AN ACT concerning State government, which may be referred to as Lilly's Law.

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 2310-640 as follows:

(20 ILCS 2310/2310-640 new)

Sec. 2310-640. Neonatal Diabetes Mellitus Registry Pilot Program.

(a) In this Section, "neonatal diabetes mellitus research institution" means an Illinois academic medical research institution that (i) conducts research in the area of diabetes mellitus with onset before 12 months of age and (ii) is functioning in this capacity as of the effective date of this amendatory Act of the 96th General Assembly.

(b) The Department, subject to appropriation or other funds made available for this purpose, shall develop and implement a 3-year pilot program to create and maintain a monogenic neonatal diabetes mellitus registry. The Department shall create an electronic registry to track the glycosylated hemoglobin level of each person with monogenic neonatal diabetes who has a laboratory test to determine that level

performed by a physician or healthcare provider or at a clinical laboratory in this State. The Department shall facilitate collaborations between participating physicians and other healthcare providers and the Kovler Diabetes Center at the University of Chicago in order to assist participating physicians and other healthcare providers with genetic testing and follow-up care for participating patients.

The goals of the registry are as follows:

(1) to help identify new and existing patients with neonatal diabetes;

(2) to provide a clearinghouse of information for individuals, their families, and doctors about these syndromes;

(3) to keep track of patients with these mutations who are being treated with sulfonylurea drugs and their treatment outcomes; and

(4) to help identify new genes responsible for diabetes.

(c) Physicians licensed to practice medicine in all its branches and other healthcare providers treating a patient in this State with diabetes mellitus with onset before 12 months of age shall report to the Department the following information from all such cases no more than 30 days after diagnosis: the name of the physician, the name of the patient, the birthdate of the patient, the patient's age at the onset of diabetes, the patient's birth weight, the patient's blood sugar level at the

onset of diabetes, any family history of diabetes of any type, and any other pertinent medical history of the patient. Clinical laboratories performing glycosylated hemoglobin tests in this State as of the effective date of this amendatory Act of the 96th General Assembly for patients with diabetes mellitus with onset before 12 months of age must report the results of each test that the laboratory performs to the Department within 30 days after performing such test.

(d) The Department shall create for dissemination to physicians, healthcare providers, and clinical laboratories performing glycosylated hemoglobin tests for patients with monogenic neonatal diabetes mellitus a consent form. The physician, healthcare provider, or laboratory shall obtain the written informed consent of the patient to the disclosure of the patient's information. At initial consultation, the physician, healthcare provider, or laboratory representative shall provide the patient with a copy of the consent form and orally review the form together with the patient in order to obtain the informed consent of the patient and the physician's, or healthcare provider's, or laboratory's agreement to participate in the pilot program. A copy of the informed consent document, signed and dated by the client and by the physician, healthcare provider, or laboratory representative must be kept in each client's chart. The consent form shall contain the following:

(1) an explanation of the pilot program's purpose and

protocol;

(2) an explanation of the privacy provisions set forth in subsections (f) and (g) of this Section; and

(3) signature lines for the physician, healthcare provider, or laboratory representative and for the patient to indicate in writing their agreement to participate in the pilot program.

(e) The Department shall allow access of the registry to neonatal diabetes mellitus research institutions participating in the pilot program. The Department and the participating neonatal diabetes mellitus research institution shall do the following:

(1) compile results submitted under subsection (c) of this Section in order to track:

(A) the prevalence and incidence of monogenic neonatal diabetes mellitus among people tested in this State;

(B) the level of control the patients in each demographic group exert over the monogenic neonatal diabetes mellitus;

(C) the trends of new diagnoses of monogenic neonatal diabetes mellitus in this State; and

(D) the health care costs associated with diabetes mellitus; and

(2) promote discussion and public information programs regarding monogenic neonatal diabetes mellitus.

(f) Reports, records, and information obtained under this Section are confidential, privileged, not subject to disclosure, and not subject to subpoena and may not otherwise be released or made public except as provided by this Section. The reports, records, and information obtained under this Section are for the confidential use of the Department and the participating neonatal diabetes mellitus research institutions and the persons or public or private entities that the Department determine are necessary to carry out the intent of this Section. No duty to report under this Section exists if the patient's legal representative refuses written informed consent to report. Medical or epidemiological information may be released as follows:

(1) for statistical purposes in a manner that prevents identification of individuals, health care facilities, clinical laboratories, or health care practitioners;

(2) with the consent of each person identified in the information; or

(3) to promote diabetes mellitus research, including release of information to other diabetes registries and appropriate State and federal agencies, under rules adopted by the Department to ensure confidentiality as required by State and federal laws.

(g) An employee of this State or a participating neonatal diabetes mellitus research institution may not testify in a civil, criminal, special, or other proceeding as to the

existence or contents of records, reports, or information concerning an individual whose medical records have been used in submitting data required under this Section unless the individual consents in advance.

(h) Not later than December 1, 2012, the Department shall submit a report to the General Assembly regarding the pilot program that includes the following:

(1) an evaluation of the effectiveness of the pilot program; and

(2) a recommendation to continue, expand, or eliminate the pilot program.

(i) The Department shall adopt rules to implement the pilot program, including rules to govern the format and method of collecting glycosylated hemoglobin data, in accordance with the Illinois Administrative Procedure Act.

(j) This Section is repealed on December 31, 2012.

Section 99. Effective date. This Act takes effect upon becoming law.