

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

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

5 Section 5. The Department of Public Health Powers and
6 Duties Law of the Civil Administrative Code of Illinois is
7 amended by adding Section 2310-640 as follows:

8 (20 ILCS 2310/2310-640 new)

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

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

17 (b) The Department, subject to appropriation or other funds
18 made available for this purpose, shall develop and implement a
19 3-year pilot program to create and maintain a monogenic
20 neonatal diabetes mellitus registry. The Department shall
21 create an electronic registry to track the glycosylated
22 hemoglobin level of each person with monogenic neonatal
23 diabetes who has a laboratory test to determine that level

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

8 The goals of the registry are as follows:

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

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

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

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

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

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

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

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

1 protocol;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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