



February 12, 2019

Roger Severino, Director  
Office for Civil Rights (OCR)  
U.S. Department of Health and Human Services

RE: Department of Health and Human Services, Office for Civil Rights Request for Information (RFI) seeking input from the public on proposed modifications to the Health Insurance Portability and Accountability Act (HIPAA) Rules, especially the HIPAA Privacy Rule (RIN 0945-AA00)

Dear Director Severino:

I am the CEO of LymeDisease.org, one of the oldest and most highly respected non-profits in the nation representing the interests of patients with Lyme disease. While I am writing this on behalf of LymeDisease.org, this letter is also informed by the fact that I am an attorney who has been intricately involved with privacy and consent as a healthcare policy matter as a representative of the community, as a patient representative on federally funded big data projects, and as the Principal Investigator of the largest patient registry in Lyme disease, MyLymeData, which is IRB approved and has enrolled over 12,000 patients.

I have served as a patient representative for the Patient Centered Outcomes Research Institute and on both the Executive and Steering Committee of its big data project, PCORnet. In the latter capacity, I also chaired the Patient Council, which included representatives from six different patient organizations that reviewed privacy ethical standards and interviewed many of the nation's experts in this arena as part of its process of recommending patient-centric consent, data sharing, and privacy standards. I also served on PCORI's Expert Panel on Open Science. As the Principle Investigator of MyLymeData, one of my first tasks was to develop patient-centric privacy and data use policies for the registry which ensure that data is used for the benefit of the patient community. We call this "patient-centered open access".

Accordingly, this letter is written from a depth of experience on the patient perspective regarding the importance of ensuring that consent and privacy policies hold the patient interest at the center. In an era in which consumers and patients see their rights to keep data private eroding at a rapid rate, we believe that the OCR has an extraordinary opportunity to truly place the patient at the center in determining who uses healthcare data and for what purpose. This has to begin with transparency about the uses being made of the patient's healthcare data, obtaining consent for those uses, and providing patients with the tools necessary to hold violators accountable for privacy violations.

To do this, the OCR will need to leave behind the paternalistic notions of the past which empower others to act in what they may have deemed to be in the best interest of the patient or of the community

or for their own commercial interests. Respect for autonomy in privacy cannot be replaced by the viewpoints or interests of others—even a majority of others. The right to privacy is rooted in autonomy. It is inherently personal and cannot be exercised by anyone other than the individual concerned.

We have grave concerns about OCR's plan to amend the current HIPAA regulations to dilute or diminished patient protections by

- sharing personal health information without patient consent,
- reducing the requirement that providers obtain an acknowledgment of receipt of Notice of Privacy Practices, or
- reducing the obligation to provide patients with an accounting for disclosures of personal health information as required under the HITECH Act.

The Centers for Disease Control estimates that over 300,000 people contract Lyme disease in the United States each year. Lyme patients report significant barriers to accessing care and substantial impairment to their quality of life. (Johnson 2011, Johnson 2014) LymeDisease.org has represented the Lyme disease community for over 30 years and has earned a reputation as one of the most trusted sources of information in the community, with our website drawing over 3 million unique visitors a year. We have also conducted and published patient surveys in peer reviewed journals for the past ten years. In 2015, we launched the only national Lyme disease patient registry and research platform, MyLymeData, which has enrolled over 12,000 patients.

Between November 5, 2018 and February 2, 2019, we conducted a survey of over 1,900 patients enrolled in the MyLymeData registry on the topic of privacy, data use, trust, discrimination and stigma (Privacy Survey). The results from the Privacy Survey as well as the underlying data for relevant portions of the survey have been made available on the public data repository, Figshare. (Johnson 2019)

Unfortunately, like HIV/AIDs, mental health, and hepatitis C, patients with Lyme disease have been medically stigmatized and marginalized. Because of this, many share legitimate concerns about patient data being used to further stigmatize, diminish, and dismiss their concerns. The results of the Privacy Survey reveal that patients face disrespect and discrimination both within and outside the healthcare system. They worry that healthcare data might be used against them by employers, insurers, and other healthcare providers. Over 75% of respondents were “very” or “somewhat” concerned about the privacy of their healthcare data generally.

The stigma of Lyme disease has a profound effect on patient access to care. The majority of patients responding reported having been treated disrespectfully by a healthcare provider (74%) or having postponed or avoided medical treatment due to discrimination, disrespect or difficulty obtaining care (67%). When we asked patients about their comfort level with physicians accessing their healthcare data, most reported that they trusted the physician who treated their Lyme disease “completely” or “a lot” (75%). However, fewer than half (41%) had the same level of trust for their other healthcare providers, and fewer still (18%) for physicians not involved in their healthcare. Hence, patient consent

to share healthcare data with physicians other than their treating physicians should be expressly obtained.

Roughly half of respondents reported being “very” or “somewhat” concerned about the use of their health data by the government (56%) and pharmacies (49%), with a higher number expressing such concern about drug company data use (60%).

Over 80% were “concerned” or “somewhat concerned” that an insurer might use their healthcare data to deny coverage in the future as a pre-existing condition. Approximately half (48%) of those employed were concerned that employers might use healthcare data to limit their career opportunities. Only 26% reported having told an employer about their Lyme disease.

Given these concerns of our community, we believe that treating institutions should obtain patient consent before sharing personal health information. Furthermore, patients should be informed about their privacy rights, should be provided with an accounting of the uses of their healthcare data upon request, and should be advised about how to enforce these privacy rights.

We were struck by the tone of the Request for Information. It appears far more concerned about regulatory “burdens” imposed on providers and institutions than on the rights of patient to know how their information is being used. It also seems indifferent to the importance of providing patients with the tools to make the type of informed choices about data sharing that are essential to safeguard their right to privacy and to protect themselves against stigma and discrimination. Patients need to know who has accessed their healthcare data and why. Lyme disease patients are very concerned that healthcare data only be used for their benefit.

Unfortunately, we believe that many patients are not aware of their right to an accounting of the uses of their information and have not availed themselves of the opportunity to receive or review this data. Rather than seeking to limit the right of patients to privacy for the convenience of healthcare institutions, we encourage OCR to expand its efforts to educate patients about their privacy rights and encourage them to exercise these rights through existing processes. The OCR needs to make this procedure as seamless as possible for patients.

Accordingly, we urge the OCR to ensure that:

- Patient permission is sought for any transfer of their data,
- Patients are provided with a copy of their privacy rights and how to enforce them, and
- Patients are provided with an accounting of those who have been given their data and of the specific purpose of that disclosure and that their access to this information be the least burdensome to patients, and
- Patients are provided with information about how to enforce any violations of their privacy rights.

While technology has made the transfer of private health information quick and easy, it has also put patient privacy at risk. Patients need to understand their privacy rights and how the policies of the institutions and providers from whom they seek care will protect those rights. No personal patient data should be shared without patient consent. Finally, patients must be able to hold accountable those who are the guardians of their information. This can only be accomplished if the patient knows who their information has been shared with and the specific reason for sharing it, as reflected in the Accounting of Disclosure. Informed consent is not an obstacle to be overcome, but a fundamental ethical principle that should be respected and enforced.

Finally, I would like to leave you with a vision of what is possible in patient-driven privacy where communities of patients come together to share data to accelerate the pace of research and the quest for a cure. MyLymeData was launched in November 2015 and has enrolled over 12,000 patients who have pooled their data in the registry to permit the largest study of Lyme disease ever conducted. Last year we published our first study using this data to examine treatment response heterogeneity. (Johnson 2018)

Our dream is for this registry to link arms with other sources of data while providing the privacy safeguards our community care deeply about to ensure that data is used for the benefit of patients and only with their consent. Ideally, patients should be able to link electronic health records (EHR) from their treating physicians to their MyLymeData account. However, the technology essential for interoperability, Application Programming Interface for their EHR, either does not exist or is not available for patients to use for this purpose. For example, patients in MyLymeData who want to share their test results can do so only by providing a pdf of those results, which would need to be hand entered into the patient registry.

With the technological tools we have available today, we can (and must) do better. However, EHR providers and the institutions they serve are not currently incentivized to provide the tool to patients to share this data electronically. We encourage OCR to help change that by requiring that EHR records be made available to patients for digital sharing through API technology.

We appreciate the opportunity to submit these comments in response to the OCR Request for Information and would be happy to respond to any questions you may have at  
[ljohnson@lymedisease.org](mailto:ljohnson@lymedisease.org).

Very truly yours,



Lorraine Johnson, JD/MBA  
CEO LymeDisease.org

## References:

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