218A.515 Requirements for contract between department and drug developer -- Intellectual property rights and other commercial rights. (Effective July 15, 2026)

(1) Before the department may contract with a drug developer, the drug developer shall provide the department with:

(a) A detailed description of the drug developer's strategy for obtaining approval for the drug development clinical trials from the United States Food and Drug Administration and a detailed drug development clinical trial design, including a description of the composition of the consortium's drug development clinical trial team and the expertise of the team members;

(b) Protocols for clinical trial participant recruitment, patient screening criteria, administration, after-care, and post-acute treatment support;

(c) A plan to seek a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. sec. 356;

(d) Financial disclosures necessary to verify that the drug developer is prepared to meet its full obligations under this section; and

(e) Certification of an existing ibogaine drug development agreement with one (1) or more other states or state-sponsored consortiums.

(2) Before the department may contract with a drug developer, the department shall negotiate a contract requiring the drug developer to substantially agree to:

(a) Match the Commonwealth's investment in drug development clinical trials with ibogaine with an equal amount of additional funding and to devote this total amount in drug development clinical trials conducted within the Commonwealth. These trials shall exclusively use in-state clinicians, facilities, and study participants;

(b) Provide reports as specified under KRS 218A.517;

(c) Establish a plan to ensure broad and accessible ibogaine treatment access to patients within the Commonwealth following approval of ibogaine by the United States Food and Drug Administration by diverse means, including but not limited to:

1. Providing priority access to ibogaine treatment to residents of the Commonwealth;

2. Seeking third-party payor approval for ibogaine treatment within the Commonwealth;

3. Developing means of access to ibogaine treatment within the Commonwealth for uninsured and low-income individuals; and

4. Training and credentialing medical providers within the Commonwealth to administer ibogaine treatment; and

(d) Provide a plan to recognize the Commonwealth's economic interest in the intellectual property generated over the course of the multistate drug development clinical trials with ibogaine, consisting of a share of the proceeds from said intellectual property which is proportional to the Commonwealth's contribution to the total cost of the multistate drug development trials, and to

deposit the state's share of those proceeds in the ibogaine research and intellectual property fund established in KRS 218A.513 at agreed-upon intervals during the period for which the drug development clinical trials are funded and during any subsequent period of commercialization.

(3) In negotiating a contract with the drug developer, the department may agree to additional terms and make reasonable deviations from the requirements of this section as long as the resulting contract is fair and creates substantially equivalent value for the Commonwealth.

(4) For purposes of this section, intellectual property rights and other commercial rights arising from multistate drug development clinical trials with ibogaine include any of the following as related to these trials:

(a) Intellectual property, technology, and inventions;

(b) Patents, trademarks, and licenses;

(c) Proprietary and confidential information;

(d) Trade secrets, data, and databases;

(e) Tools, methods, and processes;

(f) Treatment models or techniques;

(g) Administration protocols; and

(h) Works of authorship.

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