94TH GENERAL ASSEMBLY

State of Illinois

2005 and 2006

SB1517

Introduced 2/23/2005, by Sen. Jacqueline Y. Collins - Miguel del Valle

SYNOPSIS AS INTRODUCED:

20 ILCS 2310/2310-367 new

Amends the Department of Public Health Powers and Duties Law. Provides that any entity conducting a clinical drug trial on a human person in this State must register with the Department. Sets forth certain minimum requirements for the registration. Provides that the information so gathered shall be collected in a clinical trials data bank administered by the Department. Requires the Department to publish aggregates of the clinical trials data collected, at least annually, and with personal identifiers redacted. Sets forth the purposes for the publication of clinical trials data and provides that the Department shall take all steps necessary under State and federal law to protect patient confidentiality. Provides that the Department shall adopt rules as necessary to implement the requirements.

LRB094 08104 RSP 38289 b

FISCAL NOTE ACT MAY APPLY SB1517

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AN ACT concerning State government.

2 Be it enacted by the People of the State of Illinois, 3 represented in the General Assembly:

4 Section 5. The Department of Public Health Powers and 5 Duties Law of the Civil Administrative Code of Illinois is 6 amended by adding Section 2310-367 as follows:

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(20 ILCS 2310/2310-367 new)

Sec. 2310-367. Clinical drug trial registry; data bank. The 8 Department shall require that every hospital, laboratory, 9 person, or facility conducting a clinical drug trial on a human 10 person in this State must register with the Department. The 11 Department shall specify the form and content of the 12 registration, which shall at a minimum require the entity 13 conducting the clinical drug trial to disclose: (i) the name 14 15 and U.S. patent number of the drug or drugs being used in the clinical drug trial and (ii) the result or results of the 16 17 clinical drug trial.

18 The information so gathered shall be stored, categorized, 19 and collected in a clinical trials data bank to be administered by the Department. The <u>Department shall ensure, at least</u> 20 annually, the publication of clinical trials data bank 21 22 information with personal identifiers redacted and focusing on 23 the aggregate data collected and the results of the trials. The purpose of publicizing data bank information is to provide 24 relevant information about the drugs involved to patients and 25 26 physicians and to educate the public by providing relevant information in language readily comprehensible by the general 27 public. The Department shall undertake all steps necessary 28 under State and federal law to protect patient confidentiality 29 30 in order to prevent the identification of individual patients. The Department shall adopt rules as necessary to implement 31 this Section pursuant to the Illinois Administrative Procedure 32

SB1517

1 <u>Act.</u>