NEW YORK STATE BAR ASSOCIATION
One Elk Street, Albany, New York 12207 • PH 518.463.3200 • www.nysba.org

HEALTH LAW SECTION

The Honorable Kathy Hochul
Governor of New York State
NYS State Capitol Building
Albany, NY 12224

June 30, 2022

Re: *S1172-C/A9677: Proposed Amendments to New York's Hospital Patients' Bill of Rights*

Dear Governor Hochul:

We are writing to you about the bill S1172-C/A9677 (the "Bill"), which seeks to amend New York's Hospital Patients' Bill of Rights. We are concerned that the Bill's language creates ambiguity with respect to the interplay between federal and state law and may inadvertently increase the burden on hospitals conducting essential research in New York. We believe a more streamlined approach would better meet the legislative purpose and serve the public interest.

The Health Law Section of the New York State Bar Association ("NYSBA") supports robust protections for healthcare patients and all persons who participate in research. We have worked with policymakers and providers to help build a regulatory structure to augment the robust protections provided under the existing New York State statute and under federal law. To the extent the goal of the Bill is to ensure patients are fully informed of their existing rights without creating new rights or imposing new obligations on researchers in the State, we support it. But for the reasons discussed below, the NYSBA Health Law Section is concerned about the potential implications of the Bill as written.

The Bill would require New York general hospitals to add the following to the statement of patient rights required under Public Health Law § 2803(1)(g):

> "A right to be informed of any human subjects research that the attending physician taking care of the patient participates in and may directly affect a procedure or treatment to be received by the patient, and to provide voluntary written informed consent to participate, should the patient be an appropriate candidate for such human subjects research in the clinical judgment of the attending physician. The informed consent referred to here shall conform with federal requirements regarding protection for human research subjects, and any other applicable laws or regulations[.]"

Both New York State and federal law already regulate informed consent extensively in the context of human research. The Bill adds little if anything to existing patient protections. At the same time, its language is unwieldy and could be interpreted as imposing new burdens on hospitals to oversee physicians whose only affiliation with the hospital may be through staff privileges. This would not advance the goals of the proposed legislation or promote the consistent implementation of the existing statutory structure.

In its place, we propose the following streamlined statement, which provides a clear, concise explanation to patients of their rights while acknowledging the interplay between existing federal and state laws:

> "If you will be a human subject in human research that affects your treatment at the hospital you have the right to receive information necessary for you to provide your consent to participate in the human research and to sign a separate written informed consent to participate in that research as may be required by applicable law."

A brief discussion of specific issues and the justification for our recommendation follows.

Analysis Supporting Recommended Language:

1) ***The Bill should not conflate the rights of general health care patients with those of human subjects.***

We are concerned that the Bill inadvertently conflates clinical care, undertaken with the goal of providing therapeutic benefit to a patient, with clinical research, conducted to answer a scientific question. For example, the terms *"attending physician taking care of the patient"* and *"the procedure or treatment to be received by a patient*" may apply either to patients receiving general health care or to individuals participating in a research study. Additionally, patients receiving clinical care have a robust legal right protecting their right to provide fully informed, voluntary consent. The more streamlined statement suggested above would give hospital patients notice of their existing right to informed consent without creating confusion about the extent to which the disclosure imposes new obligations and burdens on institutions conducting research in New York.

2) ***The Bill should recognize and be consistent with other provisions of New York law addressing human research***.

First, the proposed language in the Bill uses the term "*human subjects research.*" New York law already defines the terms "*Human subject*" and "*Human research*" at Public Health Law §§ 2441(1) and (2), respectively. Federal law defines the term "*Human subject*" at 45 C.F.R. § 46.102(e)(1) and the term "*Research*" at 45 C.F.R. § 46.102(l). The proposed use of the term "*human subjects research*" in the Bill may create uncertainty as to the applicability of the federal and state law definitions. Our proposed language inserts the New York defined terms "*Human subject*" and "*Human research*" to avoid ambiguity and to promote consistent interpretation.

Second, Article 24A of the New York Public Health Law governs the protection of human subjects. Section 2445 provides that the provisions of Article 24A do not apply to the conduct of human research which is "subject to, and which is in compliance with, policies and regulations promulgated by an agency of the federal government for the protection of human subjects." This provision, a legislative acknowledgement that federal law is sufficiently protective of human subjects, allows research in New York to continue without adding the additional burden of requiring compliance with two different bodies of law, federal and state. The language of the Bill does not expressly recognize the reasonable exceptions in federal law. As a result, it could be misread to impose upon hospitals in New York – and hospitals alone among all sectors of the research community in New York –

burdens that do not apply to researchers in other states or sectors. This could impede research in New York hospitals without adding significant new protections to patients.

3) ***The Bill should recognize the framework of federal law governing protection of human subjects***.

Under the federal rules, an Institutional Review Board ("IRB") may in certain limited circumstances waive the requirement for informed consent or approve oral rather than written consent. Federal law provides for the protection of human subjects in research under a broad set of regulations known as the "Common Rule." Under these regulations, certain categories of research, for example, research involving educational tests or the observation of public behavior when the investigators do not participate in the activities being observed, 45 C.F.R. § 46.104(b)(3), are exempt from the informed consent requirement. An IRB may waive the requirement of informed consent in certain circumstances, for example, for research that presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, 45 C.F.R. § 46.117(c)(1)(ii). And an IRB may approve a research proposal providing for oral rather than written informed consent under the limited circumstances set out in the federal regulation, 45 C.F.R. § 46.116(a)). Our concern is that the Bill's language does not incorporate the federal framework in sufficiently clear terms to avoid inconsistent interpretation and implementation.

4) ***Use of the term "appropriate candidate" is subjective and could lead to unequal treatment of patients across the State***.

We believe the intent of the proposed new language "appropriate candidate" is that the hospital need offer informed consent only to those individuals who meet the inclusion criteria of a particular research protocol. The use of the term "appropriate candidate," however, is vague and does not recognize the inclusion criteria required by the scientific protocol for the research. What is deemed "appropriate" may be applied differently by hospitals across the State, resulting in an inconsistent application of patient rights and disparate treatment. Moreover, family members may deem their loved one to be "appropriate" for a study even if that person does not meet the inclusion criteria of the scientific research protocol, creating tension between healthcare providers or researchers and the patient and patient's family members. The use of an objective standard referencing the inclusion criteria of the applicable research protocol is superior, we suggest, to the subjective standard that results from the use of the word "appropriate."

For these reasons, we believe the streamlined version above more clearly safeguards patient rights without creating unintended uncertainty about the interpretation and implementation of existing laws governing human research.

At the very least, we urge that if the Bill is enacted in its current form, the approval include a message setting forth the express understanding that the provision requires notice to patients of their existing rights and does not expand those rights or affect the applicability of the existing federal and state statutory framework.

We thank you for your consideration and would be pleased to discuss these issues with you further if you believe it may prove helpful. Please contact NYSBA's Associate Director of Government

Relations, Cheyenne Burke at cburke@nysba.org if you wish to discuss these issues with the Health Law Section further.

Very truly yours,

The Health Law Section of the
New York State Bar Association