



February 12, 2019

Alex M. Azar II, Secretary
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

Dear Secretary Azar:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the request for information issued by the Office of Civil Rights (OCR) regarding the reduction of regulatory burdens associated with the *Health Insurance Portability and Accountability Act* (HIPAA) privacy and security regulations.

In general, the AAFP appreciates that the Department recognizes the need to address HIPAA issues that either impede the transformation to value-based health care or limit coordinated care among individuals and covered entities. We would recommend though that the Department delay any actions until the regulations required by 21st Century Cures on Information Blocking have been finalized and we have been able to determine their effect on information sharing for care coordination.

The AAFP is concerned that requirements to sign a Notice of Privacy is an administrative exercise with limited value to patients and practices. Practices have limited understanding of requirements and frequently ask patients to re-sign the Notice annually. **The requirements for patient signature should be eliminated completely.** The practice should continue to post the Notice and allow patients to receive a copy upon request, and payers should be required to notify their clients of their need for information to process payments.

The AAFP offers the following responses to the italicized questions/goals described by OCR.

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. Encouraging covered entities, particularly providers, to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, with a particular focus on the opioid crisis.

STRONG MEDICINE FOR AMERICA

President
John Cullen, MD
Valdez, AK

President-elect
Gary LeRoy, MD
Dayton, OH

Board Chair
Michael Munger, MD
Overland Park, KS

Directors
Robert Raspa, MD, *Orange Park, FL*
Leonard Reeves, MD, *Rome, GA*
Ada Stewart, MD, *Columbia, SC*
Sterling Ransone, MD, *Delataville, VA*
Windel Stracener, MD, *Richmond, IN*
Erica Swegler MD, *Austin, TX*

James Eltzy, MD, *Washington, DC*
Dennis Gingrich, MD, *Hershey, PA*
Tochi Iroku-Malize, MD, *Bay Shore, NY*
LaTasha Seliby Perkins, MD (New Physician Member), *Arlington, VA*
Michelle Byrne, MD (Resident Member), *Chicago, IL*
Chandler Stisher (Student Member), *Brownsboro, AL*

Speaker
Alan Schwartzstein, MD
Oregon, WI

Vice Speaker
Russell Kohl, MD
Stilwell, KS

Executive Vice President
Douglas E. Henley, MD
Leawood, KS

Due to misunderstandings of regulations and the fear of penalties or lawsuits, all too often physicians are reluctant to disclose protected health information (PHI) to family, caregivers and other providers involved in care. It is imperative that CMS provide clear, succinct clarification and guidance on what can be disclosed, to whom, and when, to help alleviate these fears, encourage information sharing, and ultimately improve patient care and outcomes.

OCR seeks input on whether disclosures of PHI to non-provider covered entities for care coordination and/or case management as part of treatment, and/or health care operations, should be excepted from the minimum necessary standard, and if so, to what extent.

The AAFP's [confidentiality](#) policy states the right to privacy is personal and fundamental. A confidential relationship between physician and patient is essential for the free flow of information necessary for sound medical care. Only in a setting of trust can a patient share the private feelings and personal history that enable the physician to comprehend fully, to diagnose logically, and to treat properly. Medical information may have legitimate purposes outside of the physician/patient relationship. However, patients and physicians must authorize release of any personally identifiable information to other parties. Any disclosure of medical record information should be limited to information necessary to accomplish the purpose for which disclosure is made.

The rights of patients to be free of unwelcome contact from multiple non-provider entities should also be of top concern. Patients with the capacity to make health care decisions should not be subjected to intrusive actions of non-provider covered entities. Patient consent must continue to be obtained for release of PHI to non-provider covered entities and release should remain subject to the minimum necessary standard. Patients should continue to be allowed to access their own medical records, and if they desire, share them with non-provider entities, or sign consent for the provider to release the data to non-provider entities.

If a physician believes their patient does not have the capacity to make healthcare decisions, the physician should not be penalized for sharing information they deem important to coordinate and manage care of the patient with caregivers.

Physicians (covered entities) should **not be required** to enter into agreements with entities such as social service agencies or community-based support programs. Such regulation will add unnecessary burden and will become another administrative exercise. Physicians should **be allowed** to enter into agreements that will benefit the patient. Since this is currently allowed, no change is needed to existing law.

How long does it take for covered entities to provide an individual with a copy of their PHI when requested pursuant to the individual's right of access at CFR 164.524? How long does it take for covered entities to provide copies of records that are not requested pursuant to the individual's right of access? Does the length of time vary based on whether records are maintained electronically or in another form (e.g., paper)? Does the length of time vary based on type of covered entity? For instance, do some types of health care providers or plans take longer to respond to requests than others?

The current state of technology presents barriers to data access. These challenges include the continued storage of portions of the record in paper form, off-site storage of records, and access to files from non-integrated diverse electronic systems (such as

image files and billing files). Confounding the current state of technology is a lack of records standardization and varied requests for information. Future technology should require all requests for information to be standardized with standard definitions and a listing of contents and data elements. All EHR vendors should be required to provide capability for the practice to “check the box” by simply selecting standard portions of the medical record to allow effortless and rapid transmission of defined data. Information requests should be easy to complete by practice staff. Use of standardized information sets should allow sharing of electronic data within a defined time-frame to enhance care coordination and care management. Until full electronic availability of a standardized complete record is realized, the time required to produce a full copy of a patient’s record will vary greatly depending on practice capabilities, format, size of the record, and complexity of the request.

How feasible is it for covered entities to provide PHI when requested by the individual pursuant to the right of access more rapidly than currently required under the rules (30 days with one possible 30-day extension)? What is the most appropriate general timeframe for responses? Should any specific purposes or types of access requests by patients be required to have shorter response times?

The AAFP reminds OCR that there is a promoting interoperability measure that intersects with the requirement to provide individuals with a copy of their PHI. The measure requires practices to make certain information available to the patient within four business days of it being available to the clinician. While we understand the desire for prompt responses, if the requirements are too truncated, it may inadvertently place more burden on a medical practice. This can be especially true for solo and small practices, where the timeframe for compliance may actually result in physicians and clinical staff being required to divert time away from patient care to ensure records requests are fulfilled timely to avoid a HIPAA violation. **The current HIPAA requirements are 30 days and the AAFP urges OCR to keep this timeframe.** Many practices report difficulty providing records requested in under 30 days even if they have an EHR. Practices that pay external Release of Information medical records services to process record requests may typically transfer requested PHI within about 1-2 weeks. However, many private practices do not contract with such companies and instead process records requests internally. Barriers exist as discussed in the previous section that may prevent more rapid generation of information.

Should health care clearinghouses be subject to the individual access requirements, thereby requiring health care clearinghouses to provide individuals with access to their PHI in a designated record set upon request? Should any limitations apply to this requirement?

Yes, the AAFP calls for healthcare clearinghouses to be subject to individual access requirements. Patients have a right to access any and all information about themselves and their care from any source that may gather such information. The AAFP recognizes, however, that most patients will not be familiar with the existence or functions of a clearinghouse and are unlikely to make individual requests for information from a clearinghouse. Instead, such requests will likely be made through the physician, in which case the clearinghouse should comply with the request.

Family physicians, above all else, seek to protect the well-being and health of their patients. Increasingly in today’s healthcare landscape, primary care physicians are accountable for safe and effective coordination of care and care management, as an

integral component of routine business practices. The primary care physician should have access to information contained in a clearinghouse and be given data (treatment and diagnostic codes, dates, medications, provider name/contact information) on all procedures, treatments, and diagnoses billed by all other entities to enhance the ability of primary care to safely and effectively coordinate care and manage costs. This data should be in a standard form that is importable into the EHR without special effort by the primary care physician team.

Alternatively, should health care clearinghouses be treated only as covered entities – i.e., be subject to all requirements and prohibitions in the HIPAA rules concerning the use and disclosure of PHI and the rights of individuals in the same way as other covered entities – and not be considered business associates, or need a business associate agreement with a covered entity, even when performing activities for, or on behalf of, other covered entities? Would this change or raise concerns for other covered entities about their inability to limit uses and disclosures of PHI by health care clearinghouses? For example, would this change prevent covered entities from providing assurances to individuals about how their PHI will be used and disclosed? Or would covered entities be able to adequately fulfill individuals' expectations about uses and disclosures through normal contract negotiations with health care clearinghouses, without the need for a HIPAA business associate agreement? Would covered entities be able to impose other contractual limitations on the uses and disclosures of PHI by the health care clearinghouse?

The AAFP believes leaving clearinghouses as business associates provides more transparency and protection for patients.

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?

The AAFP acknowledges the benefit of disclosing PHI for treatment purposes to another covered entity but we strongly oppose any mandate or requirement to disclose PHI to another covered entity. Physicians should not be required to share information when they feel it is inappropriate, unnecessary, or against a patient's wishes. A requirement would impose on a physician's right to protect their patients' information. Physicians should free to use their discretion when deciding if it is appropriate to disclose patient health information.

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?

Physicians should be allowed to use their discretion in releasing PHI to other healthcare providers upon request, and as determined to be in the best interests of the patient, including psychotherapy notes, genetic information and other types of PHI. Above all else, physicians are accountable for, first, doing no harm. There are instances where lack of shared medical history and treatment information would render it unsafe for the patient to undergo various medical treatment(s). Physicians should be protected from

any/all damages sought as a result of their professional decision to release/not release such information.

Should OCR expand the exceptions to the Privacy Rule's minimum necessary standard? For instance, should population-based case management and care coordination activities, claims management, review of health care services for appropriateness of care, utilization reviews, or formulary development be excepted from the minimum necessary requirement? Would these exceptions promote care coordination and/or case management? If so, how? Are there additional exceptions to the minimum necessary standard that OCR should consider?

No, the AAFP does not want OCR to expand the minimum necessary standard for claims management, review of health care services for appropriateness of care, etc. The Meaningful Use program illustrated that when requirements to exchange data exist, but without minimum necessary standards strongly in place, the sending health care organization will send everything to ensure they comply with the requirement to exchange. Since semantic interoperability does not yet exist, it becomes an enormous burden on the receiving physician to wade through all the information to find clinically relevant information.

If OCR insists on mandated disclosure for any purpose, it should only be among health care providers and for treatment purposes, except where such disclosure would conflict with a patient's right to privacy. Creating additional caveats and exceptions would add complexity and administrative burden to an already confusing set of regulations. Further, payers could request information beyond what is minimally necessary and use such information to discriminate against patients or delay care, either by denying claims or coverage for services, or requiring burdensome prior authorization for a patient's needed medication, services, or devices.

Should OCR modify the Privacy Rule to clarify the scope of covered entities' ability to disclose PHI to social services agencies and community-based support programs where necessary to facilitate treatment and coordination of care with the provision of other services to the individual?

Physicians lack confidence in their understanding of the current Privacy Rule and the AAFP strongly urges OCR to make the requirements clearer.

Should any changes be made to specifically allow parents or spouses greater access to the treatment information of their children or spouses who have reached the age of majority? If the Privacy Rule is changed to encourage parental and spousal involvement, what limitations should apply to respect the privacy interests of the individual receiving treatment? Should changes be made to allow adult children to access the treatment records of their parents in certain circumstances, even where an adult is not the parent's personal representative? Or are existing permissions sufficient? For instance, should a child be able to access basic information about the condition of a parent who is being treated for early-onset dementia or inheritable diseases? If so, what limitations should apply to respect the privacy interests of a parent?

HIPAA permits covered entities to disclose PHI to family members, regardless of age, if, in the judgment of the physician, it is in the best interest of the patient and the patient does not object. This allows adult children, spouses, parents and personal representatives to participate in an individual's care, but protects the ability of physicians

to provide confidential care to patients, including adolescents, when the physician believes it is in the best interests of the patient to do so. The AAFP believes existing HIPAA provisions are adequate and would oppose a change that would provide a blanket increase in access for parents or spouses. These kinds of changes could inadvertently put physicians in a difficult situation if they believe disclosure would be harmful to the patient. Lack of understanding and education regarding what is currently permitted under existing HIPAA rules should be addressed and clarified by OCR

What use, if any, do covered health care providers make of the signed NPP forms, or documentation of good faith efforts at securing written acknowledgments, that the Privacy Rule requires providers to maintain?

Most practices merely view this effort as a hurdle to protect themselves from lawsuits or penalties. The AAFP supports eliminating or modifying the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of receipt of a provider's notice of privacy practices (NPP).

What benefits or adverse consequences may result if OCR removes the requirement for a covered health care provider that has a direct treatment relationship with an individual to make a good faith effort to obtain an individual's written acknowledgment of the receipt of the provider's NPP? Please specify whether the benefits or adverse consequences would accrue to individuals or covered providers.

Removing the written acknowledgement requirement would reduce administrative burden, such as the need to administer, store, update and monitor compliance. A potential adverse consequence could be expanding the liability borne by physicians. To alleviate this threat OCR should publish appropriate safeguards to ensure patients can access information contained in an NPP as easily and clearly as possible, such as through simply posting a notice or supply of NPPs in the office.

Do covered entities use these model NPPs? Why or why not?

Many practices use model NPPs since they lack the time to develop their own. However, the NPP is unclear to most patients and does not provide meaningful choice or control for patients over their information. OCR could describe uses and disclosures in a brief, easy-to-understand document developed to enhance patient understanding and make the document available in multiple languages.

e. Additional Ways to Remove Regulatory Obstacles and Reduce Regulatory Burdens to Facilitate Care Coordination and Promote Value-Based Health Care Transformation
Summary

OCR seeks additional recommendations on how to amend the HIPAA Rules to further reduce burden and promote coordinated care.

AAFP Response

Since HIPAA is tremendously complex for practicing physicians, we urge HHS to make privacy and security safeguards effective, practical, flexible, and affordable to implement. We encourage HHS to remove the presumption of guilt (i.e., breach) when unsecured PHI is inappropriately used or disclosed by covered entities and business associates. The presumption of guilt on covered entities creates potentially unnecessary burden, stress, and compliance costs for physicians. Instead, HHS should base the duty to report a breach on a harm threshold.

An unauthorized use or disclosure of unsecured PHI should be reported only if the use or disclosure poses some harm to the affected individual(s). OCR should also clearly indicate that a breach notification is not required when a covered entity performs a risk assessment and determines that there is minimal risk of harm due to an impermissible use or disclosure of unsecured PHI.

In conclusion, the AAFP appreciates HHS' efforts to preserve and protect the privacy and security of a patient's health information. The AAFP would strongly oppose any mandate or requirement to disclose PHI to another covered entity for any purpose other than for treatment purposes, except where such disclosures would conflict with a patient's right to privacy. We appreciate the opportunity to comment. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 rbennett@aafp.org with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Michael Munger MD". The signature is written in a cursive style with a stylized "M" at the end.

Michael L. Munger, MD, FAAFP
Board Chair

About Family Medicine

Family physicians conduct approximately one in five of the total medical office visits in the United States per year—more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.