2026 Regular Session

HOUSE BILL NO. 1223

BY REPRESENTATIVE MCFARLAND

ECONOMIC DEVELOPMENT: Establishes the Louisiana Clinical Trial Competitiveness and Patient Access Act

AN ACT

To enact Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 51:3301 through 3306, relative to creating the Louisiana 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.

Be it enacted by the Legislature of Louisiana:

Section 1. Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950, comprised of R.S. 51:3301 through 3306, is hereby enacted to read as follows:

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.

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.

Section 3. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 1223 Reengrossed 2026 Regular Session McFarland

Abstract: Creates the La. Clinical Trial Competitiveness and Patient Access Act.

Proposed law creates the La. Clinical Trial Competitiveness and Patient Access Act.

Proposed law provides for purpose.

Proposed law defines "confidential business information", "contract research organization", "covered clinical project", "department", "designee", "external central institutional review board", "patient-identifying information", "protected health information", "research entity", and "sponsor".

Proposed law allows the Louisiana Economic Development (department) to administer proposed law and may act through a designee.

Proposed law allows the department to coordinate, verify, aggregate, and market voluntarily provided or verified La. 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.

Proposed law provides that certain implementation activity outlined in proposed law is voluntary and nonexclusive.

Proposed law allows a research entity to voluntarily provide certain information to the department or its designee for statewide clinical-trial marketing.

Proposed law allows the department to enter into confidentiality agreements and other lawful agreements to support implementation of proposed law.

Proposed law provides that nothing in proposed law authorizes the department to take certain actions outlined in proposed law.

Proposed law provides that nothing in proposed law 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.

Proposed law provides that a designee with certain affiliation shall not receive, collect, access, store, transmit, or control certain information from another research entity unless each affected person provides written consent or the information is otherwise lawfully available to the designee.

Proposed law allows the department to 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. Proposed law provides that rules or guidance may vary.

Proposed law provides that no research entity shall be required to route certain information through another research entity, the department, or a designee affiliated with a competing healthcare provider or research entity.

Proposed law provides that nothing in proposed law 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.

Proposed law provides that nothing in proposed law 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.

Proposed law provides that certain requirements of proposed law shall apply regardless of participation in department-coordinated activity.

Proposed law provides that 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.

Proposed law provides that for certain trials 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 in certain circumstances.

Proposed law provides that 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.

Proposed law provides that if an external central institutional review board has been designated as the institutional review board of record, a request pursuant to proposed law is effective only in certain circumstances. Proposed law further requires that if an external central institutional review board has approved the covered clinical project, local institutional review board ethical review shall not occur.

Proposed law provides that 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 certain criteria.

Proposed law provides that proposed law shall not apply to certain clinical trials, clinical investigations, or studies.

Proposed law provides that for a covered clinical project not described in proposed law 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.

Proposed law prohibits the delegation of approval required pursuant to proposed law.

Proposed law requires a written exception pursuant to proposed law to state the basis for the exception with reasonable specificity, to be limited to the covered clinical project, and not to establish a standing institutional exception.

Proposed law provides for what exemptions shall not be solely based on.

Proposed law provides that a research entity that relies on its own institutional review board pursuant to proposed law shall maintain documentation supporting such reliance and report aggregate, non-identifiable information to the department on a schedule established by rule or guidance. Proposed law further provides what the report shall include.

Proposed law provides for what proposed law shall not inhibit.

Proposed law provides that local institutional review shall not be used to duplicate institutional review board ethical review or delay a covered clinical project based solely on certain circumstances.

Proposed law provides that nothing in proposed law 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.

Proposed law allows the department to require only aggregate, non-identifiable information reasonably necessary to evaluate implementation of proposed law and to publish aggregate reports, implementation summaries, speed-to-trial information, capability information, and recommendations.

Proposed law provides relative to public reporting.

Proposed law provides that nothing in proposed law 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 proposed law.

(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 certain data or information except as authorized by federal and state law, contract, protocol, consent, and applicable federal requirements.

(5) Create immunity from certain law.

(6) Require or authorize certain allocation and coordination among competitors.

Proposed law allows the department to adopt rule, guidance, and other materials to implement the provisions of proposed law.

Proposed law provides for what rules or guidance may establish.

Proposed law requires that department to consult with certain entities.

Proposed law provides relative to the appropriation of funds.

Proposed law allows the department to establish voluntary programs or other agreements to support proposed law.

Proposed law provides that the requirements of proposed law 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 proposed law. 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.

Effective upon signature of governor or lapse of time for gubernatorial action.

(Adds R.S. 51:3301-3306)

Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Commerce to the original bill:

1. Make technical changes.

2. Add language relative to legislative findings and purpose.

3. Amend the definitions of "benchmark category" and "research entity".

4. Add the definitions of "receipt" and "repeated failure".

5. Add that nothing in proposed law shall be construed to require department approval for certain actions or to transfer clinical decision-making authority from a research entity to the department.

6. Amend proposed law relative to participation in the framework and relative to entering into a participation agreement.

7. Amend proposed law relative to what shall be established in a participation agreement.

8. Provide that a participation agreement shall not waive or reduce any duty imposed by proposed law except as expressly authorized.

9. Add what may be included in the registry that may be maintained by the department or their designee.

10. Provide that compliance with proposed law shall be a condition for inclusion in certain actions by the department. Further provide relative to cooperation with certain department actions for certain benchmark categories.

11. Amend what a research entity shall do relative to acknowledgment of receipt, a sponsor feasibility response or engagement determination, concurrent review, and escalation to designated research-entity and department personnel.

12. Amend proposed law relative to the issuance of any written determination of nonreliance.

13. Add relative to lawful local review that proposed law shall not be construed to eliminate.

14. Provide that nothing in proposed law shall be construed to require a research entity to accept or activate a covered clinical project in certain circumstances.

15. Remove "admitted" from admitted covered clinical projects.

16. Amend relative to the compiled information in the annual report.

17. Amend the annual report requirements.

18. Amend relative to what may happen when a research entity demonstrates repeated failure to meet applicable benchmark expectations.

19. Add proposed law regarding benchmark categories for certain circumstances.

20. Provide that nothing in proposed law shall be construed to require the department or its designee to collect or maintain identifiable patient information except in certain circumstances.

The House Floor Amendments to the engrossed bill:

1. Make technical changes.

2. Remove legislative intent.

3. Remove the definitions of "benchmark categories", "complete submission", "participation agreement", "patient-access support", "receipt", and "repeated failure".

4. Remove certain mandatory provisions required by proposed law.

5. Remove participation agreements from proposed law.

6. Remove activation standards for covered clinical projects from proposed law.

7. Remove benchmark categories from proposed law.

8. Remove required reporting to the legislature.

9. Amend the purpose of proposed law.

10. Add the definitions of "contract research organization", "designee", "patient-identifying information" and "protected health information".

11. Amend the definitions of "confidential business information", "covered clinical project", "external institutional review board", "research entity", and "sponsor".

12. Amend the department or designee's role in administering the provisions of proposed law.

13. Amend the requirements of participation in proposed law by certain research entities.

14. Amend the requirements of coordination outlined in proposed law.

15. Change the process by which certain information is gathered and shared by the department or its designee.

16. Amend requirements regarding external central institutional review boards.

17. Add provisions relative to local review.

18. Amend state coordination relative to implementing proposed law.

19. Amend the exemptions to proposed law.

20. Amend confidentiality requirements of proposed law.

21. Clarify compliance requirements to certain laws.

22. Amend the requirements of the public reporting of certain information.

23. Amend the rulemaking authority to implement in proposed law.

24. Amend appropriation provisions to implement proposed law.

25. Add provisions relative to the applicability of proposed law.