



Prescription Policy Choices

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model policies

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### **MODEL POLICY: CLINICAL TRIALS DISCLOSURE**

(a) Short title. This article may be referred to as the “Patient Safety and Drug Review Transparency Act.”

(b) Purpose. The purpose of this Act is to disclose information regarding clinical trials of prescription drugs to the public, physicians, researchers, and state policymakers and administrators. Providing public access to information about drug trials and their results through a database accessible through the Internet is necessary to protect the public health and safety of the people of this state and to assure that the State, in its role as purchaser of prescription drugs and administrator of prescription drug programs, has the information necessary to appropriately administer those programs.

(c) Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Clinical trial" is any pharmacological, pharmacokinetic or other study of the safety or efficacy of a pharmaceutical drug, biological product or vaccine, whether or not completed in full, including but not limited to (i) a clinical investigation that involves any trial to test the safety or efficacy of a pharmaceutical drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration (FDA) as part of any application for a research or marketing permit or for any other type of application, permit, procedure or requirement of the Food and Drug Administration, including but not limited to an Abbreviated New Drug Application, an Investigational New Drug Application, a New Drug Application, non-confidential additions to the Drug Master File, Postmarketing Adverse Events Recording, or compliance with the electronic or paper Common Technical Document; and (ii) any pharmacological study subsequent to initial approval for sale by the FDA, including studies assessing potential off-label applications, new therapies, new ways of using known treatments and comparative drug trials assessing the efficacy or safety of a drug compared to other therapies.

(2) "Manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer.

(d)(1) Disclosure of clinical trials of prescription drugs. A manufacturer of prescription drugs shall make publicly available in accordance with subsection (d)(3), the following information regarding clinical trials conducted or sponsored by the manufacturer, or any entity on its behalf, for each prescription drug the manufacturer sold, delivered, dispensed, offered for sale or gave away in this State:

(A) The names of all participating organizations and funding sources of the clinical trial, including the name and contact information, including institutional affiliation, of all sponsors, co-sponsors and administrators (including the name of the principal investigators and study centers) of the clinical trial;

(B) A summary of the purpose of the clinical trial, including the name of the drug being tested and its active ingredients, overall design of the study including statistical method to be employed, status/phase type of the trial, inclusion and exclusion criteria, treatment methods to be used, all hypotheses tested by the trial, the medical condition or conditions being studied and outcomes that were evaluated;

(C) The dates during which the trial took place;

(D) Information concerning the results and outcomes of the clinical trial, which shall include, but not be limited to: potential or actual adverse effects of the drug including the frequency, severity and nature of adverse events for any trial participant and numbers of participants who discontinued participation in the trial and the reasons for such discontinuance; and

(E) Any other information necessary to assure complete information about the safety of prescription drugs taken by residents of the state included in regulations adopted pursuant to subsection (i) of this section.

(2) The disclosure requirement in subsection (d)(1) shall apply to all clinical trials completed or terminated on or after January 1, 1990, including any clinical trials completed after a prescription drug has been approved for sale by the federal Food and Drug Administration.

(3) The information required to be disclosed pursuant to subsection (d)(1) shall be posted on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website. In order to satisfy the requirements of this subsection, the publicly accessible website and manner of posting must be acceptable to the department of health and shall be a free, nonsubscription website that clearly indicates the location and instructions for downloading the files or information submitted pursuant to subsection (d)(1).

(4) Disclosure of clinical trials pursuant to this section shall include clinical trials that the manufacturer, or an entity on its behalf, initiated but terminated prior to completion. For such trials the manufacturer shall include an explanation for the termination of the trial, including but not limited to potential or actual adverse effects of the drug including the frequency, severity and nature of adverse events for any trial participant and numbers of participants who discontinued participation in the trial and the reasons for such discontinuance.

(e) Fees. Beginning January 1, 2007, each manufacturer of prescription drugs that are provided to the state's residents through the state's Medicaid program shall pay a fee of \$1,000 per calendar year to the department. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection (d)(1) and other relevant sites, assessing whether

and the extent to which the state's residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection (g). Revenues received under this subsection shall be used for this purpose.

(f) Compliance dates. A manufacturer shall post the information required by subsection (d)(1) in accordance with the following:

(i) for a drug that has been approved for sale by the FDA, within ninety days after the completion or termination of the clinical trial; or within ninety days after the effective date of this Act, whichever is later;

(ii) in the case of a clinical trial performed prior to approval for sale by the FDA, within sixty days after the date of approval for sale by the FDA, or within ninety days after the effective date of this Act, whichever is later.

(g) Public education initiative. The department of health shall undertake a public education initiative to inform residents of the state about clinical trials and drug safety information.

(h) Penalties. A violation of this section is a violation of the state's Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation. Each clinical trial registration or clinical trial results disclosure that does not fully comply with the requirements of this Act shall be treated as a separate violation.

(i) Rulemaking. The Department of Health may adopt rules to implement this section. These rules may include exempting from paying or reducing the fee required under subsection (e) of this section for a manufacturer that provides only a small volume of prescription drugs through the state's Medicaid program. Rules may specify a template or other standardized reporting format for the information required in this Act.