GREEN SHEET REDIGEST

HB 1223 **2026 Regular Session** **McFarland**

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

DIGEST

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.

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Commerce, Consumer Protection, and International Affairs to the reengrossed bill

1. Prohibits proposed law from requiring or authorizing any action that is prohibited by federal law, federal regulation, or a binding federal award condition.

2. Adds nonpublic protocols to the definition of "confidential business information".