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

Submitted electronically

Re: RIN 0945-AA00: Request for Information on Modifying HIPAA Rules to **Improve Coordinated Care**

Dear Mr. Severino:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, appreciates the opportunity to respond to the Department of Health and Human Services Office for Civil Rights' request for information on modifying the Health Insurance Portability and Accountability Act to improve coordinated care.

HANYS' members are committed to implementing innovative healthcare reforms, such as New York's Delivery System Reform Incentive Payment program and other value-based payment initiatives. As these programs mature, there is an increased need for secure, timely and robust exchange of clinical data within our communities and across New York State, including through the Statewide Health Information Network for New York.

HANYS believes it is important to maintain patient privacy while facilitating efficient care coordination and transformation to value-based care. Yet, the ability of HANYS' members to accomplish these goals is unnecessarily restrained by the complicated patchwork of federal and state laws that cause confusion and disruption of care. This has significantly limited the robust sharing of patient information necessary to coordinate clinical treatment and promote population health objectives.

HANYS therefore respectfully urges the Office for Civil Rights to prioritize: (i) educating Congress about the significant barriers that conflicting regulations place upon providers to achieving these population health objectives; and (ii) working toward full federal preemption to ensure a more streamlined and integrated approach to patient privacy and security of patient information.

Doing so would effectively eliminate barriers to the sharing of patient information essential for care coordination, improve compatibility and the exchange of electronic information, and support performance measurements and improvement.

HANYS also offers the following specific comments to assist OCR in its efforts to reduce regulatory obstacles and administrative burdens to enable providers to better serve patients and coordinate care.

Promoting information sharing for treatment and care coordination

Under current law, sharing a patient's PHI for "health care operations" is limited solely to providers with whom the patient has a direct treatment relationship. However, this limitation is no longer sustainable as payment for healthcare services continues to move toward a value-based methodology that requires sharing patient information to coordinate care. In an integrated care setting, it is not feasible to require providers to have a direct treatment relationship with all of the organizations and providers that interact with a patient before allowing them to access and use the patient's PHI.

HANYS therefore supports an expansion of the "minimum necessary standard" for using and disclosing PHI to include all participant providers in an integrated care setting. Expanding the scope of this standard beyond treatment would promote greater flow of information between providers and covered entities, support efforts to advance care coordination and otherwise improve the provision of healthcare.

Promoting parental and caregiver involvement and addressing the opioid crisis and serious mental illness

Providers are often reluctant to disclose PHI, even when allowable, for fear of violating HIPAA. Although HIPAA currently affords providers discretion in the application of the minimum necessary standard, the lack of clear guidance from OCR often leads to concerns about potential noncompliance. This unnecessarily deters efficient care coordination and case management. HANYS urges OCR to address these concerns through updated and detailed guidance and education about permissible disclosures and uses of PHI, including timing and under what circumstances such disclosure is appropriate.

Clear and robust guidance would be particularly meaningful as providers continue to address opioid addiction and serious mental illness. Family, friends and caregivers often play an integral role in addressing and supporting patients suffering from these diseases. But if providers do not share information with other caregivers, patients may not obtain treatment and subsequently experience adverse outcomes. More detailed guidance would help providers better understand the permissible uses of PHI and increase parental and caregiver involvement in responding to these challenging circumstances.

HANYS also continues to support the full alignment of 42 CFR Part 2 with HIPAA to better ensure that patients with a history of substance use are appropriately treated by their physicians. This will ensure that providers have access to a patient's full medical history — medical and behavioral — and can fully integrate a comprehensive treatment plan that involves primary care, mental health and substance use disorder treatment. HANYS strongly

advocates for OCR to work with the Substance Abuse and Mental Health Services Administration to support legislative efforts in furtherance of this outcome.

Cybersecurity assistance

Hospitals and healthcare providers will continue to be an attractive target for cybersecurity attacks. HANYS' members devote substantial resources to monitoring, detecting and stopping these threats. Yet, despite their best efforts, cybersecurity attacks are becoming more frequent and sophisticated.

Rather than assist hospitals that are the victims of such attacks, OCR's response is often to focus on whether the hospital was at fault. Yet, in many instances, hospitals have taken significant steps beyond what is required by HIPAA to protect PHI and other confidential data. OCR's presumption that a cybersecurity attack must be the result of a lack of preparedness or failure to follow the rules requires a hospital to devote resources to proactively defending itself, rather than collaborating with OCR and other enforcement agencies.

HANYS agrees with the American Hospital Association that victims of attacks should be given support and resources, and enforcement efforts should rightly focus on investigating and prosecuting the attackers.

HANYS also supports the AHA's proposal to create a safe harbor for HIPAA-covered entities that have demonstrated sufficient compliance with cybersecurity best practices. A safe harbor would give covered entities clarity about the level of diligence they need to exercise, including when they agree to share and exchange PHI with other systems/organizations.

Patient privacy and commercial applications

Patients are using commercial applications to access their PHI with increasing frequency. The advent and requirement of promoting interoperability to support Application Programming Interfaces requires a market of commercial applications that is trusted by consumers and providers alike.

However, companies that develop and operate commercial applications often fall outside the definition of a HIPPA "covered entity." When a patient uses a commercial application to access his or her PHI from a hospital's information system, the PHI is no longer protected by HIPAA. Patients may be surprised when a commercial application company shares sensitive PHI with other parties and may seek to hold the hospital responsible if the PHI is sold or used for marketing or other purposes.

To address these patient privacy concerns, HANYS agrees with the AHA and urges OCR to work with the Centers for Medicare and Medicaid Services, the Office of the National Coordinator for Health Information Technology, and the Federal Trade Commission to provide model language for healthcare providers to use with their patients who access their PHI via a commercial application.

Maintaining timelines for responding to requests

HANYS supports the AHA's position to maintain the HIPAA privacy rule's existing timeliness requirements for responding to requests for access. Covered entities already take all

reasonable steps to respond promptly to requests. In addition, state and other legal requirements, including requirements related to electronic health record meaningful use, have already eclipsed the specific HIPAA requirements. This eliminates the need to revise the HIPAA rules to establish different timeliness standards. Any further reduction in the timeliness standard would inevitably prohibit covered entities from conducting appropriate quality reviews to ensure patients receive accurate and complete medical record documentation.

Accounting of disclosures

HANYS agrees with OCR's position that it should withdraw the 2011 Notice of Proposed Rulemaking (2011 NPRM) to implement the HITECH ACT requirement for an accounting of disclosures for treatment, payment and healthcare operations. Such a requirement would be unduly burdensome for covered entities and would fail to provide meaningful information to a patient seeking information about entities that may have accessed their PHI.

HANYS also supports the AHA's position that HIPAA already imposes sufficient accounting requirements on covered entities if they use and disclose a patient's PHI. For example, hospitals already have mechanisms to respond to specific patient questions regarding privacy and alleged misuse of PHI, including a detailed investigation by hospital staff and a listing of actions to remedy the concern and prevent potential misuse in the future.

Should OCR move forward, however, HANYS agrees with the AHA's position that any accounting requirements be limited to a three-year look-back period. HANYS also agrees that OCR should adopt the specific exclusions to the existing HIPAA accounting of disclosure requirements it proposed in its 2011 notice of proposed rulemaking, as well as those exclusions that are already codified in law.

Thank you for the opportunity to provide feedback on potential modifications to HIPAA. If you have any questions regarding our comments, please contact Cristina Batt, vice president, federal relations, HANYS, at (202) 488-1272 or at cbatt@hanys.org.

Sincerely,

Marie B. Grause, RN, JD

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President