

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 3204 (16 Del.C. §3204)

16 DE Admin. Code 4201

PROPOSED

PUBLIC NOTICE

4201 Cancer Registry

Health Promotion & Disease Prevention, Division of Public Health, Department of Health and Social Services (Department), has proposed amendments to the 4201 State of Delaware Cancer Registry regulation.

The proposed regulation defines procedures to be used by health care providers to report cancer to Delaware Health and Social Service's Cancer Registry. Currently, a paper-based method (form) is used by health care providers to report all cancer cases. Amendments have been made to the existing regulation that require health care providers to report all cancer cases via an electronic reporting method; using the Centers for Disease Control and Prevention (CDC) Web Plus electronic reporting software.

On May 1, 2014, the Department plans to publish proposed amendments to the 4201 State of Delaware Cancer Registry regulation and hold them out for public comment per Delaware law.

Copies of the proposed regulations are available for review in the May 1, 2014 edition of the Delaware *Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Comprehensive Cancer Control Program at 302-744-1032.

Any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit same to Deborah Harvey by 4:30 p.m. on Friday, May 30, 2014 at:

Deborah Harvey

Division of Public Health

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4201 Cancer Registry

1.0 Purpose

These regulations are promulgated by the Department pursuant to Senate Bill 372 of the 141st General Assembly. These regulations are also independently authorized by 29 Del.C. §7903. The purpose of the regulations is to implement 16 Del.C. Ch. 32.

6 DE Reg. 958 (2/1/03)

2.0 Definitions

“**Benign Tumor**” means any nonmalignant neoplasm, regardless of the tissue or origin, that appears on the American College of Surgeons most recently published list of reportable cancers and benign tumors.

“**Cancer**” means any malignant neoplasm, regardless of the tissue origin, that appears on the American College of Surgeons most recently published annual list of reportable cancers and benign tumors.

“**Clinical Laboratory**” means a facility in which tests are performed identifying findings of anatomical changes, and/or specimens are interpreted and pathological diagnoses are made.

“**The Department**” means the Department of Health and Social Services.

“**Health Care Provider**” means:

person, corporation, facility or institution licensed by this State pursuant to Titles 16 or 24 of the **Delaware Code** to perform any act to or on behalf of a patient during the patient's medical care, treatment, or confinement, or

a clinical laboratory. When a person acting as a health care provider is working for a corporation, facility, or institution, the corporation, facility, or institution shall be considered the health care provider for purposes of these regulations.

“Non-hospital reporter” means one that: is not located within a Delaware hospital and/or does not report cancer case data to such hospital’s cancer registry.

6 DE Reg. 958 (2/1/03)

3.0 Duty to Report

Each health care provider shall ~~complete and~~ submit cancer data to the Department ~~the forms~~ electronically as described in Section 4 with respect to (a) each patient whom it diagnoses with cancer or a benign tumor, and (b) each patient for whom it renders any care after the individual is diagnosed with cancer or a benign tumor. Compliance by one health care provider with this Section with respect to an individual patient shall not obviate compliance by other health care providers with respect to the same patient. Physician offices that are located in a hospital and have an electronic database accessible to the hospital cancer registry may be asked to submit to the Department an electronic data file listing of cancer cases for linkage prior to submission of case information. Once the linkage is made, any missing cases must be reported electronically as indicated in Section 4.0.

6 DE Reg. 958 (2/1/03)

4.0 ~~Forms Supplied by Department~~ Process and Specifications of Reporting Data to the Department

Cancer data should be submitted in a secure, electronic method. Non-hospital providers should submit all cancer case data utilizing the CDC’s Web Plus software. A non-hospital reporter is defined as one that: is not located within a Delaware hospital and/or does not report cancer case data to such hospital’s cancer registry. If a non-hospital provider is unable to submit data electronically, the provider may contact the Department to inquire about an exemption. Upon approval of the exemption, the Department will provide data collection forms to the provider. To request an exemption, a provider must submit a letter stating reason why they are unable to report using the electronic method to the Delaware Cancer Registry. The address can be found at: <http://www.dhss.delaware.gov/dhss/main/maps/other/oxfordbd.htm>

~~Forms prepared by the Department for use by health care providers in complying with Section 3 shall request a~~All data required by the reporting requirements of the National Cancer Data Base established by the American College of Surgeons. Forms prepared Data submitted under this section shall also request disclosure of the address at which the patient has lived for the longest period of time, the occupation at which the patient has worked for the longest period of time, and the name and address of the employer at the occupation where the patient has worked for the longest period of time, length of residence in Delaware and the type of occupation(s) if such information is available to the health care provider. A health care provider shall make reasonable efforts to obtain all information requested by the form prepared under this Section as required on the electronic reporting system. However, reasonable efforts by a clinical laboratory shall not include the interviewing of patients to obtain required information.

6 DE Reg. 958 (2/1/03)

5.0 Retention of Required Information

A health care provider who is treating a patient who has been diagnosed with cancer or a benign tumor shall ask that patient to fill out a form requesting disclosure of ~~the address at which the patient has lived for the longest period of time in his or her life, the occupation at which the patient has worked for the longest period of time in his or her life, and the name and address of the employer at the occupation where the patient has worked for the longest period of time~~ length of residence in Delaware, and the type of occupation(s) at which the patient has worked. The health care provider shall retain the form required by this Section with the patient’s medical records pursuant to generally accepted protocol for the retention of patient medical records. The health care provider shall include the information from the form required by this Section with information it submits pursuant to Section 3 of these regulations. The Department shall provide a form for use in complying with this Section.

6 DE Reg. 958 (2/1/03)

6.0 Deadlines for Submission

A health care provider shall provide the information required by Section ~~3~~ 4.0 within 180 days of the initiation of treatment of a patient or diagnosis of that patient with a cancer or benign tumor, whichever is earlier.

6 DE Reg. 958 (2/1/03)

7.0 Failure to Submit Required Information

A health care provider that fails to comply with Section 5 3.0 shall permit the Department to audit its records and abstract information that should have been provided under Section 6 4.0. The health care provider shall reimburse the Department for the cost of said audit. If the audit does not identify a compliance failure by the health care facility or provider, the cost of such audit shall not be assessed against the facility or provider.

6 DE Reg. 958 (2/1/03)

8.0 Voluntary Audit

A health care provider may voluntarily request that an audit be performed if it does not intend to submit the information required by Section 6 4.0. The Department shall determine if the request for an audit will be honored. The health care provider shall reimburse the Department for the cost of said audit if the Department honors the request. The Department shall determine whether said costs shall be prepaid, or paid upon completion of the audit.

6 DE Reg. 958 (2/1/03)

9.0 Fines

Failure to comply with Sections 6 3.0 and 6.0 of these regulations may result in a \$100 fine against the health care provider that has failed to comply. Each failure to comply shall constitute a separate violation and shall subject the health care provider to a separate \$100 fine.

6 DE Reg. 958 (2/1/03)

17 DE Reg. 1035 (05/01/14) (Prop.)