

COMMITTEE ON HEALTH, HOSPITALS AND HUMAN
SERVICES

03/20/2024-AMENDED AND REPORTED OUT TO THE FLOOR
03/19/2024-AMENDED AND REPORTED OUT TO THE COMMITTEE ON RULES AND JUDICIARY
02/07/2024-REPORTED OUT TO THE COMMITTEE ON BUDGET, APPROPRIATIONS AND
FINANCE

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, Stroke and Diabetes Registry

PROPOSED BY: Senators Ray Fonseca and Dwayne M. DeGraff
Co-sponsor: Marise C. James

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 that
3 reads as follows:

4 **“Chapter 6a. Territorial Chronic Kidney Disease, Stroke 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.

1 (b) “Health care provider” means a person, corporation, facility or institution licensed
2 in the Territory to provide health care or professional, medical services including a medical,
3 osteopathic, chiropractic or naturopathic physician; hospital; dentist; registered nurse,
4 including an advanced practice registered nurse; optometrist; podiatrist; physical therapist;
5 psychologist; pharmacist and laboratory technician.

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

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

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

13 (3) identifies the individual:

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

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

18 (d) “Registry” means the Territorial Chronic Kidney Disease, Stroke and Diabetes
19 Registry.

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

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

23 **§ 122. Establishment of the Territorial Chronic Kidney Disease, Stroke and Diabetes**
24 **Registry**

1 (a) There is established within the Department of Health, the Territorial Chronic
2 Kidney Disease, Stroke and Diabetes Registry. The Registry serves as the territorial
3 surveillance system and repository of data regarding patients who have been diagnosed with
4 chronic kidney disease, patients who are receiving dialysis, patients diagnosed with a stroke
5 and patients diagnosed with diabetes in the Territory.

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

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

9 (2) age at time of diagnosis;

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

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

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

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

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

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

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

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

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

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

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

3 (7) kidney transplant patients being treated;

4 (8) kidney transplant candidates; and

5 (9) the location of healthcare facilities and healthcare providers that offer dialysis
6 services.

7 (d) The data concerning each diagnosis of a stroke must be collected and used to
8 conduct epidemiological surveys of stroke cases in the Virgin Islands. The data collected must
9 include:

10 (1) each individual's date of diagnosis;

11 (2) age at the time of diagnosis;

12 (3) the type of stroke that was diagnosed;

13 (4) the individual's family history regarding risk factors for stroke;

14 (5) the individual's height and weight;

15 (6) the individual's sex, race, ethnicity and residential addresses; and

16 (7) the individual's health insurance/medical coverage or lack thereof.

17 (e) The Registry shall train and certify personnel designated by the reporting entities
18 as persons responsible for reporting information to the Registry.

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

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

22 (a) Within 60 days of the enactment of this act, the Registry shall create a standardized
23 form for each healthcare provider and health care facility to use to submit all reportable data.

24 Each healthcare provider and health care facility shall report in an electronic format, or any

1 other format requested by the Registry each new case of diabetes, stroke and chronic kidney
2 disease to the Registry not later than 180 days after the date of diagnosis or date of first contact
3 with the already diagnosed patient.

4 **§ 124. Confidentiality**

5 (a) All chronic kidney disease, stroke and diabetes data provided to the Registry must
6 be kept confidential. No information reported to the Registry which identifies or could lead to
7 the identification of an individual patient may be disclosed to any person or entity; except that
8 the identifying information may be disclosed to another state chronic kidney disease, stroke
9 and diabetes registry and territorial health officers.

10 (b) State chronic kidney disease, stroke and diabetes registries, chronic kidney
11 disease, stroke and diabetes researchers or federal chronic kidney disease, stroke and diabetes
12 control agencies that receive chronic kidney disease, stroke and diabetes case data from the
13 Registry shall enter into an agreement with the Registry to keep the information confidential.

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

17 **§ 125. Disclosure**

18 (a) Chronic kidney disease, stroke and diabetes case data may be shared with chronic
19 kidney disease, stroke and diabetes researchers or Federal chronic kidney disease, stroke and
20 diabetes control agencies for the purposes of chronic kidney disease, stroke and diabetes
21 prevention, control, and research upon the submittal of documentation to the Registry providing
22 that research in chronic kidney disease, stroke and diabetes prevention or control is ongoing or
23 approval for such research has been granted. If applicable, the Registry shall also request

1 evidence of compliance with the requirements of 45 CFR Part 46: Protection of Human
2 Subjects.

3 (b) The Registry may share statistical compilations of the chronic kidney disease,
4 stroke and diabetes case data with state chronic kidney disease, stroke and diabetes registries
5 and Federal chronic kidney disease, stroke and diabetes control agencies for the following
6 reasons:

7 (1) to perform studies on the sources and causes of chronic kidney disease,
8 stroke and diabetes;

9 (2) to track the changing patterns of chronic kidney disease, stroke and diabetes
10 incidences;

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

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

16 (5) for any other clinical, epidemiological, or other chronic kidney disease, stroke
17 and diabetes research.

18 **§ 126. Liability**

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

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

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

7 **§ 127. Penalties**

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

17 **§ 128. Annual Report**

18 The Registry shall publish an annual statistical compilation that does not include
19 identifying information showing the incidence of chronic kidney disease, stroke and diabetes
20 in the Territory.”

21 **SECTION 2.** The sum of \$50,000 is appropriated in the fiscal year ending September
22 30, 2024, from the General Fund of the Government of the Virgin Islands to the Department of
23 Health to create the Chronic Kidney Disease, Stroke and Diabetes Registry and is available
24 until December 30, 2024. In the fiscal years ending September 30, 2025, 2026, 2027, and 2028,

1 the sum of \$75,000 is appropriated from the General Fund of the Treasury of the Government
2 of the Virgin Islands to the Department of Health for the completion of the Chronic Kidney
3 Disease, Stroke and Diabetes Registry.

4 **BILL SUMMARY**

5 Section 1 creates title 19, chapter 6a. The new chapter is divided into eight sections.
6 Section 121 defines the terms used in the chapter; section 122 establishes the Registry; section
7 123 describes how and what entities must participate; section 124 discusses confidentiality;
8 section 125 addresses what disclosures are allowed; section 126 addresses liability; section 127
9 sets out penalties for violations of the mandates; and section 128 sets out the annual reporting
10 requirements. Section 2 appropriates funds to create the Registry.

11 **BR23-0762/November 6, 2023/HLF**

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