AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE TO ESTABLISH A REGISTRY FOR RARE DISEASES.

WHEREAS, more than 6000 rare diseases, each affecting less than 200,000 patients in the United States, cumulatively impact 30 million people in the United States; and

WHEREAS, Delawareans with rare diseases and their families face great obstacles in obtaining diagnoses, seeking treatment, and paying for care; and

WHEREAS, reliable statistics do not exist to estimate the prevalence or incidence of rare disorders in Delaware; and

WHEREAS policymakers, scientists, and advocates require reliable statistics to address the needs of the rare community.

NOW, THEREFORE:
BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:
Section 1. Amend Title 16 of the Delaware Code by adding a new chapter to read as follows:

CHAPTER 33. Rare Disease Registry Act

§3301. Short title.

This chapter may be cited as the Rare Disease Registry Act.

§3302. Purpose

The General Assembly intends to require the creation and maintenance of a rare disorders registry for the State. It delegates this responsibility to the Department of Health and Social Services, along with the authority to exercise certain powers to implement this requirement. In support of an accurate and continuing source of data concerning rare diseases, the General Assembly by this chapter requires health practitioners and all hospitals and clinical laboratories within the State to make available to the Department of Health and Social Services information contained in the medical records of individual patients who have rare diseases. The data gathered by this effort will serve as a central source of accurate, timely, and precise information regarding the relevant conditions.

§3303. Definitions.

The following words, terms and phrases, when used in this chapter, shall have the meanings ascribed to them in this section, except where the context clearly indicates a different meaning.

(1). “Rare disease” or “rare disorder” shall indicate any medical condition recognized by that affects less than 200,000 people nationwide, including but not limited to those identified by the Genetics and Rare Diseases Information Center at the National Institute of Health.

(2). “Department” shall indicate the Department of Health and Social Services.

§3304. Rare disease registry.

The Department shall adopt, promulgate, amend and repeal any rules and regulations that are consistent with law relative to this chapter and necessary to achieve its purposes and requirements. These rules and regulations shall include provisions for:

(1) The establishment and maintenance of an up-to-date registry that shall document every occurrence of rare diseases in this State;

(2) The establishment of a procedure for reporting to the Department, within 180 days of initial diagnosis or treatment, every occurrence of rare disease in this State. Such procedure shall include the reporting of specified information that the Department deems necessary and appropriate for the recognition, prevention, control or cure of rare disorders. Those required to report to the Department occurrences of rare disorders shall include:

a. Any physician, surgeon, dentist, podiatrist or other health-care practitioner who diagnoses or provides treatment for rare disorders.

b. The designated representative of any hospital, dispensary, or other similar public or private institution that diagnoses or provides treatment for rare disorders; and

c. The designated representative of any laboratory that examines tissue specimens or biomarkers which disclose the existence of rare disorder;

(3) The establishment of a procedure for the publication and distribution of forms, instructions and notices required by this chapter or necessary to accomplish the purpose of this chapter; and

(4) The establishment of a procedure to obtain follow-up information from those required to report occurrences of rare disorders pursuant to this chapter. Any follow-up information deemed necessary by the Department shall be submitted to the Department at least 1 time each year by those required to report occurrences of rare disorders.

This chapter and any rules or regulations issued pursuant to this chapter shall not apply to any person or private institution that, as an exercise of religious freedom, treats the sick or suffering by spiritual means through prayer alone.

§3305. Retroactive sharing of information

Any institution required to report information under § 3304 shall be granted one year from the effective date of this Act to report rare disease diagnoses or treatments that occurred prior to the Act's effective date. No penalties or enforcement actions under this Act shall apply to such reporting during that period.

§3306. Confidentiality of reports.

(a) Any report of an occurrence of rare disorders made pursuant to this chapter shall not be divulged nor made public in any way that might tend to disclose the identity of the person to whom it relates. However, patient-identifying information may be exchanged among health agencies as authorized by the Department and upon receipt by the Department of satisfactory assurances by those agencies of the preservation of the confidentiality of such information.

(b) No individual or organization providing information to the Department in accordance with this chapter shall be deemed to be, or held liable for, divulging confidential information.

(c) The Department will undergo an annual audit by the Delaware Office of Auditor of Accounts to ensure the confidentiality and proper handling of patient data.

§3307. Compulsion prohibited.

Nothing in this chapter shall be construed to compel any individual to submit to any medical or public health examination, treatment or supervision.

§3308. Violations.

Any person or entity who violates any provision of this chapter shall be fined $100 for each violation.

§3309. Audit and Abstraction of records by department.

(a) Upon request of a person or organization required to report by §3304 of this title, the Department may audit records and abstract information that is required to be reported.

(b) Any person or organization failing to report as required by this chapter shall permit the Department to audit records and abstract information that is required to be reported.

(c) The Department may charge a fee to be established by regulation to persons and organizations subjected to an audit pursuant to subsection (a) or (b) of this section. Said person or organization shall reimburse the Department.

Section 2.

This ball shall take effect on January 1, 2027. The Department shall promulgate regulations to effectuate the provisions of this Act by January 1, 2027.