

## THE WHITE PAPER: SUMMARY OF HHC CONCERNS

The attached document highlights in considerable detail the various provisions of federal and New York State law and regulations that address patient privilege and confidentiality, the necessity for and nature of the patient consent required to disclose information in the face of such confidentiality, and the fiduciary obligations—above and beyond the constraints imposed by this panoply of confidentiality statutes—of health care providers to their patients. HHC’s concerns can be summarized by the following broad points; the attached document provides the statutory detail that supports those points.

- ❖ Proposing that a blanket general consent might suffice to allow for uploading patient information into a RHIO, a proposition that in itself raises troubling issues concerning providers’ fiduciary obligations to its patients, nevertheless does not carry with it the assumption articulated in the White Paper that such consent may be “verbal” or “implied.” HHC can find absolutely no basis for this assumption.
- ❖ Underlying existing law is the concept that any disclosure of patient information to third parties would be subject to a human filtering agent. Disclosures to a RHIO are automatic and without such filters in place. Although HIPAA imposes no such restriction upon disclosures for treatment purposes, many of the New York confidentiality statutes and regulations do impose a “minimum necessary” standard, *including* disclosures for treatment.
- ❖ The White Paper fails to recognize or acknowledge that the confidentiality afforded to patient information, including personal, demographic, and financial information, is rooted in the fiduciary duty providers owe to their patients, a point underscored by the discussion of the Education Law provisions in the attached document.
- ❖ The White Paper fails to address the myriad instances within New York law in which, notwithstanding the legal grant of authority to disclose in the first instance, there is an express prohibition against *redisclosure*.
- ❖ The White Paper is inconsistent in its analysis of patient consent, beginning with the very terms it uses to describe such consent. The White Paper initially refers to “fully informed consent”; that term eventually morphs into allusions to “affirmative consent.” None of these terms is sufficiently defined. Moreover, this very ambiguity and failure to address directly the necessity for and nature of patient consent required to populate the RHIO, whether with minimal locator data or clinical information, undercuts the lengthy discussion of the White Paper’s stated primary goal of promoting public trust.
- ❖ The White Paper fails to address at all the significant issue of the use of Social Security Numbers in the wake of the recent enactment of legislation on that topic.

**New York Health Information and Security and Privacy Collection**  
**Standardized Consumer Consent Policies and Procedures**  
**for RHIOs in New York State**

**Summary of HHC Comments: Office of Legal Affairs**

**I. Various comments on applicable law and patient confidentiality**

White Paper (“WP”) page 9, line 26: Lists as a priority that “holders of consumer health information adhere to State and Federal privacy and security laws as they exchange information electronically.” However, the White Paper does not fully address current applicable law, including case law, with regard to patient confidentiality. The following are some examples that illustrate this point:

- It is the public policy of the State of New York that every patient is granted the right of “confidentiality in the treatment of *personal* and *medical* records . . . .” (Public Health Law § 2803-c[1], [3](f)(emphasis added)).
- “Patient Information” includes “any information concerning or relating to the examination, health assessment including, but not limited to, a health assessment for insurance and employment purposes or treatment of an identifiable subject maintained or possessed by a [healthcare provider] . . . .” (Public Health Law § 18[1](e)). A healthcare provider may not disclose patient information to any third party absent the presence of either written authorization by the subject or other qualified person, who must be authorized by law to have access to the particular type of patient information being sought, or a legislative or other legal exception, which must be noted in the subject patient’s medical record upon disclosure. (Public Health Law § 18[6]); see also Public Health Law §§ 17 (prohibiting the release of “records concerning the treatment of an infant patient for venereal disease or the performance of an abortion operation” to a parent or guardian of such infant), 18[3](i) (providing additional limitations on the disclosure of patient information)). There is a limited exception to the § 18[6] requirement for written authorization for disclosures “to practitioners or other personnel employed by or under contract with the facility . . . .” Since RHIOs cannot be deemed healthcare provider staff or personnel, it appears that written patient authorization is required prior to disclosure of patient information to a RHIO, including disclosure of patient information into a record locator system.
- The White Paper at page 14, line 9 does not address Public Health Law § 18[6]; instead it notes that consent “may be verbal or even implied for most types of health information . . . .” Since this appears to be inconsistent with Public Health Law § 18[6] and current case law, it raises the question whether participating providers will be subject to the penalties of Public Health Law § 12 for uploading information to a RHIO without written patient consent. (See Public Health Law § 12(b))(provides that “[a] person who wilfully violates any provision of [the Public Health Law], or any regulation lawfully made or established by any public officer or board under authority of this chapter . . . is

punishable by imprisonment not exceeding one year, or by a fine not exceeding two thousand dollars or by both.”)). Further, no examples have been provided where implied consent is purportedly acceptable, i.e., where it is necessary that the numerous confidentiality statutes, and their implementing regulations, would yield to strong countervailing policy purposes and public interests. In fact, since patient written consent can be obtained during the initial provider visit, and, in the overwhelming majority of circumstances, the initial upload of information into a RHIO, including record locator information, is not necessary for treatment provided by the initial disclosing provider, arguably the finding of a countervailing interest is unlikely because ample time is available for written consent to be obtained by the initial healthcare provider for disclosure to subsequent treating providers. Note that courts have broadly construed patient confidentiality provisions and have very sparingly abrogated such provisions. Moreover, obtaining “implied consent” is inconsistent with numerous provisions in the White Paper that highlight the importance of informed consent. Lastly, the disclosure of any patient information subject to the healthcare provider-patient privilege provisions found at CPLR §§ 4504, 4507, 4508, & 4510 without patient consent is most likely void against public policy; for these confidentiality/privilege rights belong solely to the patient, and only the patient can waive them. Note that the psychologist-patient privilege covered under CPLR § 4507 is the same as the attorney-client privilege. Although these rules of evidence provide no basis for a private right of action, they set the standard for the duty of confidentiality between a physician and his/her patient. As a result, violations of healthcare-provider privileges are actionable in tort for breach of an implied covenant of trust and confidence. And such violations are actionable for breach of contract. The White Paper is silent with respect to these issues.

- Under Public Health Law § 18[3](a), providers may review all requests for patient information made by qualified persons. Additionally, “[a] subject over the age of twelve years may be notified of any request by a qualified person to review his/her patient information, and, if the subject objects to the disclosure, the provider may deny the request.” (Public Health Law § 18[3](c)). The White Paper does not address these provisions of law.
- It is important to point out that the confidentiality that stems from a healthcare provider-patient relationship extends beyond personal and medical records. (See Public Health Law § 2805[g](3)(highlighting the confidentiality of “medical, social, personal [and] financial records of patients”)).
- Department of Health Regulations require general hospitals to “ensure that all patients including inpatients, outpatients and emergency service patients, are afforded their rights as set forth in [10 NYCRR § 405.7(b)].” (10 NYCRR § 405.7). With regard to assuring these rights, the hospital must “provid[e] patients with a copy of these rights as set forth in [10 NYCRR § 405.7(c)] and provid[e] assistance to patients to understand and exercise these rights.” (10 NYCRR § 405.7). One of these rights is the right to “confidentiality of all information and records pertaining to the patient's treatment, except as otherwise provided by law . . . .” (10 NYCRR §§ 405.7 (b)(13); see also 10 NYCRR § 405.7 (c)(13)(with respect to the patient Bill of Rights, provides for “confidentiality of all

information and records” pertaining to the patient's treatment, except as otherwise provided by law.); 42 CFR § 482.13(d)).

- Hospitals must also meet certain standards with respect to medical records. (See 10 NYCRR § 405.10 (a)(6)(mandating that hospitals maintain the confidentiality of patient records and prohibiting the release of medical records and the information contained therein to any person outside of “hospital staff involved in treating the patient and individuals as permitted by Federal and State laws.”); see also 42 CFR § 482.24)).

Department of Health Regulations (“DOH”) also grant nursing home residents certain rights pertaining to confidentiality, which are similar to those set forth in the Medicare regulations. These rights include “the resident’s right to approve or refuse the release of personal and clinical records to any individual outside the facility” unless such release is **required by law** or is necessary to facilitate resident transfer “to another health care institution . . . .” (10 NYCRR § 415.3(d)(1)(ii)(a-b)(emphasis added); see also 42 CFR § 483.10(e)(1-3); 10 NYCRR § 415.3(d)(1-3)).

If personal and/or medical information is provided to the patient locator with out the resident’s knowledge, how can the resident exercise his/her right to **approve** and **refuse** the disclosure of confidential information?

- Note that DOH regulations covering diagnostic and treatment centers also grant patients the right to “approve or refuse the release or disclosure of the contents of [their] medical record to any health-care practitioner and/or health care facility except as required by law or third-party payment contract . . . .” (10 NYCRR § 751.9(n); see also 10 NYCRR § 751.7(g)(noting that DTCs must “ensure that medical, social, personal and financial information relating to each patient is kept confidential and made available only to authorized persons . . . .”). Again, if patients have the right to refuse the release of the contents of their medical records to any provider, how can they exercise these rights if they are not aware that their information may be disclosed to a RHIO, including a record locator, for the primary purpose of facilitating access by subsequent healthcare providers and facilities?
- Home health agency regulations also allow patients to refuse release of records “to any individual outside the agency except in the case of the patient's transfer to a health care facility, or as required by law or third-party payment contract . . . .” (10 NYCRR § 763.2 (a)(10); see also 10 NYCRR § 766.1(a)(11); see, generally, 42 CFR § 484.10(d); 42 CFR § 484.48(b)).
- The White Paper does not address Medicare regulations covering the confidentiality of medical records. (See generally 42 CFR parts 482, 483, 484 & 491).
- The White Paper does not address applicable law pertaining to the restrictions on redisclosure of medical record information disclosed from participating providers to RHIO and other participating providers, namely, that redisclosure shall only take place where authorized by law. See Public Health Law § 18(6)(providing that any disclosure

made pursuant to Public Health Law § 18 “should be kept confidential by the party receiving such information and the limitations on such disclosure in [Public Health Law § 18] shall apply to such party”) see also Mental Hygiene Law § 33.13(f); Public Health Law § 2782[5]; 42 CFR part 2). The White Paper, at page 14, line 20 and page 15, line 24, does not note that the foregoing provisions require RHIOs to maintain the confidentiality of patient information received by the RHIO from participating providers. Nor do these portions of the White Paper note that pursuant to parts 400 and 405 of the Department of Health Regulations, RHIOs, where serving in the role of contractor of a particular service, must comply “with all pertinent provisions of [Chapter five of title ten of the Official Compilation of Code Rules and Regulations of the State of New York].” 10 NYCRR § 400.4(a)(3); see also 10 NYCRR 405.2(h), (1)(providing that any service furnished by a contractor must “comply with all applicable codes, rules and regulations” and must be pursuant to contract that meets the requirements of 10 NYCRR 400.4). Of course, Parts 400 and 405 also apply to hospitals and general hospitals, respectively. This requirement should be reflected in the White Paper.

- The White Paper does not cover the responsibility of RHIOs with respect to handling confidential HIV-related information. (See 10 NYCRR § 63.9(a), (c)(noting the training requirements employees of contractors must undergo prior to handling confidential HIV-related information).

## **II. Privacy, Trust, Patient Control, and Informed Consent Provisions**

Throughout the White Paper, patient trust and autonomy are underscored as being an important goals of RHIOs:

- WP page 3, line 16: Provides that “the establishment of public trust with respect to privacy and security of health information is the single most important goal of New York’s Health IT investment program.”
- WP page 7, line 2: Provides “[o]ne of the main functions of a RHIO is to act as a governor or trusted broker to . . . enforce privacy and security policies . . . .”
- WP page 8, line 28: Provides “[i]nformed consent that is meaningful, tracked and monitored is a key requirement to earning patient trust in [RHIOs].”
- WP page 9, line 25: Provides that consumer consent is a priority; specifically, “ensuring that consumers are able to provide informed and meaningful consent . . . .”
- WP page 10, line 17: Notes that one of NY HISPC Phase II project goals is to “[e]nsure that consumer consent is informed and knowing[.]”

Notwithstanding these provisions, the White Paper does not define what informed consent is. At a minimum, informed consent should include: (i) the disclosure of the risks inherent in uploading information into the RHIO in addition to the risks of not permitting such disclosure; (ii) the

benefits of participating in a RHIO; and (iii) the alternatives to the RHIO, if any. See, generally, Public Health Law § 2805-d[1]; 10 NYCRR § 405.7(b)(13). Elsewhere in the White Paper the term “affirmative consent” is used. Similarly, the White Paper does not define this term.

Other provisions in the White Paper are contrary to patient “informed consent” for RHIO participation. For instance, WP page 21, line 33 provides that release of medical record information to a record custodian is not a disclosure to a third party. This appears inconsistent with Public Health Law 18[6], which covers disclosures by a healthcare provider to any “person or entity other than the subject of the information or other qualified persons . . . .” Public Health Law § 18[6]. Equally as important, 18[6] only exempts practitioners and personnel under contract with the facility. Clearly, RHIOs are neither facility staff nor personnel. Moreover, this provision is inconsistent with WP page 14, line 8, which provides “[u]nlike HIPAA, New York State law provides no exception to [the] requirement [of a consent for disclosure] for treatment, payment or healthcare operations.” Thus, if disclosure of patient information to a RHIO is deemed part of a healthcare provider’s operations, then, at a minimum, a general written authorization for healthcare operations broad enough to cover RHIO operations (as part of a Treatment, Payment, and Operations combined authorization) is required. However, since the disclosure of patient information to a RHIO clearly affects patient autonomy, and yet, is not a required operation of the healthcare provider or necessary for the initial disclosing healthcare provider to treat the patient, there should at least be an opt out requirement or a separate written consent for such disclosure of patient information into a RHIO, including a RHIO record locator. Failure to provide one of these options does not appear to meet the trust, informed consent, patient control goals described throughout the White Paper.

### **III. Emergency “Break the Glass” Exception**

It is the public policy of the State of New York that “[e]very patient [has] the right to . . . refuse medication and treatment after being fully informed of and understanding the consequences of such actions.” (Public Health Law § 2803-c[1], [3][e]). Notwithstanding this policy, Public Health Law 2805-d does allow patients to be treated without informed consent where an emergency exists. Seemingly, disclosure of patient information attendant to such emergency is also most likely permitted. This is clearly distinguishable, however, from the case in which a subsequent treating provider accesses patient/medical, social, personal, or financial information under the break the glass exception if the information, including patient locator information, so accessed was uploaded to the RHIO without the patient’s written consent. In the latter example, unlike the former, the initial treating provider was not presented with an emergency; rather, a conscious choice was made not to obtain patient consent before uploading patient information and other confidential information into the RHIO. Simply put, if patients have the right to refuse medication and treatment, arguably patients have the right to refuse the disclosure of the corresponding medical records unless such disclosure is otherwise authorized by law.

#### **IV. The White Paper does not adequately address the disclosure of information pertaining to patients who have received mental health services**

- Even with the patient’s consent, facilities may choose not to release information that may be “detrimental to the patient . . .” (Mental Hygiene Law § 33.13(c)(7)).
- The approval of the Commissioner of Mental Health or the Director of a facility must be secured prior to disclosing clinical record information from one Article 28 facility emergency service to another Article 28 facility emergency service. The break the glass provision does not address this statute. (Mental Hygiene Law § 33.13(d)).
- The treating practitioner must be notified prior to fulfilling a request for access to or copying of a clinical record. If the provider determines that the release will cause “substantial and identifiable harm to the patient or client or others”, the treating practitioner may deny disclosure of all or part of the record. (Mental Hygiene Law § 33.16(c)[1], [3]).
- The clinical record may contain “sensitive information disclosed in confidence to the practitioner or treating practitioner by family members, friends, and other persons . . . .” (Mental Hygiene Law § 33.16(c)[3]).

#### **IV. Fiduciary and Professional Responsibility of a Physician and other licensed healthcare providers**

- Education Law § 6530[23] provides that professional misconduct includes the “[r]evealing of personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law.” This is a fiduciary responsibility licensed healthcare professionals owe to their patients. The White Paper does not examine whether a physician or other healthcare provider would be breaching their fiduciary duty to their patients, and ,thus, be subject to professional discipline under Education Law § 6509 if personal and health information is uploaded to the RHIO, including a record locator, without patient authorization.

#### **V. Disclosure of social security numbers into the RHIO**

- The White Paper should address the applicability of General Business Law § 399-dd, which restricts the use of social security numbers and “any number derived from such number.” (General Business Law § 399-dd[1]).
- The White Paper should address the responsibilities of RHIOs and participating providers with regard to breaches concerning private information, as that term is defined under General Business Law § 899-aa [1](b).