DIGEST

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HB 1223 Original 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", "research entity", "participation agreement", "patient-access support", and "sponsor".

Proposed law provides that La. Economic Development (department) shall 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 participation in the framework established by proposed law shall be mandatory for all entities implementing a covered clinical project located in this state.

Proposed law provides that a research entity shall enter into a participation agreement with the department or its designee.

Proposed law provides that a participation agreement shall establish expectations for all of the following:

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

(2) Primary contacts 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 provides that the department or its designee shall 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 provides that the department or its designee may 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 provides that for each covered clinical project, a research entity shall do all of the following, unless modified by rule or guidance for a specified benchmark category:

(1) Acknowledgment of receipt 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) Completeness 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) 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) A sponsor feasibility response or engagement determination within 10 business days after receipt of all materials reasonably required for such determination, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(5) Concurrent review, to the maximum extent permitted by applicable law and documented institutional requirements, 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) An initial contract response within ten 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) 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) Escalation to designated research-entity and department personnel upon failure to meet a benchmark, in accordance with the participation agreement, which may include executive-level review. Escalation may be initiated by the department or its designee, the sponsor, or the contract research organization.

Proposed law provides that for a covered clinical project for which reliance on an external institutional review board is permitted by applicable federal law, a research entity shall rely on an external institutional review board except for circumstances provided for in proposed law.

Proposed law provides that nothing in proposed law shall be construed to eliminate lawful local review relating to investigator qualifications, conflict of interest, privacy, HIPAA, billing compliance, site feasibility, ancillary safety committees, credentialing, or other institutional responsibilities that do not duplicate 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 the framework outlined in proposed law shall include benchmark categories related to clinical trial startup and execution for admitted covered clinical projects.

Proposed law provides that participation agreements shall 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 provides that public reporting shall not include patient-identifying information or sponsor proprietary commercial terms and shall be designed to minimize disclosure of sensitive nonpublic business information.

Proposed law provides relative to what the department shall report to the legislature.

Proposed law provides that participation may be modified, limited, or conditioned in accordance with the participation agreement, rule, or guidance for entities that demonstrate repeated failure to meet applicable benchmark expectations.

Proposed law provides relative to confidentiality.

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, 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.

Proposed law provides for rulemaking and implementation by the department in regards to 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)