STATE OF NEW YORK

8197

2023-2024 Regular Sessions

IN ASSEMBLY

October 27, 2023

Introduced by M. of A. SOLAGES -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to requiring clinical trials that apply for state grant funding to make certain information about such clinical trials public

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Article 2 of the public health law is amended by adding a new title 9 to read as follows:

TITLE 9

CLINICAL TRIALS

Section 269-b. Definitions.

269-c. Grant requirements.

269-d. Posting requirements.

§ 269-b. Definitions. For purposes of this title:

1. "clinical trial" shall have the same meaning as set forth in subdivision two-b of section forty-nine hundred of this chapter.

2. "health care provider" shall mean a practitioner in an individual practice, group practice, partnership, professional corporation or other authorized form of association, a hospital or other health care institution issued an operating certificate pursuant to this chapter or the mental hygiene law, a certified home health agency or a licensed home care services agency, and any other purveyor of health or health related items or services including but not limited to a clinical laboratory, a physiological laboratory, a pharmacy, a purveyor of x-ray or imaging services, a purveyor of physical therapy services, a purveyor of health or health related supplies, appliances or equipment, or an ambulance service.

§ 269-c. Grant requirements. 1. Following the effective date of this section, the commissioner shall require any sponsor of a clinical trial in this state, including but not limited to, a pharmaceutical drug

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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manufacturer, pharmaceutical drug wholesaler, academic medical center, voluntary group, federal agency or health care provider, that applies for a state grant to conduct such clinical trial, to conspicuously post certain information about such clinical trial on the department's website.

2. To the extent disclosure is permitted under federal law, the information posted in accordance with subdivision one of this section shall include, but shall not be limited to, the following:

(a) the name of all clinical trial sponsors, funders and manufacturers, including the name and contact information, as well as the institutional affiliation, of all sponsors, co-sponsors and administrators;

(b) a summary of the purpose of the clinical trial, including, but not limited to: (i) the name of the pharmaceutical drug being tested and its active ingredients, if applicable; (ii) the type of clinical trial to be conducted; (iii) the overall design of the study, including the statistical method to be employed; (iv) the status or phase type of the trial; (v) the inclusion and exclusion criteria; (vi) the treatment methods used; (vii) all hypotheses tested by the trial; and (viii) the medical condition or conditions being studied;

(c) the start date and end date of the clinical trial; and

(d) information pertaining to the clinical trial, including, but not limited to potential adverse effects of the pharmaceutical drug or biological product associated with the clinical trial.

3. The commissioner shall promulgate rules and regulations as deemed necessary to aid in the collection and posting of the clinical trial information required pursuant to this section and shall monitor the department's website for compliance with the requirements of this section.

§ 269-d. Posting requirements. 1. Following the effective date of this section, the commissioner shall require any health care provider offering a clinical trial in this state to conspicuously post certain information about such clinical trial on their website.

2. To the extent disclosure is permitted under federal law, the information posted in accordance with subdivision one of this section shall include, but shall not be limited to, the following:

(a) the therapeutic intent of the clinical trial;

(b) the name of all clinical trial sponsors, funders and manufacturers, including the name and contact information, as well as the institutional affiliation, of all sponsors, co-sponsors and administrators;

(c) a summary of the purpose of the clinical trial, including, but not limited to: (i) the name of the pharmaceutical drug being tested and its active ingredients, if applicable; (ii) the type of clinical trial to be conducted; (iii) the overall design of the study, including the statistical method to be employed; (iv) the status or phase type of the trial; (v) the inclusion and exclusion criteria; (vi) the treatment methods used; (vii) all hypotheses tested by the trial; and (viii) the medical condition or conditions being studied;

(d) the start date and end date of the clinical trial; and

(e) information pertaining to the clinical trial, including, but not limited to potential adverse effects associated with the clinical trial.

§ 2. This act shall take effect immediately.