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May 6, 2021

Robinsue Frohboese, Acting Director
Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
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:

Bi-State Primary Care Association (Bi-State) appreciates the opportunity to provide input on the Proposed Rule: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement. In general, Bi-State welcomes and encourages measures which increase transparency and access to PHI. We do, however, have some recommendations regarding this proposed rule as currently drafted.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization promoting access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 21 Federally Qualified Health Centers, one Look-Alike, one Rural Health Clinic, Planned Parenthood of Northern New England, Vermont Coalition of Clinics for the Uninsured, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in both Vermont and New Hampshire. All of our provider members provide a wide range of services, including mental health and substance misuse services and have a high level of collaboration with other providers within their community.

We appreciate the opportunity to comment on the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) notice of proposed rulemaking (NPRM) on "Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement". Bi-State encourages OCR to a) balance strengthening patient access rights with adequately safeguarding primary care practice operational concerns; b) streamline care coordination and case management activity by clarifying the limits of what PHI

health care practices can disclose to third parties; and c) develop a new Model Notice of Privacy Practices that is easier for patients to locate and comprehend, while also providing adequate support for health centers to effectively document patient awareness of privacy practices.

Health Information Technology has sometimes exacerbated health inequities; however, we believe it could, if properly applied, instead narrow health disparities by proactively enabling the health care community to more effectively coordinate care and integrate value-based, patient-centered care into the electronic health record (EHR), payment and business operations workflow.

Individual Right of Access

Bi-State supports strengthening patients' access to their PHI by allowing photographs and recordings during health care appointments.

Many communities across the U.S experience challenges accessing essential health care services due to economic, cultural, or linguistic barriers. One way our primary care practices, including health centers, can address these barriers is by providing a variety of methods for patients to inspect their PHI during health care appointments, including photographs, recordings, and notetaking. Bi-State supports OCR creating policies that will encourage patients to become more engaged during health care visits and providing additional opportunities to inspect records in person. However, it is important that the Department provides clarity on how primary care practices can establish protocols that ensure inspection will occur during mutually convenient times and do not infringe on other patients' privacy. Covered entities should be permitted to allow this type of access but also exercise judgment, where appropriate, to limit the right to inspection when not feasible.

Bi-State encourages OCR to keep the existing timeliness requirement for responding to access requests within 30 days.

Primary care providers' current practice is to respond promptly to requests, and typically these practices can do so well within the current timeline for access requests. The proposed changes to shorten timeframes for responding to access requests fail to take into account a multitude of factors, including the amount of staff time required to access the various record formats, e.g., electronic and non-electronic. Bi-State recognizes the challenges patients face when requesting access to their records and support OCR taking steps to mitigate complicated processes that impede this access as it can have a negative impact on health outcomes. We welcome guidance on the best practices for managing and timely fulfilling patients' access requests within 30 days.

Bi-State supports requiring covered entities to establish written policies for prioritizing urgent access requests to foster consistency and standardization for patient's right to access, however we request guidance in this area.

Bi-State encourages OCR to provide more clarity on best practices to establish effective and efficient written policies to prioritize urgent access requests. From the patient perspective, there are a number of requests that can be defined as "urgent". However, it is not always clear

which requests are urgent as defined by OCR. Traditionally, the medical records staff that respond to access requests do not have the requisite medical knowledge to determine what type of requests qualify as “urgent”. In addition to providing guidance to primary care practices so that they can create new policies for urgent requests, we would ask that OCR also develop trainings to educate clinical staff on how to prioritize and filter urgent requests. We would request that OCR provide sufficient time for practices to adopt these new policies and train their staff. If OCR finalizes this proposal, this requirement is another reason to keep the timeliness standard at 30 days to ensure that the urgent requests are prioritized.

Additionally, our practices value building trustworthy and respectable relationships with our communities and do not feel it is necessary to require patients to disclose the purpose of their access requests. This could erode trust in the practices. Bi-State supports patients accessing their PHI and will support our practices in their efforts to reduce barriers to timely access for all requests.

Bi-State encourages OCR to establish safe harbors for covered entities responding to a patient’s oral request to direct electronic copies of PHI in an EHR to a third party.

The proposed requirement permitting patients to make oral requests creates challenges for our primary care practices - increasing chances for miscommunication and inaccurate responses. Covered entities benefit from written requests by increasing accuracy rates and providing more opportunity to verify the requestor’s identity before disclosing PHI to third parties. Bi-State encourages practices to be cautious with receiving oral requests and take all measures to protect patients’ PHI. We support verification requirements that do not create additional barriers to care and welcome culturally competent guidance from OCR on verifying patients’ identities. If this proposal is finalized, OCR should establish safe harbors for covered entities that chose to not disclose a patient’s oral request to disclose electronic copies of PHI in an EHR to a third party based upon valid concerns about the access request. OCR should clarify that a covered entity may require patients to request access through a different format (written, portal, etc.) if the initial oral request does not meet the covered entity’s verification procedure. Additionally, OCR should provide guidance on best practices for handling oral requests, record keeping, and coordinating with third parties. Our primary care practices value their relationship with community partners and work to ensure they protect patient’s PHI while honoring requests for access.

Disclosures for Care Coordination and Case Management

Care coordination is the process of working in a coordinated way with community partners (social services, counselors, pharmacies, and others) to support the full range of health needs for patients. It involves several parts, including: identifying the patients who are or who may get the sickest; sharing information among involved health care stakeholders; and managing the patient’s use of care to prevent unnecessary services. A primary care practice’s ability to manage and control higher-risk patients through the full range of their care needs leads to better health outcomes. It may include tracking referrals, working with the pharmacy to manage a patient’s medication use, and aligning treatment plans when there are several health issues. It is a way to build better care plans, prevent care gaps, and prevent emergency room

(ER) visits. It is also a way to help patients gain more self-control over their care. Bi-State applauds OCR for proposing policies that will facilitate more care coordination and better health outcomes by addressing common administrative burdens.

Bi-State supports creating an exception to the minimum necessary standard for individual-level care coordination and case management uses and disclosures.

The minimum necessary standard serves as an important protection for patients in many circumstances. However, it also acts as an obstacle to crucial information sharing between and among health care providers and health plans. Trying to balance the minimum necessary standard prior to disclosing health information often delays or inhibits the effective provision of care to individuals. Bi-State supports the creation of an exception to the minimum necessary standard because greater flexibility alleviates confusion for the disclosing provider and shifts the focus to meeting the patient's needs. OCR's proposed flexibilities could lead to more of our practices using new care coordination tools and sharing more relevant data with social services and other patient designated health support entities. Many health care providers are improving patients' wellness by partnering with social service providers and community-based organizations to improve access to food, housing, transportation, education, job training, and more. For example, if a care coordinator wanted to sign up a patient for medically-tailored meal service, this change would enable the health center to coordinate without the fear of violating the minimum necessary standard. This exception would ease administrative burdens by reducing staff time spent on determining what information should be limited and minimize liability concerns for primary care practices – allowing more time to be spent on improving patient health outcomes. OCR should provide best practices for covered entities that establish standardize approaches that limit the use of personal judgement. As covered entities are subject to extensive rules regarding how PHI may be used, we appreciate that this exception will not open the door to potentially abusive practices as such disclosures are to other covered entities.

We do, however, recommend that OCR clarify that these types of disclosures be made in the context of clear communication and shared care planning between patients and providers. We request that OCR provide more educational resources for covered entities on how to follow the minimum necessary standard when exceptions do not apply. Examples of best practices would position practices to disclose PHI more efficiently and educate patients on the type of PHI required for care coordination and case management between other health care providers and health plans.

Bi-State supports OCR's efforts to improve care coordination but encourages the Department to maintain existing patient authorization requirements when disclosing PHI to certain third parties.

Permitting covered entities to disclose PHI to a non-health care provider for individual-level care coordination and case management without a patient's authorization presents important challenges and potential unintended consequences that must be thoughtfully considered. There could be a negative impact on a patient's health outcomes and utilization of health care services if patients lose trust in their primary care providers due to a lack of assurances of

confidentiality about where and with whom their information will be shared. Bi-State encourages OCR to evaluate when patient authorization is not required in light of potential unintended consequences. Our practices prefer to involve patients in important decisions about their lifestyle and wellness because patient involvement in care decisions leads to better health outcomes. Additionally, requiring patient authorization provides patients with oversight as to how their PHI is used and disclosed. This underscores the importance of crafting policies and practices that strike an appropriate balance of facilitating information sharing for care coordination - while also preserving patient trust, privacy, and confidentiality. Bi-State requests that OCR provide guidance and best practices to covered entities related to conversations with patients about information sharing, including with whom the information will be shared; what information will be shared; and the intended purpose of the disclosure.

Bi-State encourages OCR to require covered entities to execute a written agreement that explicitly limits uses any further disclosures of a patient's PHI prior to disclosing PHI to third parties providing individual-level care coordination and case management. We encourage OCR to provide educational outreach and guidance, including a sample agreement, to help covered entities comply with this requirement.

Covered entities face many challenges when coordinating with third parties that are not covered entities because the HIPAA requirements do not extend once a patient's PHI is disclosed. It is imperative for covered entities, like primary care practices and health centers to enter upfront agreements that establish how the third party will store the PHI, their commitment to maintain the patient's privacy, and restrictions for disclosing the PHI to other entities. Bi-State is concerned that our practices could jeopardize their community reputations if patients feel they have been taken advantage of or their PHI has not been handled properly in working with third parties. For example, a covered entity could share a patient's PHI with a local women's shelter to coordinate housing for a patient. Although the covered entity is bound by the HIPAA Privacy Rule, the women's shelter would not be bound by the same legal standards. This third party could take actions with the patient's PHI that are out of the covered entities' control, such as selling the data to another company. Despite the covered entity taking the proper actions, they could be exposed to legal liability based on the patient's relationship. Bi-State encourages OCR to provide primary care practices with more guidance and educational outreach on how to draft agreements before disclosing PHI to third parties, including clarification that such relationships do not meet the definition of a business associate.

Notice of Privacy Practices

The HIPAA Privacy Rule requires health plans and covered health care providers to develop and distribute a notice that provides a clear, user-friendly explanation of patients' rights with respect to their personal health information and the privacy practices of health plans and health care providers. Our practices endeavor to maintain Notices of Privacy Practices that adequately empower patients as to the nature of the information created and maintained and their rights to exercising control over that information. Accordingly, Bi-State appreciates the proposals by OCR regarding changes to the Notice of Privacy Practices under the HIPAA Privacy Rule.

Bi-State supports eliminating the requirement for certain covered health care providers to obtain patients' written acknowledgment of receipt of the Notice of Privacy Practices.

The Notice of Privacy Practices is an important tool in helping patients understand how their PHI may be used and disclosed; however, patients often have difficulty interpreting the notice due to various linguistic, cultural, or other challenges. Our practices also find that the current HIPAA signature and recordkeeping requirements associated with the distribution of the Notice of Privacy Practices impose an unnecessary administrative burden and we appreciate modifications to these requirements. Many of OCR's proposed changes appear to be aligned with the intent to remove barriers for patients. However, the proposal to eliminate the requirement for covered entities to document attempts at notification of privacy practices triggers the liability risk for the covered entity if a patient disputes having been notified of the privacy practices. Bi-State encourages OCR to grant primary care providers the flexibility to maintain a policy for written or verbal acknowledgment of receipt of the Notice of Privacy Practices. This would allow the practice to keep a written record if they and the patient agree to such action.

Bi-State encourages OCR to develop guidance around recording patient acknowledgment of the Notice of Privacy Practices.

Our primary care practices welcome the opportunity to ease barriers to care and appreciate OCR's efforts to remove the requirement for covered entities to obtain a written acknowledgment of the Notice of Privacy Practices. However, as stated above, this triggers a potential liability issue because it could leave them open to questions about whether or not they can prove having verbal acknowledgment or discussion regarding privacy practices. Bi-State recommends that OCR develop guidance to educate health centers on precisely what types of documentation adequately demonstrate verbal acknowledgment or discussion regarding privacy practices. This guidance would apply in scenarios where practices and patients have chosen to not maintain written acknowledgment of receipt of the Notice of Privacy Practices. Such an approach would be ideal because: a) it reduces administrative burden to train staff and develop models; b) it would help to standardize practices across the country; and c) patient care will be improved because vital resources will remain focused on serving our patients, rather than being diverted towards training and program development duties.

Bi-State supports the proposed change of locating designated contact information in the earlier portions of the new Model Notice of Privacy Practices.

Bi-State members serve a unique population of patients and strive to create educational materials that convey straightforward and clear communication to them. Bi-State is eager to empower patients to understand their rights and appreciates OCR's proposal to adjust the location of designated contact person information to the Header section of the Model Notice of Privacy Practices. Placing the relevant information about how to identify designated contact persons to discuss the Notice of Privacy Practices in an easy-to-access location ensures that individuals are able to understand and make decisions based upon the information contained in the Notice of Privacy Practices. Additionally, this proposed change aligns with the Department's declared goal of improving individual's understanding of, and ability to exercise their rights

under the Privacy Rule. Bi-State encourages OCR to engage its resources around education and distribution of a new model form so that both covered entities and their patients are able to understand how this development can improve communication between providers and patients, ultimately leading to better health care outcomes.

Thank you for your consideration of these comments. Should you have any questions about these comments, please feel free to contact Georgia Maheras at gmaheras@bistatepca.org or 802-229-0002 ext. 218.

Sincerely,

Tess Kuenning

Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer