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HOUSE FLOOR AMENDMENTS

2026 Regular Session

Amendments proposed by Representative McFarland to Engrossed House Bill No. 1223 by Representative McFarland

AMENDMENT NO. 1

On page 1, line 3, change "3310," to "3306," and delete "Early-Phase Clinical"

AMENDMENT NO. 2

On page 1, delete lines 4 through 8 and insert in lieu thereof the following:

"Clinical Trial Competitiveness and Patient Access Act; to provide for purpose; to provide for definitions; to provide for responsibilities of Louisiana Economic Development; to provide for the participation of certain entities; to provide for the sharing of information; to provide relative to external institutional review boards; to provide for reporting; to provide for rulemaking authority; to provide for funding; and to provide for related matters."

AMENDMENT NO. 3

On page 1, line 11, change "3310," to "3306,"

AMENDMENT NO. 4

On page 1, delete lines 12 through 18 and insert in lieu thereof the following:

"CHAPTER 70. LOUISIANA CLINICAL TRIAL COMPETITIVENESS AND PATIENT ACCESS ACT

§3301. Purpose

A. The purpose of this Chapter is to make Louisiana more competitive for clinical trials by supporting sponsor-facing readiness, speed-to-trial information, external central institutional review board reliance, avoidance of unnecessary duplicate institutional review board ethical review, patient access, role-based collaboration, and statewide visibility of confirmed clinical-trial capabilities, while preserving patient choice, institutional clinical authority, lawful local review, direct sponsor relationships, confidential business information, and protected health information.

B. Nothing in this Chapter shall be construed to designate any research entity, healthcare system, academic medical center, cancer program, clinical partner, affiliate, or other person as the exclusive or preferred statewide provider, gateway, broker, coordinator, sponsor-facing representative, or patient-referral destination for covered clinical projects.

C. Nothing in this Chapter shall be construed to designate, deny, confer, limit, or impair any research entity's status, role, application, partnership, eligibility, or recognition with respect to National Cancer Institute designation, National Cancer Institute-supported networks, federal grant requirements, accreditation standards, cancer-center designation standards, or other federal or private designation programs.

§3302. Definitions

For purposes of this Chapter, the following terms have the following meanings:

(1) "Confidential business information" means nonpublic trade secret, proprietary, competitively sensitive, commercially sensitive, sponsor-specific, contract-research-organization-specific, research-entity-specific, investigator-specific, or project-specific information, including trial pipelines, feasibility, recruitment, referral strategy, contracts, budgets, rates, pricing, intellectual property, commercialization strategy, site-selection strategy, sponsor strategy, or market strategy.

(2) "Contract research organization" means an organization that provides clinical research services to a sponsor or trial manager.

(3)(a) "Covered clinical project" means an industry-sponsored interventional clinical trial, or a federally supported interventional clinical trial designated by rule or voluntary written election by the research entity, involving a drug, biologic, medical device, radiopharmaceutical, diagnostic, combination product, or other product regulated by the United States Food and Drug Administration and conducted or proposed to be conducted at a site located in this state. A Phase IV clinical trial is included only if interventional and designated by rule or voluntary written election by the research entity.

(b) The term does not include a purely observational study, retrospective chart review, registry-only study, quality-improvement activity, or expanded-access treatment outside a clinical trial unless voluntarily included by the research entity or designated by rule for a limited implementation purpose.

(4) "Department" means Louisiana Economic Development.

(5) "Designee" means a public or private entity, organizational unit, contractor, or other person lawfully designated by the department to assist with administrative, technical, market-facing, or implementation functions pursuant to this Chapter. A designee shall be subject to the limitations, confidentiality restrictions, patient-data restrictions, no-gatekeeper provisions, no-forced-routing provisions, no-steering provisions, and antitrust-related limitations of this Chapter.

(6) "External central institutional review board" means an institutional review board that serves as the single institutional review board or institutional review board of record for a covered clinical project pursuant to a federally compliant reliance arrangement, is registered in accordance with applicable federal requirements, is not subject to an active federal restriction, suspension, disqualification, or enforcement action that prohibits or materially limits review of the covered clinical project, and is not the local institutional review board of the research entity conducting the covered clinical project.

(7) "Patient-identifying information" means information that identifies or can reasonably be used to identify a patient, research participant, or potential research participant, including health, biological specimen, genomic, imaging, referral, eligibility, or clinical information associated with that person.

(8) "Protected health information" has the same meaning as provided in 45 CFR 160.103.

(9)(a) "Research entity" means a hospital, academic institution, institutional healthcare provider, healthcare system, private clinical research site, research organization, cancer research program, academic medical center platform, community oncology program, pediatric research program, translational research program, or other institutional entity serving as a trial site or otherwise exercising institutional responsibility for a covered clinical project at a site located in this state.

(b) The term does not include an individual healthcare provider acting solely in an individual professional capacity and not on behalf of an institutional trial site.

(10) "Sponsor" means a pharmaceutical company, biotechnology developer, medical device manufacturer, diagnostic developer, radiopharmaceutical developer, academic sponsor, federal sponsor, foundation sponsor, or other entity advancing an investigational product.

§3303. Department role; voluntary participation; limitations

A. The department may administer this Chapter and may act through a designee.

B. The department may coordinate, verify, aggregate, and market voluntarily provided or verified Louisiana clinical-trial capabilities to sponsors, contract

research organizations, federal partners, site-selection teams, and other persons involved in clinical-trial development, site selection, patient access, or economic-development activities in a neutral, nonexclusive, and capability-based manner.

C. Department-coordinated marketing, capability-presentation, sponsor-facing, site-identification, pilot, cooperative endeavor agreement, or other implementation activity is voluntary and nonexclusive. No research entity, sponsor, contract research organization, patient, or referring provider shall be required to use or route communications through the department or its designee, or participate in such activity, as a condition of conducting, considering, referring to, contracting for, or participating in a covered clinical project.

D. A research entity may voluntarily provide capability, contact, site-readiness, speed-to-trial, or role-based collaboration information to the department or its designee for statewide clinical-trial marketing.

E. The department may enter into confidentiality agreements and other lawful agreements to support implementation of this Chapter, to the extent permitted by law. Nothing in this Chapter shall require a research entity, sponsor, or contract research organization to provide the department or its designee with patient-identifying information, protected health information, confidential business information, feasibility information, trial-pipeline information, patient or referral information, contract or budget terms, recruitment strategy, market strategy, or other competitively sensitive information except pursuant to law or voluntary written agreement.

F. Nothing in this Chapter shall authorize the department or its designee to approve or disapprove a protocol, contract, budget, local operational determination, site activation decision, patient referral, sponsor selection, contract research organization selection, site-selection decision, clinical judgment, credentialing decision, licensure determination, coverage determination, or federal research determination.

G. Nothing in this Chapter shall transfer ownership of research programs, clinical operations, faculty governance, medical judgment, licensure standards, credentialing authority, contracting authority, budget authority, institutional review authority, or clinical decision-making authority from a research entity to the department or its designee.

H. A designee affiliated with a research entity, healthcare provider, healthcare system, academic medical center, clinical partner, affiliate, or other person that competes with a research entity shall not receive, collect, access, store, transmit, or control another research entity's confidential business information, patient-identifying information, protected health information, feasibility information, trial-pipeline information, patient or referral information, contract or budget information, recruitment strategy, market strategy, or other competitively sensitive information unless each affected person provides written consent or the information is otherwise lawfully available to the designee.

I. Coordination in accordance with this Chapter shall be nonexclusive and shall not require or authorize allocation of markets, patients, sponsors, trials, investigators, service lines, territories, prices, reimbursement, contract terms, budget terms, referral sources, or commercial opportunities among research entities or other persons.

§3304. Speed-to-trial and capability information

A. The department may establish by rule or guidance categories, formats, and criteria for voluntarily provided or aggregate speed-to-trial and capability information useful to sponsors, contract research organizations, and site-selection teams.

B. Rules or guidance issued pursuant to this Section may vary by project type, trial phase, therapeutic area, trial complexity, research entity type, site capability, institutional infrastructure, sponsor or contract research organization submission completeness, or voluntary participation in department-coordinated activity.

C. No rule or guidance issued pursuant to this Section shall require final contract execution, final budget agreement, study acceptance, site activation, enrollment commitment, use of the department or its designee, or disclosure of information protected by law or contract.

D. No research entity shall be required to route sponsor or contract research organization communications, feasibility information, patient or referral information, contract or budget terms, recruitment strategy, trial-pipeline information, patient-access strategy, referral strategy, or other confidential business information through another research entity, the department, or a designee affiliated with a competing healthcare provider or research entity.

E. Nothing in this Chapter shall authorize the department, its designee, or any research entity to require a sponsor, contract research organization, patient, or referring provider to use a particular research entity, healthcare system, cancer program, clinical partner, affiliate, or designee, or to route communications, referrals, or confidential business information through a competing research entity, except with the written consent of the affected parties and as otherwise authorized by law.

F. Nothing in this Chapter shall prohibit voluntary collaboration, consolidated feasibility responses, hub-and-spoke arrangements, decentralized trial arrangements, teletrial arrangements, shared-investigator participation, specialist-access planning, community-access partnerships, local follow-up support, or patient-access support, where lawful, clinically appropriate, operationally feasible, and consistent with patient consent, privacy law, institutional credentialing, sponsor requirements, protocol requirements, and clinical judgment.

G. Nothing in this Chapter shall require a research entity to accept, open, activate, or enroll a covered clinical project for which the research entity reasonably determines that sufficient patient population, clinical expertise, investigator availability, facility readiness, staffing, data capacity, credentialing, coverage analysis, or operational capability is lacking.

§3305. External central institutional review board; local review

A. The requirements of this Section apply regardless of participation in department-coordinated activity.

B. When an external central institutional review board is designated as the institutional review board of record or has approved the covered clinical project, a research entity shall not require separate local institutional review board approval or conduct duplicate local institutional review board ethical review. Nothing in this Subsection shall limit lawful local review preserved by this Section.

C. For a first-in-human clinical trial, Phase I clinical trial, early-feasibility device trial, or dose-escalation trial, a research entity shall rely on an external central institutional review board as the institutional review board of record where permitted by law and where a federally compliant reliance arrangement is available, unless external central institutional review board reliance is prohibited by federal law, state law, or binding federal award condition, or the sponsor or its authorized representative states in writing that the research entity's institutional review board serve as the institutional review board of record.

D. A lack of a preexisting master agreement alone shall not make an external central institutional review board unavailable if a lawful study-specific reliance arrangement can be executed.

E. If an external central institutional review board has been designated as the institutional review board of record, a request pursuant to Subsection C of this Section or Paragraph (F)(1) of this Section is effective only if the sponsor or its authorized representative withdraws that designation or confirms in writing that the external central institutional review board is unavailable. If an external central institutional review board has approved the covered clinical project, local institutional review board ethical review shall not occur.

F. For a Phase II clinical trial or Phase III clinical trial, a research entity shall rely on an external central institutional review board as the institutional review board of record where permitted by law and where a federally compliant reliance arrangement is available, unless either of the following applies:

(1) The sponsor or its authorized representative requests in writing that the research entity's institutional review board serve as the institutional review board of record.

(2) The chancellor, chief executive officer, or highest-ranking executive officer of the research entity or institutional operating unit with formal legal or operational responsibility for the covered clinical project approves and signs a written project-specific exception based on one or more of the following:

(a) External central institutional review board reliance is prohibited by federal law, state law, or binding federal award condition.

(b) Extraordinary project-specific circumstances involving project feasibility, participant rights, safety, or welfare require review by the research entity's own institutional review board for that covered clinical project.

(c) A specific federal or state legal requirement requires review by the research entity's own institutional review board for that covered clinical project.

G.(1) Notwithstanding any provision of this Chapter to the contrary, this Section shall not apply to any clinical trial, clinical investigation, or study that is a Phase IV clinical trial, a Phase 4 clinical trial, or otherwise postmarketing, post-approval, post-authorization, post-clearance, or post-classification, if the trial, investigation, or study is conducted after approval, licensure, clearance, authorization, or classification by the United States Food and Drug Administration of the product for the indication or use being studied, regardless of whether the trial, investigation, or study is interventional, observational, required, requested, agreed to, or voluntary. No rule, guidance, pilot, cooperative endeavor agreement, written agreement, or other implementation material pursuant to this Chapter shall make such a trial, investigation, or study subject to this Section. Nothing in this Paragraph shall prohibit the voluntary use of an external central institutional review board when otherwise lawful.

(2) For a covered clinical project not described in Paragraph (1) of this Subsection and designated by rule, pilot, cooperative endeavor agreement, or written agreement of the affected parties, external central institutional review board reliance standards may be established by rule, pilot, cooperative endeavor agreement, or written agreement of the affected parties.

H. No approval required pursuant to Paragraph (F)(2) of this Section may be delegated. The approving official shall be the chancellor, chief executive officer, or highest-ranking executive officer of the research entity or institutional operating unit with formal legal or operational responsibility for the covered clinical project. The approving official shall not be the institutional review board chair, head of the local institutional review board, direct supervisor of the head of the local institutional review board, principal investigator, department chair, compliance officer, legal counsel, or other person primarily responsible for institutional review board administration or review, unless that person is also the highest-ranking executive officer of the research entity or institutional operating unit with formal legal or operational responsibility for the covered clinical project.

I. A written exception pursuant to Paragraph (F)(2) of this Section shall state the basis for the exception with reasonable specificity, shall be limited to the covered clinical project, and shall not establish a standing institutional exception. The research entity shall transmit the written exception, or a summary sufficient to identify the statutory basis for the exception, to the sponsor, contract research organization if applicable, and the department or its designee in a form that does not disclose patient-identifying information, protected health information, or confidential business information.

J. An exception pursuant to Paragraph (F)(2) of this Section shall not be based solely on institutional policy or preference, administrative convenience, staffing limitation, customary practice, generalized concern regarding external institutional review board review, preference for duplicate ethical review, disagreement with the use of external institutional review boards generally, or desire to control sponsor, referral, patient-access, or contracting relationships.

K. A research entity that relies on its own institutional review board pursuant to this Section shall maintain documentation supporting such reliance and report

aggregate, non-identifiable information to the department on a schedule established by rule or guidance, but not more frequently than semiannually. The report shall not include patient-identifying information, protected health information, confidential business information, sponsor-specific nonpublic information, contract-research-organization-specific nonpublic information, research-entity-specific nonpublic information, investigator-specific nonpublic information, or project-specific nonpublic information. The department may set the form and schedule for reports in accordance with this Subsection, but shall not expand, narrow, waive, or modify the institutional review board requirements, exceptions, prohibitions, or local-review protections established in this Section.

L. Nothing in this Chapter shall prohibit lawful local institutional review relating to contracts, budgets, coverage analysis, investigator qualifications, conflicts of interest, privacy, HIPAA, billing compliance, credentialing, pharmacy, investigational-drug logistics, device logistics, radiation safety, radiopharmaceutical handling, biosafety, cellular therapy readiness, BMT readiness, CAR-T readiness, gene-therapy readiness, pediatric safeguards, facility readiness, site feasibility, ancillary safety committees, local consent-language requirements, data security, scientific review, disease-group review, Protocol Review and Monitoring System review, Protocol Review and Monitoring Committee review, data and safety monitoring, clinical protocol and data management, local context submissions, or equivalent review required by law, applicable federal award conditions, accreditation standards, cancer-center designation standards, reliance agreements, or written objective institutional requirements directly related to local operational readiness, participant safety, or institutional compliance.

M. Local institutional review preserved by this Section shall not be used to duplicate institutional review board ethical review or delay a covered clinical project based solely on institutional preference, generalized practice, administrative convenience, staffing limitation, customary internal sequencing, or disagreement with external central institutional review board reliance generally.

N. Nothing in this Chapter shall require a research entity to waive or disregard legal requirements, safety obligations, federal research requirements, federal award conditions, accreditation standards, cancer-center designation requirements, reliance agreement responsibilities, or documented institutional responsibilities.

§3306. Reporting; rulemaking; funds

A. The department may require only aggregate, non-identifiable information reasonably necessary to evaluate implementation of this Chapter and may publish aggregate reports, implementation summaries, speed-to-trial information, capability information, and recommendations. Information required pursuant to this Subsection shall not include patient-identifying information, protected health information, confidential business information, sponsor-specific nonpublic information, contract-research-organization-specific nonpublic information, research-entity-specific nonpublic information, investigator-specific nonpublic information, or project-specific nonpublic information unless provided pursuant to law or voluntary written agreement.

B. Public reporting in accordance with this Chapter shall be aggregated and shall not include patient-identifying information, protected health information, confidential business information, sponsor-specific nonpublic information, contract-research-organization-specific nonpublic information, research-entity-specific nonpublic information, investigator-specific nonpublic information, or project-specific nonpublic information.

C. Nothing in this Chapter shall be construed to do any of the following:

(1) Create a state warranty of site performance, patient outcome, sponsor selection, site selection, enrollment success, clinical outcome, federal designation, regulatory approval, investment outcome, or commercial success.

(2) Create a private cause of action based solely on implementation of this Chapter.

(3) Require disclosure of information prohibited from disclosure by federal or state law or by enforceable contractual obligation.

(4) Require or authorize the department or its designee to receive, store, transmit, access, control, collect, maintain, audit, or validate identifiable patient-level data, source data, endpoint data, adverse-event data, protected health information, or patient-identifying information except as authorized by federal and state law, contract, protocol, consent, and applicable federal requirements.

(5) Create immunity from federal or state antitrust law, unfair trade practice law, fraud law, abuse law, conflict-of-interest law, procurement law, or ethics law.

(6) Require or authorize market allocation, patient allocation, sponsor allocation, trial allocation, referral-source allocation, price coordination, contract-term coordination, budget-term coordination, or service-line allocation among competitors.

D. The department may adopt rules in accordance with the Administrative Procedure Act to implement this Chapter and may issue guidance, templates, reporting formats, capability tools, confidentiality procedures, conflict-of-interest procedures, model provisions, and other nonregulatory implementation materials, but only for the department's economic-development, speed-to-trial, capability-presentation, marketing, aggregate-reporting, consultation, voluntary-program, funding, and implementation functions pursuant to this Chapter.

E. Rules or guidance may establish categories of covered clinical projects, standards for voluntarily provided or aggregate speed-to-trial and capability information, capability criteria, aggregate reporting formats, external central institutional review board reliance procedures, exception procedures, confidentiality procedures, role-based collaboration categories, hub-and-spoke models, teletrial models, decentralized trial models, patient-access criteria, voluntary program criteria, and phased implementation by project type, institution type, therapeutic area, trial phase, site, or pilot cohort. Rules or guidance shall not authorize the department or its designee to regulate clinical judgment, protocol content, site activation decisions, contracting decisions, patient referrals, sponsor selection, substantive institutional review board determinations, or local operational determinations.

F. The department shall consult with research entities subject to this Chapter, sponsors, contract research organizations, the Louisiana Department of Health, patient-access stakeholders, privacy experts, clinical-trial operations experts, and persons with relevant clinical, research, operational, contracting, regulatory, academic medical center development, biomedical innovation, or economic-development expertise.

G. Nothing in this Chapter shall be construed to require a specific appropriation of funds or the creation of new positions. Subject to appropriation and availability of funds, the department may seek, accept, and expend federal funds, grants, gifts, donations, philanthropic contributions, private contributions, cooperative endeavor funds, matching funds, and other lawful funds made available for purposes of this Chapter.

H. Subject to appropriation, available funds, and applicable law, the department may establish voluntary programs or enter into case-by-case cooperative endeavor agreements or other written agreements to support this Chapter. Before providing funds or other things of value, the department shall determine in writing that the program or agreement serves a public purpose and reasonably advances patient access, clinical-trial competitiveness, speed-to-trial, statewide capability development, rural or underserved access, academic medical center development, research investment, or another purpose of this Chapter. No program or agreement shall confer market exclusivity, require use of or routing through the department or its designee, require disclosure of information protected by law or contract, or require surrender of the right to conduct, consider, refer to, contract for, or participate in a covered clinical project independently."

AMENDMENT NO. 5

Delete pages 2 through 12 in their entirety

AMENDMENT NO. 6

On page 13, delete lines 1 through 14 in their entirety and insert in lieu thereof the following:

"Section 2. The requirements of this Act shall apply prospectively to covered clinical projects for which the initial sponsor, contract research organization, site-selection, or feasibility submission is received on or after the effective date of this Act. Requirements established by rule, guidance, capability tool, criterion, or other implementation material apply prospectively only after the effective date of that rule, guidance, tool, criterion, or material."

AMENDMENT NO. 7

On page 13, line 15, change "Section 2." to "Section 3."