

# 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

### FINAL

### ORDER

#### 4201 Cancer Registry

#### NATURE OF THE PROCEEDINGS:

The Delaware Department of Health and Social Services (“DHSS”) initiated proceedings to adopt the State of Delaware Regulations Governing the Delaware Cancer Registry. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Del.C.** §3204.

On May 1, 2014 (Volume 17, Issue 11), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by May 30, 2014, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying “Summary of Evidence.”

#### SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulation Governing the Delaware Cancer Registry were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*.

Entities offering written comments include:

- State Council for Persons with Disabilities, Denise McMullin-Powell, Chairperson
- Governor’s Advisory Council for Exceptional Citizens, Terri A. Hancharick, Chairperson

Public comments and the DHSS (Agency) responses are as follows:

#### **State Council for Persons with Disabilities, Denise McMullin-Powell, Chairperson:**

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/ Division of Public Health’s (DPH’s) proposal to amend the State of Delaware Cancer Registry regulations. Specifically, the Division proposes to amend its implementing regulations to convert health care provider reporting from a “paper” system to an “electronic” system. The proposed regulation was published as 17 **DE Reg.** 1035 in the May 1, 2014 issue of the *Register of Regulations*. SCPD endorses the concept of switching to an electronic reporting system subject to consideration of the following amendments.

First, in §4.0, SCPD recommends deletion of the third sentence. It is redundant to reiterate the definition of a “non-hospital reporter” which is already defined in §2.0.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has deleted the third sentence as per the suggestion of the commenter.

Second, in §4.0, sixth sentence, SCPD recommends substituting “it is” for “they are” since the antecedent noun (provider) is singular.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has substituted the words “it is” for “they are” as suggested by the commenter.

Third, in §4.0, the eighth “sentence” reads as follows: “All data required by the reporting requirements of the National Cancer Data Base established by the American College of Surgeons.” This is not a sentence since it lacks a predicate.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has revised the sentence as suggested by the commenter.

Fourth, in §4.0, ninth sentence, SCPD believes “request” should be “include”.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has substituted the word “request” with the word “include” as suggested by the commenter.

Fifth, §§4.0 and 5.0 condense the scope of information related to patient residence and employment. This may not comport with the enabling legislation. Consider the following:

A. Title 16 **Del.C.** §3204(2) requires reporting of the patient’s “primary residential address”. The regulation omits any reference to collection of such information.

B. Section §3204(2) requires reporting of “the location and nature of the patient’s primary past employment.” The regulation deletes the requirement of reporting the “name and address of employer” and merely contemplates identification of type of occupation. This is not consistent with the enabling law.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has revised the regulations as suggested by the commenter to be consistent with the enabling law.

**Governor’s Advisory Council for Exceptional Citizens, Terri A. Hancharick, Chairperson:**

The Governor’s Advisory Council for Exceptional Citizens (GACEC) has reviewed the Division of Public Health (DPH) proposal to amend its implementing regulations converting health care provider cancer registry reporting to an “electronic” system from the current “paper” system. The Division is required to maintain a cancer registry by the Delaware Cancer Control Act codified at 16 **Del.C.** §§3201-3209. Council **endorses** the concept of switching to an electronic reporting system subject to consideration of the following amendments.

First, in §4.0, Council recommends deletion of the third sentence. It is unnecessary to reiterate the definition of a “non-hospital reporter” since it is already defined in §2.0.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has deleted the third sentence as per the suggestion of the commenter.

Second, in §4.0, sixth sentence, Council recommends substituting “it is” for “they are” since the antecedent noun (provider) is singular.

**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has substituted the words “it is” for “they are” as suggested by the commenter.

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**Agency Response:** The Agency appreciates and acknowledges these comments. The Agency has revised the regulations as suggested by the commenter to be consistent with the enabling law.

The public comment period was open from May 1, 2014 through May 30, 2014. Based on comments received during the public comment period, only non-substantive changes have been made to the proposed regulations. The regulations have been reviewed by the Delaware Attorney General’s office and approved by the Cabinet Secretary of DHSS.

**FINDINGS OF FACT:**

Based on public comments received, non-substantive changes were made to the proposed regulations. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing the Delaware Cancer Registry are adopted and shall become effective July 1, 2014, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

**4201 Cancer Registry**

**1.0 Purpose**

These regulations are promulgated by the Department pursuant to Senate Bill 372 of the 141<sup>st</sup> 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.

## 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 it is]~~ 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 as indicated]** by the reporting requirements of the National Cancer Data Base established by the American College of Surgeons **[is required]**. ~~Forms prepared~~ Data submitted under this section shall also **[request include]** 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)]** patient’s length of residency in Delaware, **primary residential address in Delaware and the location and nature of the patient’s primary past employment]** 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]~~ patient's length of residency in Delaware, primary residential address in Delaware and the location and nature of the patient's primary past employment]. 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 3.0 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 3.0 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 5.0 shall permit the Department to audit its records and abstract information that should have been provided under Section 6.0. 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 6.0. 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 6.0 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)**

**18 DE Reg. 63 (07/01/14) (Final)**