HOUSE COMMITTEE AMENDMENTS

2026 Regular Session

Amendments proposed by House Committee on Commerce to Original House Bill No. 1223 by Representative McFarland

AMENDMENT NO. 1

On page 2, between lines 9 and 10, insert the following:

"(5) For low-volume, highly specialized, or referral-dependent categories of covered clinical projects, statewide coordination, referral pathways, and cross-institutional collaboration may improve patient access and Louisiana's competitiveness.

(6) Participation in a covered clinical project depends upon factors including patient availability, relevant clinical expertise, and institutional capability, and the purpose of this Chapter is to reduce avoidable process barriers for covered clinical projects for which a research entity is otherwise reasonably capable."

AMENDMENT NO. 2

On page 2, line 10, change "(5)" to "(7)"

AMENDMENT NO. 3

On page 2, delete lines 21 and 22 and insert in lieu thereof the following:

"covered clinical projects, including categories reflecting trial phase, therapeutic complexity, participant risk profile, operational intensity, disease prevalence or rarity, required subspecialty expertise, referral-network dependence, participant-sourcing model, and operational setting."

AMENDMENT NO. 4

On page 3, delete lines 21 through 23 and insert in lieu thereof the following:

"(9) "Receipt" means actual electronic or physical delivery to the designated intake contact identified by the research entity pursuant to this Chapter. If delivery occurs after five p.m. local time or on a weekend or legal holiday, receipt shall be deemed to occur on the next business day.

(10) "Repeated failure" means failure to meet the same required benchmark on two or more covered clinical projects within a rolling twelve-month period, or such other threshold as may be established by rule for a specified benchmark category.

(11) "Research entity" means a healthcare provider, hospital, academic institution, research organization, or other entity serving as a trial site or otherwise exercising institutional responsibility for a covered clinical project at a site located in this state."

AMENDMENT NO. 5

On page 3, line 24, change "(10)" to "(12)"

AMENDMENT NO. 6

On page 4, between lines 17 and 18, insert the following:

"F. Nothing in this Chapter 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."

AMENDMENT NO. 7

On page 4, delete lines 19 through 23 and insert in lieu thereof the following:

"A. Participation in the framework established by this Chapter shall be mandatory for any research entity with respect to any covered clinical project conducted at a site located in this state. Nothing in this Chapter shall be construed to require participation with respect to research activities that are not covered clinical projects.

B. A research entity shall enter into a participation agreement with the department or its designee for purposes of coordination, contact designation, benchmark-category implementation, reporting, and escalation pursuant to this Chapter."

AMENDMENT NO. 8

On page 4, delete lines 27 and 28 and insert in lieu thereof the following:

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

AMENDMENT NO. 9

On page 5, delete lines 1 and 2 and insert in lieu thereof the following:

"(3) Institution-specific addenda, if any, that supplement the standardized checklist; provided that any such addenda shall be limited to nonduplicative materials reasonably necessary to address a specific legal requirement or documented institutional responsibility."

AMENDMENT NO. 10

On page 5, between lines 12 and 13, insert the following:

"D. A participation agreement shall not waive or reduce any duty imposed by this Chapter except as expressly authorized by rule or guidance for a specified benchmark category."

AMENDMENT NO. 11

On page 6, line 11, after "coordination." and before "Any" insert the following:

"The registry may include, to the extent practicable, therapeutic area or subspecialty focus, trial phase experience, active covered clinical project categories, institutional affiliation, and other information relevant to sponsor or contract research organization feasibility assessment and statewide gap identification."

AMENDMENT NO. 12

On page 6, between lines 18 and 19, insert the following:

"H. Compliance with this Chapter shall 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.

I. For benchmark categories designated by rule or guidance as rare-disease, precision-medicine, pediatric specialty, bone marrow transplant, cellular therapy, cell-therapy, gene-therapy, or other low-volume or highly specialized categories, research entities shall 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."

AMENDMENT NO. 13

On page 6, delete line 22 and insert in lieu thereof the following:

"(1) Acknowledgment of receipt by the designated intake contact or its designee of a sponsor, contract research organization"

AMENDMENT NO. 14

On page 7, delete lines 5 through 7 and insert in lieu thereof the following:

"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 this Chapter, unless a different benchmark is designated by rule or guidance for a specified benchmark category."

AMENDMENT NO. 15

On page 7, delete lines 9 through 11 and insert in lieu thereof the following:

"and by previously adopted written institutional requirements specifically identified in the participation agreement, 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."

AMENDMENT NO. 16

On page 7, delete lines 18 through 21 and insert in lieu thereof the following:

"(8) Escalation to designated research-entity and department personnel upon failure to meet a benchmark, which may include executive-level review and may be carried out in accordance with any applicable participation agreement. Escalation may be initiated by the department or its designee, the sponsor, or the contract research organization."

AMENDMENT NO. 17

On page 8, delete lines 3 through 5 and insert in lieu thereof the following:

"submission, shall state with reasonable specificity the federal or state legal requirement or project-specific participant safety consideration supporting the determination, and shall be provided to the sponsor and the department or its designee."

AMENDMENT NO. 18

On page 8, delete line 9 and insert in lieu thereof the following:

"other site-specific institutional 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."

AMENDMENT NO. 19

On page 8, between lines 13 and 14, insert the following:

"F. Nothing in this Chapter 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. This Subsection shall not be construed to excuse compliance with the timelines and process standards applicable to making such determination."

AMENDMENT NO. 20

On page 8, line 16, delete "admitted"

AMENDMENT NO. 21

On page 9, delete lines 4 and 5 and insert in lieu thereof the following:

"information regarding performance benchmark categories and shall publish such aggregated information in the annual report required by Subsection H of this Section."

AMENDMENT NO. 22

On page 9, delete lines 14 through 21 and insert in lieu thereof the following:

"H. The department or its designee shall submit an annual report to the House Committees on Appropriations and Commerce and the Senate Committees on Finance and Commerce, Consumer Protection and International Affairs by January first of each year summarizing research entities, active benchmark categories, number of covered clinical projects, median timelines by benchmark category to the extent practicable, aggregate counts of external institutional review board reliance and nonreliance determinations, including to the extent practicable such counts by benchmark category, barriers encountered in implementation, including to the extent identified by research entities patient-population limitations, subspecialty workforce gaps, referral-network limitations, infrastructure gaps, and category-specific operational issues, department or designee implementation capacity constraints and resource needs for effective administration of this Chapter, and recommendations for statutory, administrative, or budgetary changes.

I. A research entity that demonstrates repeated failure to meet applicable benchmark expectations may have its inclusion in department-coordinated feasibility responses, site-identification efforts, sponsor-facing coordination, or presentation of verified capabilities modified, limited, or conditioned in accordance with rule or guidance and any applicable participation agreement.

J. For benchmark categories designated by rule or guidance as bone marrow transplant, cellular therapy, cell-therapy, gene-therapy, or other highly specialized modalities, the department shall establish specialized process standards, in consultation with research entities conducting such trials, that account for the clinical urgency, specialized infrastructure, relevant subspecialty expertise, and operational requirements of such categories."

AMENDMENT NO. 23

On page 10, between lines 5 and 6, insert the following:

"(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."