DIGEST

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HB 1223 Engrossed 2026 Regular Session McFarland

Abstract: Provides relative to the La. Early-Phase Clinical Trial Acceleration Framework.

Proposed law provides for legislative findings and purpose.

Proposed law defines "benchmark category", "complete submission", "contract research organization", "covered clinical project", "department", "external institutional review board", "receipt", "repeated failure", "research entity", "participation agreement", "patient-access support", and "sponsor".

Proposed law requires La. Economic Development (department) to administer a clinical trial acceleration coordination function within existing resources.

Proposed law provides for how the department may implement provisions of proposed law.

Proposed law provides that nothing in proposed law shall be construed to require department approval of a protocol, contract, local operational determination, or site activation decision, or to transfer clinical decision-making authority from a research entity to the department or its designee.

Proposed law provides that participation in the framework established by proposed law is mandatory for any research entity with respect to any covered clinical project conducted at a site located in this state.

Proposed law requires a research entity to enter into a participation agreement with the department or its designee.

Proposed law requires a participation agreement to establish expectations for all of the following:

(1) Benchmark categories or project types for research entities.

(2) Primary contacts and internal routing procedures for intake, contracts, budgets, institutional review board reliance, ancillary reviews, and escalation.

(3) Institution-specific addenda, if any, that supplement the standardized checklist.

(4) Local review categories that remain applicable when an external institutional review board is used.

(5) Provision of information reasonably necessary to support performance evaluation and fair distinction between institution-controlled time and sponsor-controlled time.

(6) Escalation contacts and internal accountability procedures applicable when a covered clinical project becomes stalled or repeatedly misses benchmark expectations.

(7) Any category-specific limitations, capacity constraints, or participation conditions the research entity elects to disclose.

Proposed law prohibits a participation agreement from waiving or reducing any duty imposed by proposed law except in certain circumstances.

Proposed law requires the department or its designee to publish standardized completeness checklists and intake procedures for covered clinical projects within benchmark categories.

Proposed law provides for coordination between the department and other entities to implement the provisions of proposed law.

Proposed law allows the department or its designee to maintain, subject to applicable confidentiality protections and participation agreements, a registry of research investigators, sites, benchmark categories, and verified operational capabilities for use in sponsor, contract research organization, and site-selection coordination. Proposed law further provides what may be included in the registry.

Proposed law allows the department or its designee to facilitate lawful referral, navigation, and patient-access support activities in coordination with research entities and community providers.

Proposed law requires compliance with proposed law to be a condition for inclusion in any department-coordinated feasibility response, site-identification effort, sponsor-facing coordination, or presentation of verified capabilities conducted by the department or its designee.

Proposed law requires that certain benchmark categories designated by rule or guidance to cooperate in department-coordinated feasibility review, de-identified prescreening, referral pathways, and specialist-access planning, subject to applicable privacy law, patient consent requirements, institutional credentialing requirements, and clinical appropriateness.

Proposed law requires that for each covered clinical project, a research entity will do all of the following, unless modified by rule or guidance for a specified benchmark category:

(1) Acknowledge receipt by the designated intake contact or its designee of a sponsor, contract research organization or site-selection feasibility inquiry within two business days, provided that acknowledgment of receipt shall not constitute acceptance of feasibility or commitment to participate in the study.

(2) Complete confirmation or a single consolidated deficiency notice not later than five business days after receipt of a submission. A submission shall be deemed complete on the sixth

business day if no such notice is issued.

(3) Provide no serial deficiency notices for items that were reasonably available to be identified in the initial completeness review, except for sponsor-requested changes, newly arising issues, or categories designated by rule or guidance.

(4) Provide a sponsor feasibility response or engagement determination within 10 business days after receipt of the materials identified by the department for feasibility review in the standardized checklist, applicable guidance, and any applicable institution-specific addendum permitted by proposed law, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(5) Provide for concurrent review not based solely on institutional preference, generalized practice, or staffing limitations, and that cannot reasonably be performed concurrently, of contracts, budgets, coverage analysis, ancillary reviews, pharmacy review, operational readiness, and other nonduplicative startup functions that need not await completion of another function.

(6) Provide an initial contract response within 10 business days after receipt of a sponsor draft or applicable model agreement, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(7) Provide an initial budget response within 10 business days after receipt of the sponsor budget or budget template, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(8) Upon failure to meet a benchmark, escalation to designated research-entity and department personnel which may include executive-level review and may be carried out in accordance with any applicable participation agreement.

Proposed law requires that for certain covered clinical projects, a research entity will rely on an external institutional review board except for circumstances provided for in proposed law.

Proposed law provides relative to any written determination of nonreliance outlined in proposed law.

Proposed law provides that nothing in proposed law shall be construed to eliminate lawful local review relating to certain responsibilities expressly required by law or by previously adopted written institutional policy directly related to local operational readiness or participant safety and not based solely on institutional preference, generalized practice, or duplication of ethical review of the protocol.

Proposed law further provides that nothing in proposed law shall be construed to require a research entity to waive or disregard legal requirements, safety obligations, or documented institutional responsibilities in order to satisfy a benchmark established in proposed law.

Proposed law provides that nothing in proposed law shall be construed to require a research entity to accept or activate a covered clinical project for which the research entity reasonably determines that sufficient patient population, relevant clinical expertise, or operational capability is lacking.

Proposed law requires that the framework outlined in proposed law includes benchmark categories related to clinical trial startup and execution for covered clinical projects.

Proposed law requires participation agreements to incorporate expectations aligned with benchmark categories and may provide for pilot implementation by benchmark category.

Proposed law provides for what the benchmark categories may include.

Proposed law provides relative to information from a research entity for the department to compile and publish.

Proposed law prohibits certain information in public reporting.

Proposed law outlines what the department shall report to the legislature.

Proposed law provides for what may happen to a research entity that demonstrates repeated failure to meet applicable benchmark expectations.

Proposed law requires that for certain benchmark categories designated by rule or guidance, the department will establish specialized process standards.

Proposed law provides relative to confidentiality requirements.

Proposed law provides proposed law shall not be construed to do any of the following:

(1) Create a state warranty of site performance, patient outcome, sponsor selection, enrollment success, or commercial success.

(2) Create a private cause of action based solely on benchmark expectations, participation decisions, referrals, feasibility coordination, or public reporting in accordance with proposed law.

(3) Require a research entity to disclose information prohibited from disclosure by federal or state law or by enforceable contractual obligation.

(4) Require the department or its designee to collect or maintain identifiable patient information except as otherwise expressly authorized by federal and state law and by patient consent.

Proposed law designates the authority for rulemaking and implementation to the department for proposed law.

Proposed law provides that nothing in proposed law shall be construed to require a specific appropriation of funds or the creation of new positions. Proposed law shall be implemented within existing resources unless otherwise provided by law.

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

(Adds R.S. 51:3301-3310)

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.