



Academy of
Managed Care
Pharmacy®

February 12, 2019

US Department of Health and Human Services
Office for Civil Rights
Attn: RIN 0945-AA00
Hubert H. Humphrey Building, Room 509F
200 Independence Ave., SW
Washington, DC 20201

Re: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care [HHS-OCR-0945-AA00]

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to provide comments to the Department of Health and Human Services (HHS) Office of Civil Rights (OCR) in response to its [Request for Information on Modifying HIPAA Rules to Improve Coordinated Care](#) [HHS-OCR-0945-AA00]. AMCP supports modernization of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, specifically as it relates to aligning 42 CFR Part 2 (Part 2) requirements with HIPAA.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP offers the following comments in Section I of the RFI:

OCR seeks public input, including from individuals, covered entities, other health care providers, business associates, and other members of the public, on the scope of this problem, and on whether there are potential revisions to the Privacy Rule to support and promote care coordination and/or case management, including by requiring timely transfer of PHI for this purpose or other purposes, such as when a patient switches medical providers and their new provider requests the transfer of records from the previous provider.

AMCP agrees that the Privacy Rule should be revised to encourage care coordination and implementation of value-based care models by managed care organizations. Managed care organizations, which include health plans, pharmacy benefit managers, integrated delivery networks, and accountable care organizations, are establishing and implementing value-based care. They are however, limited by lack of available PHI for operational, treatment and payment decisions.

A targeted survey of 29 AMCP members who are leaders in managed care organizations fielded January 28-February 4, 2019, showed, 70% of respondents reported limited data on health outcomes as a barrier to implementing value-based care models or programs. AMCP anticipates expanding upon these findings later in 2019.

Some examples of the types of value-based programs and model health plans, PBMs and other managed care organizations engage in include risk sharing with physicians and provider organizations where financial incentives are aligned to deliver quality care and manage total costs; outcomes-based contracts with manufacturers, where the payment for drugs are tied to patient outcomes; and medication therapy management, where the medication therapies for high-risk patients are managed closely to avoid adverse events and optimize patient outcomes.

OCR also seeks feedback from stakeholders on promoting information sharing for treatment and care coordination and/or case management by amending the Privacy Rule to encourage, incentivize, or require covered entities to disclose PHI to other covered entities. Additionally, OCR is requesting input on whether it should modify or otherwise clarify provisions of the Privacy Rule to encourage covered entities to share PHI with noncovered entities when needed to coordinate care and provide related health care services and support for individuals in these situations.

AMCP agrees with the need to modify or otherwise clarify provisions of the Privacy Rule on sharing PHI between covered and non-covered entities. Specifically, because the outcomes of care may be captured or recorded in a number of settings, or by various covered entities or business associates, managed care organizations may require access to PHI from organizations with which a business associate agreement has not been established. The provision of value-based care should not be limited by inability to share PHI when it is being used by covered entities and their business associates. As new care delivery models emerge to manage the various needs of diverse and heterogeneous patient populations, access to PHI from non-covered entities or settings such as social services and community-based support programs should be supported.

Finally, OCR seeks feedback on eliminating or modifying the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of

receipt of providers' Notice of Privacy Practices, to reduce burden and free up resources for covered entities to devote to coordinated care without compromising transparency or an individual's awareness of his or her rights.

AMCP agrees that coordination and delivery of value-based care by managed care organizations such as health plans or PBMs should not be impeded or delayed by requirements for individual providers' Notice of Privacy Practices when a good faith effort has been made to obtain acknowledgement.

AMCP offers additional comments to OCR on its request for feedback on the following questions in Section II of the RFI:

(7) Should covered entities be required to disclose PHI when requested by another covered entity for treatment purposes? Should the requirement extend to disclosures made for payment and/or health care operations purposes generally, or, alternatively, only for specific payment or health care operations purposes; and

7(a) Would this requirement improve care coordination and/or case management? Would it create unintended burdens for covered entities or individuals? For example, would such a provision require covered entities to establish new procedures to ensure that such requests were managed and fulfilled pursuant to the new regulatory provision and, thus, impose new administrative costs on covered entities? Or would the only new administrative costs arise because covered entities would have to manage and fulfill requests for PHI that previously would not have been fulfilled; and

7(b) Should any limitation be placed on this requirement? For instance, should disclosures for healthcare operations be treated differently than disclosures for treatment or payment? Or should this requirement only apply to certain limited payment or health care operations purposes? If so, why?

AMCP encourages OCR to maintain flexibility in PHI disclosure requirements to allow for use for operations, treatment or payment. Coordination and implementation of value-based care models by health plans, PBMs or other managed care organizations, may require use of PHI for operations, treatment or payment purposes. It is unclear what additional burden or administration costs this may pose to covered entities. OCR is encouraged to work with industry to understand this potential impact and propose guidance for determining unnecessary requests (e.g., Requests for PHI on patients not covered or treated by the requesting entity), appropriate timelines for responding to requests, and guidance on which entity is responsible for the administrative cost of data sharing (e.g., the requestor). OCR is encouraged to work with CMS to estimate the savings

that may be achieved by better care coordination due to PHI disclosures for operations, treatment or payment.

(11) Should OCR create exceptions or limitations to a requirement for covered entities to disclose PHI to other health care providers (or other covered entities) upon request? For example, should the requirement be limited to PHI in a designated record set? Should psychotherapy notes or other specific types of PHI (such as genetic information) be excluded from the disclosure requirement unless expressly authorized by the individual?

In response to Question 14 below, we summarize the negative impact CFR 42 Part 2 has had on the ability to coordinate care for patients with substance use disorders. We discourage limits on the types of PHI that may be requested and encourage OCR to work with health care stakeholder (including patients) to provide guidance on when individual authorization or disclosures may be appropriate for types of PHI (such as genetic information).

(14) How would a general requirement for covered health care providers (or all covered entities) to share PHI when requested by another covered health care provider (or other covered entity) interact with other laws, such as 42 CFR part 2 or state laws that restrict the sharing of information.

Due to 42 CFR Part 2's strict requirements, providers and health plans have long struggled over the use and disclosure of substance use disorder treatment records as part of coordinated care efforts. As such, AMCP encourages OCR to clarify where HIPAA is harmonized with Part 2 requirements on the confidentiality of certain substance use disorder patient records for the purpose of treatment, payment, and health care operations.

The current barriers to accessing a patient's entire medical record, including addiction records, lead to potentially dangerous medical situations such as harmful drug-drug interactions and lack of patient-centric, integrated care. As the country moves forward with combating the opioid epidemic, a focus should remain on integrating substance use disorder, mental health, and primary care services to improve patient outcomes and support care coordination.

AMCP continues to support the need for codification of these provisions into the HIPAA statute, but in the meantime, providers, patients and payers require clear guidance in this area. Lack of clarity around the intersection of HIPAA and Part 2 places a significant burden on clinicians to interpret compliance with existing regulations. If clinicians could better understand these regulations, they could better coordinate care and minimize a substantial source of burden.

(16) What considerations should OCR take into account to ensure that a potential Privacy Rule requirement to disclose PHI is consistent with rulemaking by the Office of the National

Coordinator for Health Information Technology (ONC) to prohibit “information blocking,” as defined by the 21st Century Cures Act?

OCR is encouraged to work with the ONC to ensure requirements for data sharing for a new or revised Privacy Rule are implementable within electronic medical records and other health information IT. OCR for example may encourage standardized ways for sharing PHI that are compatible with various needs. The intent of revising the Privacy Rule may not be fully realized if entities are sharing PHI in unusable file formats. Aforementioned concerns for administrative burden may be minimized by using standards for data exchange instead of needing to reformat PHI files for each requestor.

Conclusion

AMCP appreciates your consideration of the recommendations and concerns outlined above and looks forward to continuing work on these issues with OCR. If you have any questions regarding AMCP’s comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell. RPh, CAE
Chief Executive Officer