



February 11, 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: RIN 0945-AA00 – Request for Information on Modifying HIPAA Rules To Improve Coordinated Care

Dear Secretary Azar:

America's Physician Groups (APG) appreciates the opportunity to assist the Office for Civil Rights (OCR) and the Department of Health and Human Services (HHS) in identifying provisions within the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that may impede our nation's movement toward a value-based health care system. APG believes that current HIPAA rules can be revised to further promote coordinated care between covered entities while continuing to protect the privacy and security of patients' protected health information.

APG is a professional association representing over 300 physician groups nation-wide. Our tagline, "Taking Responsibility for America's Health," truly represents our members' vision and efforts to improve the health of the patients and communities they serve by practicing accountable, coordinated care through value-based alternative payment models. Our preferred model of capitated, managed care avoids incentives for the high utilization and siloed care planning associated with traditional fee-for-service reimbursement. Instead, our model aligns incentives for physicians to provide the right care, at the right time, in the right setting, thus improving the health of entire populations – particularly chronically ill and fragile individuals. We hope that by making common sense modifications to HIPAA, we can encourage a system that treats the whole patient and helps erase the stigma of mental health disease and substance abuse disorders.

HIPAA modified existing law to further protect individuals' medical records and other individually identifiable health information, a mission that APG fully supports. However, as advances in medicine and new technology become more integrated, so too must existing law be modified to ensure that regulatory obstacles do not impede provider access to the information needed to provide value-based and coordinated health care.

Summary of APG's Comments

- **Promoting Information Sharing for Treatment and Care Coordination** – APG supports expanding the Privacy Rule to cover the sharing of medical records between care providers who are not within the same system or practice. Requests must be actively acknowledged and the electronic medical record (not paper) should be available through the eHealth exchange for the provider's use within five calendar days (or another acceptable deadline).
- **Promoting Parental and Caregiver Involvement and Addressing the Opioid Crisis and Serious Mental Illness** – APG supports modernizing HIPAA with respect to the disclosure of substance use disorder or mental health disease information without requiring explicit written consent in certain circumstances.
- **Accounting of Disclosures** – APG opposes a mandate that requires providers must report disclosures made for Treatment, Payment and Healthcare Operations (TPO) purposes in an electronic health record and that this must also be reported to patients.
- **Notice of Privacy Practices** – APG supports eliminating the requirement that providers gather written acknowledgment from patients when they receive their Notice of Privacy Practices (NPP) when that acknowledgement is documented in the medical record.
- **Additional Ways To Remove Regulatory Obstacles and Reduce Regulatory Burdens To Facilitate Care Coordination and Promote Value-Base Health Care Transformation** – APG believes the Privacy Rule, with its current requirements for patient notification and reporting and the potential modification to include TPO reporting and accountability, creates burdens and unnecessary obstacles to achieving HHS Office of National Coordinator Electronic Health Record (EHR) interoperability and Meaningful Use goals. APG recommends that HHS develop more effective communication tools for the patients to understand the implications of “opt-out” of sharing information within Health Information Exchange (HIE). Additionally, the authorization form to release information should be modified to contain clear, simple, and patient-facing language. HHS should explore the designation of an CIN/IPA as an OHCA (organized health care arrangement) to promote data sharing.

Promoting Information Sharing for Treatment and Care Coordination

Under the HIPAA Privacy Rule, patients have the right to access and obtain a copy of their protected health information (either electronic or hard copy) within 30 days after a request is made. APG supports this but believes the Privacy Rule should be modernized to better facilitate case management and care coordination.

As new health care delivery system models evolve, the flow of information among and between providers is critical. Case managers and care coordinators are often integral in assuring that care amongst various providers is coordinated, expedited, and appropriately delivered to meet individual patient needs, particularly for complex cases. Providers, on behalf of their patients, should have timely access to their patients' records.

There currently is no deadline or requirement to disclose records when requested by another provider. Not having such a requirement impedes value-based coordinated care and can be dangerous to patients – especially those with behavioral health needs. We recommend that providers (who have already received authorization from the patient) can receive the complete electronic medical records from other providers within 48 hours of request unless a critical situation is present. The current standard of 30 days (both electronic and paper) for a formal request from patient should be modified to five calendar

days from providers with electronic medical records (or another acceptable deadline) that are participating in standards-based health information exchange programs for the sole purpose of care coordination. Other purposes such as legal or insurance purposes can remain at 30 days to transfer medical record information.

Requests between providers, especially regarding behavioral health, can often go unfilled and many APG members have faced difficulty obtaining comprehensive records needed to fully understand individual care needs. Behavioral health has a significant impact on the cost of care and care outcomes. It is important we find ways to make the sharing of behavioral health information between key providers less burdensome.

Other issues that are impacting the transfer of timely information for care coordination among providers include the lack of national standards for information disseminated through the HIE. This allows some facilities to filter large amounts of information hindering quality care. Even the most open HIEs will limit access to only some information rather than viewing the entire treatment history (e.g. test name but not report narrative, ECG tracings, radiology images) which leads to duplicative services and potentially misdiagnosis.

Additionally, providers are receiving conflicting recommendations from accrediting agencies regarding if the Privacy Rule extends to separate facilities under the same ownership. For example, if a patient gives access to a single hospital, this does permit the provider to access information from all hospitals under the same corporate ownership. Some providers, facilities, and regulatory/ accreditation bodies are defining it very narrowly thus preventing timely exchange of urgent information due to the “minimal access” standard based upon purpose of the request in the Privacy Rule.

APG supports expanding the Privacy Rule to cover requests for records between care providers. Requests must be actively acknowledged and fulfilled in a timely manner (less than 48 hours) and records should be automatically sent to a new provider if that new provider can document (via health plan primary care assignment or an attestation mechanism to be implemented) that they are truly delivering the care. The active acknowledgment of requests is critical.

In terms of care under emergency situations, the flow of information in the HIE should be swift and transparent. Currently, providers are experiencing significant delays while attempting to gather time-sensitive information and while navigating the filters of the HIE. Once an emergency condition has been identified, the providers should have broad latitude in accessing information in the HIE. HHS should develop clear guidance on type and speed of electronic data sharing among providers in an urgent situation.

Promoting Parental and Caregiver Involvement and Addressing the Opioid Crisis and Serious Mental Illness

The Privacy Rule allows for the disclosure of medical records to caregivers in certain circumstances, including certain emergency circumstances. We encourage separate OCR rulemaking to improve the flow of information between providers, covered entities, and family caregivers in the interest of promoting timely and efficient EHR interoperability, and the implementation of Meaningful Use and care coordination.

APG wrote in support of H.R. 6082, the Overdose Prevention and Patient Safety Act and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations (CFR) 2 which

governs confidentiality of drug and alcohol treatment and prevention records. However, we believe that modifications should be made to this legislation to enhance care coordination. As it stands, the bill authorizes the disclosure of substance use disorder patient records without a patient's written consent to: (1) a covered entity for the purposes of treatment, payment, and health care operations; and, (2) a public health authority, if the content of the disclosure meets current HIPAA standards regarding de-identified information. HIPAA could be modified to include the above changes specific to both substance use disorders and serious mental illness as part of the overall statute.

Currently, patients are required to give multiple consents, creating a barrier for integration and coordination of health care. A lack of access to the full scope of medical information for each patient can result in the inability of providers and organizations to deliver safe, high-quality treatment and care coordination. We recommend that if an initial patient authorization to share and disclose behavioral health information is obtained and documented in a medical record, that be considered sufficient permission to share behavioral health information with other key providers of care without the need for additional patient consent. This should include a one-time notification to the patient of their right to modify this authorization at any time.

Additional interim guidance from HHS would be helpful regarding distribution of the above information covered under 42 Code of Federal Regulations (CFR) 2 which includes substance abuse treatment. Some plans interpret this section narrowly as only data regarding services “directly” provided by Part 2 providers are withheld, while other plans have a very broad definition including information from any diagnosis or procedure code that may slightly indicate services by Part 2 providers are withheld. Clear guidance by HHS would be helpful in resolving this inconsistency.

Accounting of Disclosures

APG does not recommend HHS mandate the reporting of TPO medical record disclosures within an electronic medical record and to patients as the benefits to patients does not appear to outweigh the burden on providers.

The Privacy Rule mandates that covered entities provide an accounting of the medical record disclosures when requested. Certain disclosures are excluded, including TPO. Congress has directed HHS to modify the Privacy Rule to require an accounting of disclosures, include those made for TPO purposes and those that can be done through an electronic health record and be made available to patients. While APG appreciates the spirit of this intent, we are concerned this will unduly burden our members with little actual benefit to patients. This type of disclosure information does little to improve care coordination, reduce health care costs, improve the patient experience, or improve the health of populations. As indicated in the RFI, when HHS initially sought feedback in 2011, there was overwhelming pushback. Little has changed since that time to improve the ability of providers to comply with this requirement. This is especially true for our members who have their own EMRs, which are designed to focus more on individual patient care planning and overall population health rather than billing workflows.

Notice of Privacy Practices

The Privacy Rule requires covered providers and health plans to develop a NPP that describes individuals' health information privacy rights and how their health information may be used and disclosed by a covered entity. Providers must provide the NPP to individuals by the date of first service

delivery, provide it to any individual upon request, and make a good faith effort to obtain a written acknowledgement of receipt. APG believes that obtaining written acknowledgement from the patient of NPP receipt does little to ensure that he or she is adequately informed and adds an additional layer of administrative burden for providers. It also creates a manual process that impedes the smooth flow of EHR data between providers entities. Therefore, we recommend this requirement be eliminated or that a one-time NPP, acknowledged by the patient and documented in the medical record, be permitted with no requirement to issue future NPPs.

Additional Ways To Remove Regulatory Obstacles and Reduce Regulatory Burdens To Facilitate Care Coordination and Promote Value-Base Health Care Transformation

OCR is seeking public input on ways to modify HIPAA to facilitate efficient care coordination and/or case management and promote the transformation to value-based health care. APG is supportive of HHS's efforts to foster EHR interoperability across the country as described by the Office of The National Coordinator for Health Information publication " Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap." Interoperability is defined by ONC as:

According to section 4003 of the 21st Century Cures Act, the term 'interoperability,' with respect to health information technology, means such health information technology that— "(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; "(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and "(C) does not constitute information blocking as defined in section 3022(a)."

Additionally, APG believes the HHS ONC mandated goals of Meaningful Use creates a call to action to assure the Privacy Rule does not create unnecessary impediments to achieving the HITECH goals stated below:

Meaningful Use Criteria

Stage 1 Data Capture and Sharing	Stage 2 Advance Clinical Processes	Stage 3 Improved Outcomes
<ul style="list-style-type: none"> • <i>Electronically capture health information in a standardized format</i> • <i>Use that information to track key clinical conditions</i> • <i>Communicate that information for care coordination processes</i> • <i>Initiate the reporting of clinical quality measures and public health information</i> 	<ul style="list-style-type: none"> • <i>More rigorous HIE</i> • <i>Increased requirements for e-prescribing and incorporating lab results</i> • <i>Electronic transmission of patient care summaries across multiple settings</i> • <i>More patient-controlled data</i> 	<ul style="list-style-type: none"> • <i>Improve quality, safety, and efficiency, leading to improved health outcomes</i> • <i>Decision support for national high-priority conditions</i> • <i>Patient access to self-management tools</i> • <i>Access to comprehensive patient data through patient-centered HIE</i> • <i>Improve population health</i>

Stage 1 Data Capture and Sharing	Stage 2 Advance Clinical Processes	Stage 3 Improved Outcomes
<ul style="list-style-type: none"> • <i>Use information to engage patients and their families in their care</i> 		

HIE = health information exchange.
Source: ONC

Through HIPAA, patients have specific rights over their medical records which include obtaining copies, requesting corrections, receiving notices about how health information is used, determining how and where the patient will be contacted, and filing a complaint if any of these rights have been violated. All of these rights are detailed in NPPs, which must be provided to patients when the present at a hospital or physician’s office. EHR requirements include:

- “Access controls” (i.e. passwords and PIN numbers) that help limit access to patient information;
- “Encrypting” stored information so health information cannot be read or understood except by someone who can “decrypt” it using a special “key” made available only to authorized individuals;
- An “audit trail,” which records who accessed a patient’s information, what changes were made and when; and,
- If a patient’s data has been seen by someone who should not see it, federal law requires doctors, hospitals, and other health care providers to notify the patient of a “breach” of health information.

We believe that HIPAA should be modified to align with and support the goals of Meaningful Use and EHR interoperability, but without resulting in additional provider burden. It is essential that the conditions under which protected health information is transmitted are addressed so that it is consistent and supportive of the patient’s right to privacy and security but does not impede or confound efforts to achieve and develop Meaningful Use and interoperability. Currently, multiple repeated requests/requirements for patient authorization and reporting of disclosures must occur before electronically communicating patient care data. This truly inhibits the fluidity, ease, and timeliness of data transmittal. A mandate to report all TPO disclosures will make this effort even more complicated.

EHR requirements regarding data protection are already rigorous and comprehensive. APG believes capturing a one-time written authorization for using a patient’s records from the patient and storing this in the medical record is sufficient to cover the sharing of medical records in most situations (i.e. between providers, for TPO purposes, research, behavioral health etc.).

State laws also hinder the timely transfer of patient information, with some state laws indicating that the medical records are the “property” of the physician. This has prevented patients from receiving their records in a reasonable amount of time, and, at times, patients have incurred substantial costs in obtaining these records when a simple electronic transfer could have been achieved.

Patients are selecting to “opt-out” of sharing information within the HIE without fully understanding the impact of the decision. Providers need better materials to educate patients on the benefits and the security measures found in the HIE. For example, patients are often surprised to find that when they “opt-out,” emergency physicians are unable to quickly query lab tests done previously from another provider (thus requiring a duplicative test).

The authorization of the release of information is extremely complex and long due to the nine elements required on the forms. The authorization form must be shortened, and the language modified so it is easy for patients to understand.

Another point of confusion is regarding inclusion of CINs as an OHCA. Designating a CIN/IPA as an OHCA would promote data sharing and avoid current inconsistencies among legal authorities advising the CINs. This would facilitate transfer of information among CINs that are in risk-based arrangements like Accountable Care Organizations (ACOs).

Conclusion

APG applauds OCR and HHS for soliciting stakeholder feedback on ways to improve care coordination while maintaining and respecting patient privacy and ownership of protected health information. We thank you in advance for your consideration and appreciate the opportunity to submit these comments. Further, we offer ourselves and our members as a resource to you as you continue to work to strengthen and improve coordinated care in our nation. Please do not hesitate to contact me or my Federal Affairs staff (Valinda Rutledge, VP of Federal Affairs vrutledge@apg.org; Margaret Peterson, Director of Federal Affairs mpeterson@apg.org) with any questions you may have.

Sincerely,

Donald H. Crane
President & CEO
America's Physician Groups