



December 21, 2015

**Comments on the Statewide Health Information Network for New York (SHIN-NY),
addition to Part 300 to Title 10 NYCRR (published Nov. 4, 2015)**

By e-mail to REGSQNA@health.ny.gov

Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237

Dear Ms. Ceroalo,

On behalf of the New York Civil Liberties Union, we submit these comments to voice deep, continuing concern for the path that New York has taken and is taking in establishing a statewide system of electronic medical records (“Statewide Health Information Network for New York,” or “SHIN-NY”).¹ As we have said since the beginning of our advocacy on SHIN-NY, the electronic sharing of medical information has the potential to significantly improve patient care. But these benefits will not be fully realized, and indeed may be undermined, if New Yorkers cannot trust that the system will protect the privacy of their health records and the confidentiality of their conversations with their health care providers. Privacy and confidentiality are the cornerstones of a functioning health care system—a recent study found that a majority of adults consider the state of their health and the medicines that they take to be “very sensitive” information, the most sensitive category of data after their social security numbers.²

We are troubled that the proposed SHIN-NY regulation published on November 4, 2015, not only failed to address many of the privacy concerns that the NYCLU has raised previously, but also eliminated certain privacy protections that existed in the prior version of the regulation released last year—including, for example, the section of the regulation

¹ The NYCLU, the state affiliate of the American Civil Liberties Union, is a not-for-profit, nonpartisan organization with eight offices and over 50,000 members statewide. The NYCLU’s mission is to defend and promote the fundamental principles, rights and constitutional values embodied in the Bill of Rights of the U.S. Constitution and the Constitution of the State of New York. The right to privacy is central to these values. The NYCLU has previously advocated for patient privacy in SHIN-NY through participation in the Department’s work groups and the submission of comments through New York’s eHealth Collaborative.

² Mary Madden, *Public Perceptions of Privacy and Security in the Post-Snowden Era*, Pew Research Center, (Nov. 12, 2014), <http://www.pewinternet.org/2014/11/12/public-privacy-perceptions/>.

that was titled “patient rights” (the former § 300.6). Rather than repeating the same detailed comments that we submitted last year, we focus these comments on highlighting several major deficiencies in the proposed regulation, including conflicts between the proposed regulation and privacy protections under state law.³

1. The Proposed Regulation Does Not Require Data Segregation Capacity.

The proposed regulation is silent on remedying one of the greatest shortcomings of New York’s current electronic health records system: the lack of data segregation capacity. *See* § 300.4(b) (imposing certain technological requirements, but not the capacity for data segregation). Data segregation allows the system to treat categories of health information differently and gives patients the flexibility to exercise granular control over the sharing of health information. For example, if a system has data segregation capacity, a person living in a small, rural town may be able to choose to disclose his general medical records to the local podiatrist while keeping private his substance abuse treatment records from years ago. A 17-year old may be able to choose to withhold her psychotherapists’ notes from her pediatrician, whom she visits with her parents. A woman seeing a doctor for a workers’ compensation claim may choose to segregate out that she sought fertility treatment—especially if she suspects that her efforts to start a family may interfere with pay raises and promotion prospects.⁴

In a system like SHIN-NY that lacks data segregation, patients are forced to choose between sharing *all* or *none* of their medical records with their healthcare providers. This all-or-nothing approach to medical records disclosure raises conflicts with New York laws protecting medical records privacy. For example, New York requires that any disclosure of a patient’s medical records to third parties, even with consent, be “limited to that information necessary in light of the reason for disclosure,” N.Y. Pub. Health Law § 18(6)—but an all-or-nothing system cannot limit the disclosure of past medical records to those records necessary for the treatment that is being sought. Neither can an all-or-nothing system comply with the specific state-law protection that limits disclosure of mental health

³ The NYCLU’s comments from last year, (“NYCLU comments 2014”) are attached as an exhibit to these comments. Last year, our comments on the proposed regulation included comments on the version of the Privacy and Security Policies and Procedures that was released at the same time. We understand that updated policies and procedures were not released at the same time as the proposed regulation this year and assume that the policies and procedures will have to be revised after the regulation is finalized.

⁴ These are not merely theoretical concerns. *See, e.g.,* Elizabeth McCarthy, *Patients Voice Growing Concerns About Privacy*, Sacramento Bus. J. (Apr. 4, 1999, 9:00 PM PDT), <http://www.bizjournals.com/sacramento/stories/1999/04/05/focus4.html> (describing experience of a woman who was seeing a physician for work-related injuries to her wrists and was shocked to discover that her medical file contained records on recent fertility treatment and pregnancy loss); Theo Francis, *Spread of Records Stirs Patient Fears of Privacy Erosion*, Wall St. J. (Dec. 26, 2006, 11:59 PM EST), <http://www.wsj.com/articles/SB116709136139859229> (describing experience of a woman whose disability claim for chronic back pain was denied because of misinterpretation of her psychotherapists’ notes which were a part of the records). *See also* Charles Orenstein, *Policing Patient Privacy: Small-Scale Violations of Medical Privacy Often Cause the Most Harm*, ProPublica (Dec. 10, 2015, 5:00 AM), <http://www.propublica.org/article/small-scale-violations-of-medical-privacy-often-cause-the-most-harm> (describing small-scale breaches that have exposed, in damaging detail, sensitive health information in patients’ medical records).

care records, even with consent, to “persons and entities who have a demonstrable need for such information,” and only if the “disclosure will not reasonably be expected to be detrimental to the patient.” N.Y. Mental Hyg. Law § 33.13(c)(7). The lack of data segregation further raises a host of problems with limiting disclosure in a way that complies with laws on minors’ consent patient information and on public health access to medical records. *See infra* Point 2, n. 11; 3.

New York’s resistance to data segregation is out of step with the growing national recognition that some level of data segregation capacity is achievable and essential to a functional electronic health records system. In 2010, the President’s Council of Advisors on Science and Technology, an advisory group of the nation’s leading scientists and engineers, concluded that data segregation—“break[ing] data down into smallest individual pieces that make sense to exchange or aggregate”—in an electronic health records system is achievable and “must be designed in from the start.”⁵ Similarly, the National Committee on Vital Health Statistics, the statutory public advisory body to the Secretary of Health and Human Services on health information policy, recommended that the federal government invest in technology that allows for “granular patient consent” and context-specific release of health care information.⁶ In 2012, the Veterans Health Information Systems and Technology Architecture (VistA) successfully tested how a medical records system with data segregation capacity could be implemented.⁷ A 2013 study found that patients want to be able to exercise granular control over sharing their own health information, and that “for privacy to have meaning, patient-directed granular control over [electronic medical records] is necessary.”⁸

Although requiring data segregation capacity may seem technologically burdensome now, it is a worthwhile—and indeed an indispensable—investment for building an electronic health records system that will best serve patients into the future. The NYCLU urges the Department to amend the proposed regulation to establish a time table for requiring data segregation capacity in SHIN-NY.

2. The Proposed Regulation Contravenes State Law Protections for Minor Consent Patient Information.

The proposed regulation imprudently gives parents the general authority to consent to the disclosure of the entirety of their minor children’s medical records, including records

⁵ President’s Council of Advisors on Sci. & Tech., *Report to the President Realizing the Full Potential of Health Information Technology to Improve the Healthcare for Americans: The Path Forward* 4 (Dec. 2010), <https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf>.

⁶ Letter from Nat’l Comm. on Vital Health Statistics (NCVHS) to Kathleen Sebelius on Recommendations Regarding Sensitive Health Information (Nov. 10, 2010), <http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf>.

⁷ *See, e.g.*, Joseph Conn, *HHS, VA Go Granular in Info Exchange Demo*, *Modern Healthcare* (Sept. 17, 2012), available at <http://www.modernhealthcare.com/article/20120917/NEWS/309179956>.

⁸ *See* Kelly Caine & Rima Hanania, *Patients Want Granular Privacy Control Over Health Information in Electronic Medical Records*, 20 *J. Am. Med. Informatics Ass’n* 7-9 (2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3555326/>.

relating to treatment that unemancipated minors received without parental consent (“minor consent patient information”), unless prohibited by “federal law or regulation.” §§ 300.5(b)(2), (b)(3)(i) (“In general, a minor’s minor consent patient information may be disclosed to qualified entity participant if the minor’s parent or legal guardian has provided authorization for that qualified entity participant to access the minor’s patient information through the SHIN-NY”).⁹ This proposal, which conspicuously refuses to acknowledge state law despite NYCLU’s prior comments, contravenes state law’s privacy protections.

First, the proposed regulation correctly recognizes that state law requires “written authorization” for disclosure of medical records even for treatment purposes, § 300.5; N.Y. Pub. Health Law § 18(6), but fails to appreciate that parental “written authorization” may not constitute meaningful and voluntary consent to disclose all of their minor children’s medical records. This is because minors have the right to consent to certain care, including mental health care and reproductive health care, without the involvement of their parents. *See, e.g.*, N.Y. Mental Hyg. Law § 33.21(c) (describing when minors can consent to outpatient treatment); N.Y. Mental Hyg. Law § 9.13(a) (permitting minors age 16 or older to consent to inpatient treatment); *Carey v. Population Servs. Int’l*, 431 U.S. 678, 693 (1977) (plurality opinion) (“[T]he right to privacy in connection with decisions affecting procreation extends to minors as well as to adults.”). When minors consent to their own care, they have the right to keep records of such treatment private from their parents. *See, e.g.*, N.Y. Pub. Health Law § 17 (prohibiting the release of medical records pertaining to a minor’s abortion or treatment for venereal disease to the parents without explicit consent from the minor); *id.* § 18 (limiting parental authority to inspect medical records of minors to records involving treatment to which the parents gave consent and to emergency treatment, and only if such access would not have “a detrimental effect on the provider’s professional relationship with the [minor], or on the care and treatment of the [minor], or on the [minor’s] relationship with his or her parents or guardian”); *see also* § 300.5(b)(3)(ii) (requiring minor children’s authorization before disclosing minor consent patient information to their parents). This means that parents may not know that minor consent patient information is in their minor child’s records, much less what that information reveals. Parents are therefore not in the position to make an informed decision to authorize the disclosure of their children’s minor consent patient information. The minors who consented to the care and who know what the records of that treatment contain are the ones who are in the position to sign a knowing and voluntary authorization for disclosure of records.¹⁰

⁹ Minors who are parents of a child, have married, or are otherwise emancipated have the right to control the disclosure of their own minors’ consent patient information under the law and under the proposed regulation. *See* § 300.5 (b)(3)(i). When referencing “minors” in these comments, we refer to unemancipated minors.

¹⁰ This is consistent with the general principle, also recognized under federal law, that the authority to control disclosure of medical records follows from the authority to consent to treatment. *See e.g.*, 45 C.F.R. § 164.502(g)(3)(i) (generally providing parents the authority to control medical records of unemancipated minors, except in certain circumstances including when the minors have consented to their own treatment under the laws); U.S. Dep’t of Health & Human Servs., Office for Civil Rights, *Guidance on Significant Aspects of the Privacy Rule: Personal Representatives* (Sept. 19, 2013) (“In general, the scope of the personal representative’s authority to act for the individual under the Privacy Rule derives from his or her authority under applicable law to make health care decisions for the individual.”),

Second, giving parents the authority to disclose minors' HIV related information even where the minors consented to their own HIV testing specifically violates New York law on HIV testing. New York law authorizes minors who have the "capacity to consent" to consent to HIV testing on their own without parental involvement or notification. N.Y. Pub. Health Law §§ 2780(5), 2781. It further limits most disclosures of the HIV testing information except with the specific written authorization from the subject of the test with the capacity to consent—i.e., the minor if the minor had consented to the testing in the first place. N.Y. Pub. Health Law § 2780(9); § 2782(1).

The Department cannot circumvent this protection by declaring in its proposed regulation that any access of minors' patient information through the SHIN-NY will always be "deemed necessary to provide appropriate care or treatment to the minor." § 300.5(3)(i). Although New York law permits disclosure of HIV related information to other healthcare providers "when knowledge of the HIV related information is necessary to provide appropriate care or treatment to the protected individual," N.Y. Pub. Health Law § 2782(1)(d), this section implies that there are times when disclosure of HIV related information is not necessary for treatment purposes and calls for a context-specific determination as to the necessity of disclosure. The proposed regulation violates the HIV confidentiality law by attempting to undermine the strong protections that the Legislature gave to this highly sensitive information.

For these reasons, the proposed regulation's approach to minor consent information must be revisited as it currently conflicts with state laws that protect minors' rights to confidential health care. *See Matter of Jones v. Berman*, 37 N.Y.2d 42, 53 (1975) ("Administrative agencies can only promulgate rules to further the implementation of the law as it exists; they have no authority to create a rule out of harmony with the statute." (citations omitted)). Minors should, as a general matter, have control over the sharing of their minor consent patient information. This is a logical rule that could be implemented in a system with data segregation capacity.¹¹

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/personalreps.html>; Sarah Rosenbaum et al., *Health Information Law in the Context of Minors*, 123 Pediatrics S116, S117 (2009) ("The power to control health information can be thought of as a logical extension of the right to privacy and autonomy in health care decision-making."),

http://pediatrics.aappublications.org/content/123/Supplement_2/S116.

¹¹ The proposed regulation correctly recognizes that minor consent patient information may not be disclosed to parents or guardians without the parents' authorization. *See* § 300.5(b)(3)(ii). The regulation, however, does not spell out how this prohibition will be enforced in a system without data segregation capacity. As the NYCLU commented previously, a system incapable of data segregation raises complex problems and possibilities of inadvertent disclosure of minor consent patient information. *See* NYCLU Comments 2014, at 6. The regulation should at minimum require adoption of sufficient consent protocols and technology that would guard against both explicit and implicit disclosure of the existence of minor consent patient information.

3. The Proposed Regulation Authorizes Overbroad Access By Government Entities.

The proposed regulation allows certain public health disclosures without written authorization, including disclosures authorized by law to a public health authority for public health activities and to a health oversight agency for health oversight activities. *See* § 300.5(c)(2)(ii)(a)-(b). We reiterate our comments from last year that the regulation must make clear that a public health agency is entitled to access *only* that information within a patient’s medical records which it is authorized to access by law, and nothing more. *See* NYCLU Comments 2014, at 6.

This is a significant concern for the NYCLU because of the lack of data segregation capacity in SHIN-NY that, as explained above, limits sharing of data to an all-or-nothing approach. That public health agencies have the authority to access *some* health information under the law does not mean that they have the right to access *all* of the patients’ medical records. *See, e.g.,* N.Y. Mental Hyg. Law § 33.13(f) (“Any disclosure made pursuant to this section [required public health law disclosures] shall be limited to that information necessary in light of the reason for disclosure.”). SHIN-NY should not give public health agencies access to patients’ entire medical files and trust them not to abuse the capability they have to view more than what they are entitled to see.

4. The Proposed Regulation Authorizes Unlawful Emergency Access.

The proposed regulation permits disclosure to a healthcare provider without patient consent in the case of an emergency. *See* § 300.5(c)(3). Although the NYCLU believes that such access in an emergency may be warranted in most circumstances, we reiterate our previous comments that nothing in current law authorizes such access. *See* NYCLU Comments 2014, at 3. Current law permits providers to treat patients without their consent in the case of an emergency. However, the power to treat does not encompass the power to access a patient’s entire medical record—particularly when the record cannot be segregated and may contain sensitive health information that is not necessary to the emergency treatment. The NYCLU urges the Department to address emergency access to medical records by seeking legislative change and by offering patients the opportunity to opt out so that those patients who want to do so may choose to disallow access to their health information in any circumstance, including an emergency. *See also infra* Point 5.

5. The Proposed Regulation Does Not Require Consent to Upload Data or a Choice to Opt Out.

The proposed regulation codifies the misguided decision that New York made years ago to allow patient medical records to be uploaded into SHIN-NY without patient consent. It further gives health care providers the option to, but does not require them to, give patients the choice of opting out of uploading their data to SHIN-NY. *See* § 300.5(a) (“Qualified entity participants *may*, but shall not be required to, provide patients the option to withhold patient information, including minor consent patient information, from the SHIN-NY.” (emphasis added)). The NYCLU continues to be concerned that the decision to

strip patients of control over the upload of their own health information into a shared exchange may deter individuals from seeking the care that they need and undermine the benefits of an electronic health records system.

6. Certain Privacy Protections That Existed in the Prior Version of the Regulation Have Been Eliminated From This Proposed Regulation.

We were troubled to find that some of the privacy protections that existed in the prior version of the regulation released last year have been eliminated. For example:

- Former § 300.6, titled “patient rights,” a free-standing provision that emphasized the importance of certain patient rights to the electronic health records system, has been eliminated.
- Former § 300.2(a)(6), which required outreach and public education relating to SHIN-NY, has been eliminated. This is a disappointing step backward, given that the NYCLU previously flagged the importance of a robust public campaign led by the Department to educate providers and patients on the landscape of shareable electronic health records. *See* NYCLU comments 2014, at 4.
- Many of the obligations that the 2014 version of the regulation imposed on the Department are no longer obligations but options to be exercised at the discretion of the Department. *See, e.g.*, § 300.2 (describing ways in which DOH “may” establish SHIN-NY, compared to the 2014 regulation which required that DOH “shall” enter into a contract with certain minimum standards); § 300.3(a) (stating that DOH “may” establish SHIN-NY policy guidance, compared to the 2014 regulation which required that DOH “shall develop and propose SHIN-NY policy standards” as set forth in the regulation); § 300.4(f)(stating that DOH “may, as it deems appropriate” conduct audits, compared to the 2014 regulation which required that DOH “shall establish procedures for monitoring and enforcement through periodic audits”). The regulations have little force where they do not impose obligations.

These changes seriously call into question the Department’s commitment to patient privacy in establishing the electronic health records system. The Department should restore these pieces of the previous version of the regulation that prioritized privacy and consumer rights.

* * *

For the reasons stated here and in previous comments, the NYCLU urges the Department to significantly revise the proposed regulation and invest in an electronic health records system that serves the privacy needs of New Yorkers into the future. New York was a pioneer in protecting the confidentiality of medical records,¹² and should be a leader in implementing an electronic medical records system that continues to uphold patient right to privacy at its core. Thank you for the opportunity to submit these comments, and please feel free to contact Mariko Hirose at (212) 607-3322 or Beth Haroules at (212) 607-3325 if you have any questions.

Sincerely,

Mariko Hirose
Senior Staff Attorney

Beth Haroules
Senior Staff Attorney

¹² See *Wheeler v. Comm’r of Soc. Servs. of the City of N.Y.*, 233 A.D.2d 4, 8-9 (2d Dep’t 1997) (“Having pioneered the use of statutes to protect the confidentiality of medical records, New York has been zealous in safeguarding those privacy concerns.” (footnote call and citations omitted)).