HB5405

LRB10337925CESS68057b

103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB5405

Introduced 2/9/2024, by Rep. Marcus C. Evans, Jr.

SYNOPSIS AS INTRODUCED:

20 ILCS 2310/2310-730 new

Amends the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois. Sets forth requirements for any State entity or hospital that receives funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices. Provides that the Department of Public Health, in consultation with relevant research organizations, shall analyze and provide recommendations on: (i) the demographic groups and populations that are currently represented and underrepresented in clinical trials in the State, including representation of groups based on their geographic location; (ii) the barriers that prevent persons who are members of underrepresented demographic groups from participating in clinical trials in the State, including barriers related to transportation; and (iii) approaches for how clinical trials can successfully partner with others to provide outreach to underrepresented communities. Provides that the Department shall report to the General Assembly on the results of the study by July 1, 2025. Sets forth definitions of underrepresented community and underrepresented demographic group. Provides that the Department shall review guidance published by the United States Food and Drug Administration and use existing infrastructure to encourage participation in clinical trials of drugs and medical devices by persons who are members of underrepresented demographic groups. Authorizes the Department to apply for any grants related to the encouragement of underrepresented demographic groups related to the United Food and Drug Administration's guidance.

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A BILL FOR

AN ACT concerning State government.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois is amended by adding Section 2310-730 as follows:

(20 ILCS 2310/2310-730 new)

Sec. 2310-730. Diversity in clinical trials.

(a) As used in this Section, "underrepresented community" or "underrepresented demographic group" means a community or demographic group that is more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, and geographic location.

(b) The Department of Public Health shall adopt rules requiring any State entity or hospital that receives funding from the National Institutes of Health for the purpose of conducting clinical trials of drugs or medical devices to:

(1) adopt a policy that will result in the identification and recruitment of persons who are members of underrepresented demographic groups to participate in the clinical trials and that:

(A) includes a requirement for investigators who

are conducting the clinical trials to collaborate with community-based organizations; and

(B) uses methods recognized by the United States Food and Drug Administration to identify and recruit those persons to participate in the clinical trials;

(2) provide information to trial participants in languages other than English;

(3) provide translation services or bilingual staff for trial screening;

(4) provide culturally specific recruitment materials alongside general enrollment materials; and

(5) provide electronic consent options when not prohibited by the granting entity or federal regulations.

(c) The Department, in consultation with academic organizations, community-based organizations, and other relevant research organizations, shall analyze and provide recommendations on the following:

(1) the demographic groups and populations that are currently represented and underrepresented in clinical trials in Illinois, including representation of groups based on their geographic location;

(2) the barriers that prevent persons who are members of underrepresented demographic groups from participating in clinical trials in Illinois, including barriers related to transportation; and

(3) approaches for how clinical trials can

successfully partner with community-based organizations and others to provide outreach to underrepresented communities.

By July 1, 2025, the Department shall report to the General Assembly the results of the analysis required under this subsection and any recommendations to increase diversity and reduce barriers for participants in clinical trials.

(d) The Department shall review the most recent guidance on race and ethnicity data collection in clinical trials published by the United States Food and Drug Administration and establish, using existing infrastructure and tools, a program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in such clinical trials. The program must include, without limitation:

(1) collaboration with medical facilities, health authorities and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research relating to drugs or medical devices to assist those investigators and institutions in identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(2) the establishment and maintenance of an Internet website that:

(A) provides information concerning methods

recognized by the United States Food and Drug Administration for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(B) contains links to Internet websites maintained by medical facilities, health authorities and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research relating to drugs or medical devices in this State.

The Department may apply for grants from any source, including, without limitation, the Federal Government, to fund the requirements of this Section.