits covered entities to make disclosures of an individual's PHI without an individual authorization: (i) to any person, for the covered entity's own health care operations purposes (including care coordination and case management), or (ii) to another covered entity that has or had a relationship with the individual, for the recipient covered entity's health care operations purposes (including care coordination and case management). Although these provisions are viewed by OCR as permitting disclosures to non-HIPAA covered entities for a health plan's care coordination and case management purposes, OCR seeks to clarify this interpretation by broadly authorizing PHI disclosures to "a social services agency, community-based organization, home and community based services provider, or similar third party that provides health or human services to specific individuals for individual-level care coordination and case management activities."<sup>4</sup> Given the opportunity for clarification and the likely impact of such clarification, whether such disclosures should be permitted and if so, under what conditions, is a critical decision for OCR to make.

AGS believes that it would be unwise to blanketly allow disclosures of PHI for care coordination and case management purposes to non-HIPAA covered entities. We do believe care coordination and cases management are critical components of maintaining health, particularly for older adults who need support outside the traditional health care context, and that some PHI may need to be shared to facilitate effective care coordination and case management (such as medication adherence, implementing dietary requirements and restrictions, arranging for appropriate exercise, etc.), especially for older adults with limited capacity to keep track of their own healthcare regimens. But we are very concerned about disclosures of PHI to non-HIPAA covered entities at this point in the development of privacy law in the United States. Given the limited scope of current health information privacy laws at the U.S. federal and state levels, many recipient CCOs may be subject to minimal (and in some cases no) requirements or restrictions that would protect PHI once received by them.

**Recommendations.** To address these concerns, AGS believes that OCR's proposal to amend the Privacy Rule to permit disclosures of PHI to "a social services agency, community-based organization,

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<sup>2</sup> 45 C.F.R. § 164.501 (emphasis added).

<sup>3</sup> 86 Fed. Reg. at 6476.

<sup>4</sup> Proposed 45 C.F.R. § 164.506(c)(6).

home and community based services provider, or similar third party that provides health or human services to specific individuals for individual-level care coordination and case management activities”<sup>5</sup> should be cabined.<sup>6</sup> One way to limit its scope, as suggested by OCR in its requests for comments on the Proposed Modifications, would be to further define the types of persons and entities to whom disclosures should be allowed. However, we are concerned about an appropriate line to draw, given the broad variety of organizations that can meaningfully assist in care coordination or case management and the likelihood that the contours of these types of organizations may evolve. And even with a more limited list of permissible recipients, we are concerned, as noted, about the lack of any health information privacy regulations governing many (if not most) non-HIPAA covered entities.

Our proposal would be to limit the permissible recipients to those who can demonstrate a commitment and capability to protect and use the PHI responsibly. One way for a CCO to make such a demonstration, as OCR suggested in seeking comments on the Proposed Modifications, would be to execute an agreement with the disclosing covered entity “that describes and/or limits the uses and further disclosures allowed by the third party recipients.”<sup>7</sup> Effectively, this would create a parallel to the business associate agreement and data use agreement frameworks already established by the Privacy Rule. AGS would support this approach in theory, but believes in practice it could hinder beneficial care coordination and case management by imposing additional paperwork requirements on covered entities, as well as CCOs, that might be viewed as excessively cumbersome and thus not pursued.

Another alternative would be to establish a mechanism similar to that instituted under the EU-US Safe Harbor and Privacy Shield frameworks,<sup>8</sup> which, although currently invalid for reasons not relevant here, enables intended U.S. recipients of personal data to certify their adherence to a set of privacy protection principles and thereby attain the status of an effectively “approved” recipient under the privacy law of the European Union. Because this certification is a public representation, an action of the certifying entity inconsistent with the privacy principles is a misrepresentation in violation of Section 5 of the Federal Trade Commission Act, which prohibits deceptive and unfair conduct. Accordingly, the Federal Trade Commission can bring a complaint against a certified entity that fails to live up to the commitments made in its certification.

Applying this approach in the Privacy Rule context could facilitate case management and care coordination while protecting the privacy and security of PHI. Covered entities would not need to enter into individual agreements with CCOs in order to share with them PHI for care coordination or case management purposes; rather, covered entities could simply check to see if a particular CCO had certified to protect the privacy and security of PHI (under terms similar to those of a business associate agreement). If a list of the certified agencies were available in an online, publicly accessible database such as the Privacy Shield list maintained by the Commerce Department,<sup>9</sup> this check would take minutes rather than the days, weeks or even months required to execute an individual agreement with the CCO. And it would create an even playing field for all CCOs upon which to base their PHI-protective measures.

Finally, consistent with our recommendation above regarding requiring a covered entity to obtain consent prior to disclosing more than the minimum necessary amount of PHI for care

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<sup>5</sup> Proposed 45 C.F.R. § 164.506(c)(6).

<sup>6</sup> We also recommend, to the extent OCR decides to retain the quoted language, that the word “and” between “care coordination” and “case management activities” be changed to “or.”

<sup>7</sup> 86 Fed. Reg. at 6,477.

<sup>8</sup> See <https://www.privacyshield.gov/article?id=How-to-Join-Privacy-Shield-part-1>.

<sup>9</sup> See <https://www.privacyshield.gov/list>.

coordination or case management purposes as part of health care operations, we recommend that covered entities be required to obtain consent from an individual before disclosing any of such individual's PHI for these purposes to persons or entities that are neither HIPAA covered entities nor other health care providers.

To effectuate the above-suggested changes to the Proposed Modifications, we recommend adding the underlined text below to proposed 45 C.F.R. § 164.506(c)(6):

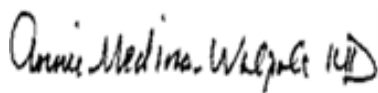
A covered entity may disclose an individual's protected health information to a social services agency, community-based organization, home and community based services provider, or similar third party that provides health or human services to specific individuals for individual-level care coordination and case management activities (whether such activities constitute treatment or health care operations as those terms are defined in § 164.501) with respect to that individual, provided that the covered entity has obtained (i) the consent of the individual to make such disclosure, and (ii) satisfactory assurance that the recipient of the protected health information will appropriately safeguard the information.

As stated above with respect to obtaining consent to make disclosures of more than the minimum necessary amount of PHI, we do not recommend prescribing the content, form or mode of consent required to be obtained in this context. Regarding the means of obtaining "satisfactory assurance" from the intended recipient of the PHI as referred to in the suggested text, that could be defined elsewhere in the Privacy Rule to mean either (i) executing a data protection agreement with the intended recipient (similar to a data use agreement or business associate agreement) or (ii) confirming that the intended recipient has certified to the HIPAA PHI protection principles that would be set forth under a Privacy Shield-like framework, as described above.

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Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, [agoldstein@americangeriatrics.org](mailto:agoldstein@americangeriatrics.org).

Sincerely,



Annette Medina-Walpole, MD  
President



Nancy E. Lundebjerg, MPA  
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