

BILL NO. 35-0207

Thirty-Fifth Legislature of the Virgin Islands

December 11, 2023

An Act amending title 19 Virgin Islands Code, part I, adding chapter 6a to create the Territorial Chronic Kidney Disease and Diabetes Registry

PROPOSED BY: Senator Ray Fonseca

1 *Be it enacted by the Legislature of the Virgin Islands:*

2 **SECTION 1.** Title 19 Virgin Islands Code, part I, is amended by adding a chapter 6a
3 that reads as follows:

4 **“Chapter 6a. Territorial Chronic Kidney Disease and Diabetes Registry**

5 **§ 121. Definitions**

6 As used in this chapter:

7 (a) “Health care facility” means hospitals; health care clinics; health centers; skilled
8 nursing facilities; mental health facilities; kidney disease treatment centers, including
9 freestanding hemodialysis units; intermediate care facilities; ambulatory surgical facilities;
10 rehabilitation facilities; health maintenance organizations; and hospice care facilities.

11 (b) “Health care provider” means a person, corporation, facility or institution licensed
12 in the Territory to provide health care or professional, medical services including a medical,

1 osteopathic, chiropractic or naturopathic physician; hospital; dentist; registered nurse,
2 including an advanced practice registered nurse; optometrist; podiatrist; physical therapist;
3 psychologist; pharmacist and laboratory technician.

4 (c) “Individually identifiable health information” means information that is a subset of
5 health information, including demographic information collected from an individual, and:

6 (1) is created or received by a health care provider, health plan, employer, or
7 health care clearinghouse;

8 (2) relates to the past, present, or future physical or mental health or condition
9 of an individual; the provision of health care to an individual; or the past, present or future
10 payment for the provision of health care to an individual; and

11 (3) identifies the individual:

12 (A) by such common identifiers as name, address, birth date, social
13 security number and other common identifies, or

14 (B) with respect to which there is a reasonable basis to believe the
15 information can be used to identify the individual.

16 (d) “Registry” means the Territorial Chronic Kidney Disease and Diabetes Registry.

17 (e) “Reporting entity” means a healthcare facility that provides services to individuals
18 who are diabetic and/or have chronic kidney disease and those receiving dialysis treatments.

19 (f) “Territory” means the Virgin Islands of the United States.

20 **§ 122. Establishment of the Territorial Chronic Kidney Disease and Diabetes Registry**

21 (a) There is established within the Department of Health, the Territorial Chronic
22 Kidney Disease and Diabetes Registry. The Registry serves as the territorial surveillance
23 system and repository of data regarding patients who have been diagnosed with chronic kidney

1 disease, patients who are receiving dialysis, and patients diagnosed with diabetes in the
2 Territory.

3 (b) The data concerning each case of diabetes is to be collected and used to conduct
4 epidemiological surveys of diabetes cases in this Territory. The data collected must include:

5 (1) an individual's date of diagnosis;

6 (2) age at time of diagnosis;

7 (3) the type of diabetes that was diagnosed;

8 (4) whether the individual has a known history of any type of diabetes in the
9 individual's family;

10 (5) the individual's height and weight, and

11 (6) the individual's sex, race, ethnicity, and residential address.

12 (c) The data concerning each person with chronic kidney disease is to be collected and
13 used to conduct epidemiological surveys of chronic kidney disease cases in this territory. The
14 data collected must include:

15 (1) the patient's height, weight, medical history, diet, and lifestyle;

16 (2) the patient's sex, race, ethnicity, and residential address;

17 (3) kidney disease stage (1-early, 2-mild, 3-moderate, 4-severe, 5-end stage), and
18 information about related comorbidities such as heart disease, hypertension, and diabetes;

19 (4) the total number of patients on dialysis, per each island, and whether the
20 patient is receiving hemodialysis or peritoneal dialysis;

21 (5) laboratory values for diagnostic tests, and medications;

22 (6) insurance coverage details of chronic kidney disease patients including
23 whether the patient is uninsured, or utilizing private insurance, Medicaid, or Medicare;

24 (7) kidney transplant patients being treated;

1 (8) kidney transplant candidates; and

2 (9) the location of healthcare facilities and healthcare providers that offer dialysis
3 services.

4 (d) The Registry shall train and certify personnel designated by the reporting entities
5 as persons responsible for reporting information to the Registry.

6 (e) The Commissioner of Health shall promulgate administrative guidelines as may
7 be amended from time to time to ensure that the Registry performs its mandate.

8 **§ 123. Participation in the program**

9 (a) Within 60 days of the enactment of this act, the Registry shall create a standardized
10 form for each healthcare provider and health care facility to use to submit all reportable data.
11 Each healthcare provider and health care facility shall report in an electronic format, or any
12 other format requested by the Registry each new case of diabetes and chronic kidney disease
13 to the Registry not later than 180 days after the date of diagnosis or date of first contact with
14 the already diagnosed patient.

15 **§ 124. Confidentiality**

16 (a) All chronic kidney disease and diabetes data provided to the Registry must be
17 kept confidential. No information reported to the Registry which identifies or could lead to the
18 identification of an individual patient may be disclosed to any person or entity; except that the
19 identifying information may be disclosed to another state chronic kidney disease and diabetes
20 registry and territorial health officers.

21 (b) State chronic kidney disease and diabetes registries, chronic kidney disease and
22 diabetes researchers or federal chronic kidney disease and diabetes control agencies that receive
23 chronic kidney disease and diabetes case data from the Registry shall enter into an agreement
24 with the Registry to keep the information confidential.

1 (c) All Registry employees and researchers shall sign a confidentiality agreement.
2 These agreements remain effective after the employee or researcher no longer has a relationship
3 with the Registry, and will expire after two years.

4 **§ 125. Disclosure**

5 (a) Chronic kidney disease and diabetes case data may be shared with chronic kidney
6 disease and diabetes researchers or Federal chronic kidney disease and diabetes control
7 agencies for the purposes of chronic kidney disease and diabetes prevention, control, and
8 research upon the submittal of documentation to the Registry providing that research in chronic
9 kidney disease and diabetes prevention or control is ongoing or approval for such research has
10 been granted. If applicable, the Registry shall also request evidence of compliance with the
11 requirements of 45 CFR Part 46: Protection of Human Subjects.

12 (b) The Registry may share statistical compilations of the chronic kidney disease and
13 diabetes case data with state chronic kidney disease and diabetes registries and Federal chronic
14 kidney disease and diabetes control agencies for the following reasons:

15 (1) to perform studies on the sources and causes of chronic kidney disease and
16 diabetes;

17 (2) to track the changing patterns of chronic kidney disease and diabetes
18 incidences;

19 (3) to provide patient education and support, individualized to patients' stage of
20 disease and related health conditions;

21 (4) to create a robust database of patient outcomes, perceptions, priorities and
22 activities that will facilitate research, clinical care and policy decisions to improve
23 patients' experience and outcomes; and

1 (5) for any other clinical, epidemiological, or other chronic kidney disease and
2 diabetes research.

3 **§ 126. Liability**

4 (a) No person, who in good faith, discloses privileged or confidential information or
5 provides chronic kidney disease and diabetes case reports to the Registry or allows the Registry
6 access to a chronic kidney disease and diabetes case report is liable in any civil action.

7 (b) The license of a health care provider or a health care facility may not be
8 suspended or revoked for the disclosure of information provided to the Registry pursuant to
9 this chapter.

10 (c) The protection from liability provided in subsection (a) and (b) does not apply to
11 the unauthorized disclosure of confidential or privileged information when the disclosure is due
12 to gross negligence or willful misconduct.

13 **§ 127. Penalties**

14 Any person who violates a reporting provision of this chapter or regulations or orders
15 pertaining to the reporting of information to the Registry is subject to a civil fine of not less
16 than \$1,000 per case but not more than \$5,000 per case. Before assessing the fine, the
17 Commissioner of Health, or the Commissioner's designee, shall conduct a hearing with the
18 person or entity to ascertain the reason for noncompliance and determine if an adjustment in
19 the fine is warranted. Funds collected pursuant to this subsection must be deposited in an
20 account established by the Department of Health within the Department of Finance. The
21 monies in this account must be used exclusively to assist in the funding of the chronic kidney
22 disease and diabetes Registry as prescribed by law.

23 **§ 128. Annual Report**

