



To: New York State Bar Association Health Law Section

The New York City Bar Association supports the proposed rule-making put forth by the New York State Bar Association Health Law Section (the “Section”) in the form of a revision to 10 NYCRR 58.1.8.

Since its founding in 1870, the New York City Bar Association has grown to over 24,000 members who work for the public good through consideration of and advocacy for legal reform. The Science and Law Committee (the “Committee”) whose membership includes lawyers with backgrounds in engineering and the physical and social sciences, is committed to forward-thinking solutions to complex legal and ethical problems influenced by rapidly changing developments in the fields of science and technology. Our membership includes lawyers with extensive experience in many aspects of litigation and regulation.

We write in support of the rule-making proposed by the New York State Bar Association Health Law Section in the form of a revision to 10 NYCRR 58.1.8. We share the Section’s concerns regarding the ability of a provider to interpret clinical research results and also regarding the mechanisms for transmitting information as permitted under the proposed rule. However, we believe, as does the Section, that such concerns can be resolved via the development of stakeholder-informed guidance. We have some additional concerns we believe should also be addressed with relevant stakeholders, as described below.

Ensuring fair implementation of optional information sharing

- We recommend that guidelines be developed to ensure that research laboratories opting to share information do so in a non-discriminatory way that ensures that all clinically equivalent patients are treated in the same way. It should not be the case that only certain patients with the same clinical result are contacted. If a specific clinical result (for example a result suggesting likelihood of a serious illness) is medically significant, all study participants should reap the same benefit in the form of receiving the information, or no study participant should receive the information.

Clarifying the role of the care provider who would receive clinical results

- We recommend guidelines for care providers who would receive such information about research participants. It would be desirable to clarify a research study’s care provider’s duty with respect to the received results. May the care provider use professional judgment to determine whether to contact the patient or must the care provider alert the study participant that information was provided from the research study? What action, if any, must a care provider take if the care provider is not trained to interpret the results provided? What, if any, action should a research laboratory take to ensure the clinical results provided are clear and interpretable?

- We recommend guidelines to address the possibility of research participants who do not have a clinical care provider to designate to receive their results. It is possible, even likely, that research subjects do not have a medical provider to designate for the purpose of receiving clinical results. This is likely to exclude study participants from receiving clinical results, which would have an unfair impact on such potential study participants. We recommend exploring the option of a research laboratory having a default care provider or some other way for such participants to benefit from the optional information sharing.

Ensuring informed consent

- In cases of members of vulnerable populations who have difficulties receiving medical treatment (low-income populations, extremely rural populations, etc), their ability to potentially receive a preliminary and free diagnosis via a study should be a factor considered by research organizations in how they recruit for their studies and whether it is appropriate to advertise such clinical information. We recommend developing guidelines as to how or whether the potential for information sharing should affect study participant recruitment processes.
- There is a danger that study participants believe a research organization's option to contact their care provider means that a research organization is likely to contact their care provider. It is essential that the language provided in consent forms emphasize the optional nature of the information sharing. Additionally, it would be even more desirable to require research organizations to elect whether they will or will not share the results at the time of receiving participant consent (absent significantly changed scientific understanding or other material circumstances that might justify changing this option after a study has begun). We recommend developing guidelines regarding how and when the option for a research laboratory to share information is exercised and communicated.

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