CHAPTER 57A
CANCER REGISTRY

Authority

N.J.S.A. 26:2-104 et seq., particularly 26:2-106.

Source and Effective Date

Effective: June 16, 2025.
See: 57 N.J.R. 1603(a).

Please Note

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§ 8:57A-1.1 Purpose and scope

(a) The purpose of this subchapter is to:
1. Implement N.J.S.A. 26:2-104 through 109, which authorizes the Department of Health to establish and maintain the New Jersey State Cancer Registry (NJSCR) as the Statewide repository

of records of cases of cancer and specified cases of tumorous or precancerous disease that occur in New Jersey;
2. Set forth standards for maintaining confidentiality of information submitted to the NJSCR; and
3. Set forth standards for the establishment, use and maintenance of the NJSCR.

(b) The purpose of the NJSCR is to:
1. Monitor cancer incidence and mortality trends in New Jersey;
2. Conduct epidemiologic surveys of cancer and cancer-related diseases in New Jersey; and
3. Assist physicians, researchers, public health officials, epidemiologists and health care facility administrative officers by providing data, subject to the confidentiality provisions established at N.J.A.C. 8:57A-10, to understand cancer, improve cancer treatment, increase survival, improve long-term quality of life for cancer patients and identify the most appropriate cancer prevention and control measures.

(c) This subchapter applies to:
1. All health care facilities, physicians, dentists and other health care providers that diagnose or treat cancer patients;
2. Clinical laboratories located in New Jersey that conduct hematology examinations or examine tissue specimens that are positive for the existence of cancer or other specified tumorous and precancerous disease; and
3. All health care insurers and other third-party health care payers providing benefit plans to residents of New Jersey that are cancer patients.

§ 8:57A-1.2 Incorporated and referenced documents

(a) The Department incorporates by reference, as amended and supplemented, the following documents in this subchapter:
1. Artificial Intelligence in Medicine Incorporated. "The e-path Reporting Site Information Checklist," which is based on the National Cancer Institute's Surveillance Epidemiology End Results (SEER) Program Case Finding List, effective January 2010, and will be used by pathology laboratories to send site information in order to implement electronic cancer case-finding and pathology data gathering for the NJSCR, and is available through request to the NJSCR, and for which the contact information is Artificial Intelligence in Medicine Incorporated, 2 Berkeley Street, Suite 403, Toronto, Ontario, Canada M5A 2W3;
2. The National Cancer Institute, Division of Cancer Control and Population Sciences, Surveillance Research Program, Cancer Statistics Branch/SEER Program. "The SEER Program Coding and Staging Manual 2016, updated January 4, 2017," which is used for abstracting and coding cancer data, and is available online at: http://seer.cancer.gov, and for which the contact information is NCI, 9609 Medical Center Drive, MSC 97608, Bethesda, MD 20892-9760, Telephone: 1-800-4-CANCER (1-800-422-6237) in English and Spanish languages;
3. The North American Association of Central Cancer Registries (NAACCR), Inc. "The NAACCR Data Standards for Cancer Registries -- Data Standards and Data Dictionary (Volume II-Version 16)," which is used by health care facilities, physicians, dentists, and other health care providers to electronically submit data to the NJSCR, and is available online at: http://www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx, and for which the contact information is NAACCR, 2050 W. Iles, Suite A, Springfield, IL 62704-4194, Telephone: (217) 698-0800;

4. The North American Association of Central Cancer Registries (NAACCR), Inc. "The NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting, Version 4.0 (effective April 1, 2011), including Chapter 3: "Implementation guidelines with rules for formatting messages carrying synoptic reports," which sets forth the Health Level 7 (HL-7) Version 2.5.1 standard protocol that clinical laboratories may use to make reports to the Department electronically and is available online at: http://www.naaccr.org/StandardsandRegistryOperations/VolumeV.aspx, and for which the contact information is NAACCR, 2050 W. Iles, Suite A, Springfield, IL 62704-4194, Telephone: (217) 698-0800; and
5. World Health Organization. "International classification of diseases for oncology (ICD-O)--3rd edition, 1st revision, 2013," which is used to classify oncologic conditions for inclusion in cancer registry data, and which is available online at http://apps.who.int/iris/bitstream/10665/96612/1/9789241548496_eng.pdf.

(b) The Department references the following documents, as amended and supplemented, as guidance in this subchapter:
1. New Jersey State Cancer Registry (NJSCR), Cancer Epidemiology Services, New Jersey Department of Health. "The NJSCR 2017 Program Manual: Instructions For Health Care Facilities," which provides guidance to health care facilities on the electronic transmission of data to the Department and information from Federal programs that establish standards for cancer registries and which is available online at: http://www.nj.gov/health/ces/reporting-entities/registrars/index.shtml; and
2. New Jersey State Cancer Registry (NJSCR), Cancer Epidemiology Services, New Jersey Department of Health. "The NJSCR Abstract Instruction Manual For Physicians, Ambulatory Care Centers and Radiation Treatment Facilities 2017," which provides guidance to physicians, ambulatory care centers (ACCs), and radiation treatment facilities (RTFs) on the electronic transmission of data to the Department and which is available online at: http://www.nj.gov/health/ces/reporting-entites/non-hospital/.

§ 8:57A-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Administrative officer" means a person at a health care facility assigned with the responsibility of ensuring that reports of every case of cancer at the health care facility are made to the Department pursuant to the reporting requirements of this chapter.

"Certified Tumor Registrar" or "CTR<(R)>" means a person who holds certification as such, or an equivalent credential, from the Council on Certification of the National Cancer Registrars Association (NCRA), for which the contact information is NCRA, 13340 Braddock Place, Suite 520, Alexandria, VA 22314, telephone: (703) 299-6640, telefacsimile: (703) 299-6620, e-mail: ctrexam@ncra-usa.org, website: http://www.ctrexam.org.

“Clinical laboratory" means a facility that conducts tests on tissue or cellular specimens and/or hematologic examinations in order to diagnose or otherwise characterize a disease.

"Commissioner" means the Commissioner of the New Jersey Department of Health, or his or her designee.

"Department" means the New Jersey Department of Health.

"Health care facility" means a facility as defined at N.J.S.A. 26:2H-1 et seq., as amended and supplemented.

"Health care provider" means a health care professional who is directly involved in the provision of health care services and whose practice is regulated pursuant to Title 45 of the New Jersey Statutes and State professional board rules, who in the course and scope of work duties, independently or under the supervision of the appropriate authority, diagnoses or treats patients with cancer or other specified tumorous and precancerous diseases as set forth at N.J.A.C. 8:57A-1.11.

1. Health care provider includes physicians and dentists.

"NJSCR" means the New Jersey State Cancer Registry established by the Department pursuant to this chapter and the authority of N.J.S.A. 26:2-104 et seq.

"NJSCR mailing address" means the mailing address of the New Jersey State Cancer Registry, which is: Cancer Epidemiology Services, New Jersey State Cancer Registry, New Jersey Department of Health, PO Box 369, Trenton, New Jersey 08625-0369.

"NJSCR webpage" means the webpage of the New Jersey State Cancer Registry available at www.nj.gov/health/ces.

§ 8:57A-1.4 Reporting of cancer; general requirements

(a) Every New Jersey health care facility, physician, dentist, other health care provider, and clinical laboratory shall report to the Department the reportable diseases and conditions established at N.J.A.C. 8:57A-1.11.
(b) Every New Jersey health care facility, physician, dentist, other health care provider, and clinical laboratory shall submit all case reports within six months of the date of first contact with the patient for the reportable condition as defined by the NAACCR Data Standards for Cancer Registries--Data Standards and Data Dictionary (Volume II--Version 16).
(c) Every New Jersey health care facility shall submit follow-up data on each cancer case, as requested and in the format specified by the Department, to confirm the patient's vital status until the patient's death.
(d) Every New Jersey health care facility, physician, dentist, and other health care provider shall use the SEER Program Coding and Staging Manual 2016 when abstracting and coding cancer data.
(e) A health care facility, physician, dentist, other health care provider, or clinical laboratory may apply for a no-cost software program to report information on cases of cancer electronically to the NJSCR by contacting the NJSCR at njscrdat@doh.nj.gov

§ 8:57A-1.5 Health care facility reporting

(a) The administrative officer of every health care facility shall report to the Department every case of cancer or other specified tumorous and precancerous disease when it is initially diagnosed, when the patient is first admitted or treated for any reason in that facility, including admissions and discharges to inpatient or outpatient services, and when subsequent primary cancer is diagnosed in that patient.

(b) A CTR® shall perform all abstracting work and oversee all case-finding for a health care facility that diagnoses and/or treats 100 or more cancer cases per year.

1. Either the health care facility or an abstract-coding service under contract with the health care facility shall employ the CTR(R); and
2. A health care facility shall notify the NJSCR by e-mail to
3. ops.njscr@doh.nj.gov
4. of the name and contact information for the CTR(R), and of any changes to registry staff or contact information; and
5. A health care facility that contracts with an abstract-coding service shall be responsible for ensuring the abstract-coding service complies with the provisions of this chapter.

(c) The administrative officer of every health care facility shall ensure that the information to be reported, as set forth in (a) above, is submitted electronically using the NAACCR Data Standards for Cancer Registries -- Data Standards and Data Dictionary (Volume II -- Version 16), as amended and supplemented, and includes all required data elements set forth in the NAACCR Data Standards for Cancer Registries--Data Standards and Data Dictionary (Volume II), such as patient identifying information, medical history, cancer treatment, and cancer stage at diagnosis.

(d) Health care facilities may use the NJSCR 2017 Program Manual: Instructions For Health Care Facilities, incorporated herein by reference, as amended and supplemented, for guidance in abstracting and reporting.

(e) Health care facilities that lack adequate internal capabilities to report cases in accordance with the requirements of (b) and (c) above shall contract with the Department or its designee to provide abstracting services.

(f) The Department or its designee shall charge a fee, based upon the fair market value of services, to health care facilities for the provision of services set forth at (e) above.

(g) A health care facility that fails to comply with the provisions of this subchapter shall be liable for a penalty of up to $ 500.00 per unreported case of cancer or other specified tumorous and precancerous disease.

(h) A health care facility that fails to report cases of cancer or other specified tumorous and precancerous diseases electronically shall be liable for a penalty not to exceed $ 1,000 per business day.

§ 8:57A-1.6 Physician, dentist, and other health care provider reporting

(a) Every physician, dentist, or other health care provider who diagnoses or provides treatment for cancer patients shall submit an electronic report to the Department with an initial diagnosis of each case of cancer or other specified tumorous and precancerous disease and for each subsequent primary cancer diagnosed in that person, using either the NAACCR Data Standards for Cancer Registries -- Data Standards and Data Dictionary (Volume II -- Version 16) or another standard electronic reporting format approved by the Department that includes all required data elements

set forth in the "NAACCR Data Standards for Cancer Registries--Data Standards and Dictionary (Volume II)," such as patient identifying information, medical history, cancer treatment, and cancer stage.

(b) The physician, dentist, or other health care provider may use the "NJSCR Abstract Instruction Manual For Physicians, Ambulatory Care Centers and Radiation Treatment Facilities 2017," incorporated herein by reference, as amended and supplemented, as guidance when reporting.

(c) A physician, dentist, or other health care provider who fails to report cases of cancer or other specified tumorous and precancerous diseases shall be liable for a penalty of up to $ 500.00 per unreported case for violation of the Cancer Registry Act.

§ 8:57A-1.7 Clinical laboratory reporting

(a) The director of every clinical laboratory shall report electronically to the Department the results of examinations of tissue specimens and/or hematology examinations that are positive for the existence of cancer or other specified tumorous and precancerous disease using the HL-7 standard protocol set forth in the NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting or the NAACCR Data Standards for Cancer Registries--Data Standards and Data Dictionary (Volume II--Version 16), which includes all available patient identifying information, the tissue examined, and the results of the pathologic examination, and the name, address and/or telephone number of the referring physician.

(b) A clinical laboratory that fails to report cases of cancer or other specified tumorous and precancerous diseases shall be liable for a penalty of up to $ 500.00 per unreported case.

§ 8:57A-1.8 Health care insurer reporting

Health care insurers and other third-party health care payers providing benefit plans to residents of the State shall report electronically to the Department information on cases of cancer or other specified tumorous and precancerous diseases based upon selection criteria, established at N.J.A.C. 8:57A-1.11, upon request of the Department in the format specified by the Department in the request set forth in this section; and that includes patient identifying information and medical information, such as medical history, cancer treatment, cancer stage at diagnosis information, and co-morbid conditions.

§ 8:57A-1.9 Supplemental information

(a) Every New Jersey health care facility, physician, dentist, other health care provider, and clinical laboratory shall report supplemental information necessary to clarify medical or demographic data upon request of the Department, such as copies of pathology and/or hematology reports, operative reports, treatment information, history and physical sections of the medical records and discharge summaries, and other information as deemed necessary by the NJSCR.

(b) If the NJSCR determines that more information is needed, NJSCR staff will contact, as appropriate, the health care facility physician, dentist, other health care provider, and clinical laboratory, to obtain this information in the form and manner specified by the NJSCR at that time of the request.

§ 8:57A-1.10 Access to information and records

(a) Every health care facility, clinical laboratory, physician, dentist, and other health care provider diagnosing or providing treatment for cancer patients and health care insurers and other third-party health care payers providing benefit plans to residents of the State shall allow representatives of the Department, or its designee, to obtain information from all medical, pathological, and other pertinent records and logs related to cancer cases, as necessary for fulfilling the functions of the NJSCR.

1. Access to records set forth in (a) above shall be given through secure, electronic remote means where requested and where available.

(b) Every health care facility, clinical laboratory, physician, dentist, and other health care provider diagnosing or providing treatment for cancer patients and health care insurers and other third-party health care payers providing benefit plans to residents of the State shall permit representatives of the Department access to information or provide necessary information on specified cancer patients and other patients specified by characteristics for research studies related to cancer etiology, prevention, and control, which are conducted by the Department subject to the following:

1. The Department's designated Institutional Review Board shall:
   i. Review the studies to assure protection of human subjects; and
   ii. Approve or disapprove the studies, as appropriate, based on the outcome of the review.
2. This access or provision of information shall include patients who came under the care of the health care facility, physician, dentist or other health care provider prior to November 18, 1977.

(c) Representatives of the Department shall:

1. Provide advance notice to the health care facility, physician, dentist or other health care provider, independent clinical laboratory, health care insurer or other third-party health care payer in order to access patient records of cancer patients pursuant to (a) and (b) above; and
2. Present valid identification at the time of access, including, Department or designee issued identification, if on-site access to patient records is necessary.

(d) Only the Department and such other agencies as may be designated by the Commissioner shall use the reports made pursuant to this subchapter.

1. These reports shall not be:
   ii. Otherwise divulged or made public; or
   iii. Subject to public inspection and copying pursuant to the Open Public Records Act, N.J.S.A. 47:1A-1 et seq.

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

(f) The Department shall not make public any information reported to the NJSCR that discloses the identity of any person to whom the information relates.

1. The Department will refer individuals wishing to confirm the inclusion of their medical information in the NJSCR to their health care provider or treating health care facility.
2. A patient who was diagnosed with, or treated for, cancer, or, if the patient is deceased, that patient's next-of-kin may request that the Department release summary information about that patient with a signed Authorization to Release Health Information form.
3. A patient's physician who, or licensed facility that, diagnosed that patient with, or is treating that patient for, cancer may submit a request in writing to the Department for a release of that patient's diagnostic, treatment, and follow-up information.

(g) The Department shall report all violations of (c) above by any individual or organization to the appropriate professional licensing authorities and public financing programs.

(h) Failure to permit access to information and records to representatives of the Department shall be cause for legal action.

§ 8:57A-1.11 Reportable diseases and conditions

(a) Every New Jersey health care facility, physician, dentist, other health care provider, and clinical laboratory shall report to the Department, in accordance with this chapter, any case having a diagnosis meeting the criteria at (b) below that contains any of the following terms in the final diagnosis:

Apparent(ly);

Appears;

Compatible/Compatible with;

Consistent with;

Favors;

Malignant appearing;

Most likely;

Presumed;

Probable;

Suspect(ed);

Suspicious (for); and/or

Typical (of).

(b) Subject to (c) below, every New Jersey health care facility, physician, dentist, other health care provider, and clinical laboratory shall report to the Department, in accordance with this chapter, all cases having the following diagnoses:

1. All *in situ* or invasive neoplasms that have behavior codes "/2" or "/3" in the ICD-O; or
2. All solid tumors of the brain and the central nervous system, including the meninges and intracranial endocrine structures, that have the following behavior codes in the ICD-O:
   ii. "/0" benign disease;
   iii. "/1" disease of uncertain malignant potential;
   iv. "/2" *in situ* disease; or
   v. "/3" malignant disease.

(c) The following diagnoses are not to be reported to the Department:

1. Basal cell carcinomas of the skin, except when they are diagnosed in the labia, clitoris, vulva, prepuce, penis, or scrotum; or
2. Carcinoma *in situ* of the cervix and/or cervical squamous intraepithelial neoplasia III (CIN III).

(d) Insofar as soft tissue tumors can arise in almost any body site, the primary site of the soft tissue tumor shall also be examined for any questionable neoplasm.

(e) If any uncertainty regarding the reporting of a particular case exists, the health care facility, physician, dentist, other health care provider, or clinical laboratory shall contact the Department for guidance at (609) 633-0500 or view information on the following website: http://www.nj.gov/health/ces/njscr.shtml.

§ 8:57A-1.12 Audit, Letter, and notice of violations and enforcement actions

(a) A health care facility, physician's, dentist's, other health care provider's office, and clinical laboratory shall be subject to audit at the discretion of the Commissioner by authorized representatives of the Department.

(b) The Department, or its designee, shall evaluate completeness and timeliness of reporting as specified by this subchapter by reviewing documents, such as medical records, diagnostic indices of radiation, laboratory, cytology and/or pathology reports, and discharge records.

(c) Authorized representatives of the Department shall conduct the audit during normal operating hours.

(d) The Department's authorized representatives may cite a deficiency upon a determination that the health care facility, physician's, dentist's, other health care provider's office, and clinical laboratory does not comply with the reporting requirements established in this subchapter.

(e) At the conclusion of the audit or within 10 business days thereafter, the Department or its designee shall provide the health care facility, physician's, dentist's, other health care provider's office or independent clinical laboratory with a written Letter of Potential Violation and Potential Assessment (Letter) summarizing any factual findings used as a basis to determine that reporting has not been complete or timely.

1. The Department or its designee shall set forth in the Letter the proposed assessment of civil monetary penalties, and as applicable, the specific reasons for the action.

(f) The Department or its designee shall serve the Letter on a facility, physician, dentist, other health care provider or independent clinical laboratory or its, his or her registered agent in person or by certified mail.

(g) A health care facility, physician, dentist, other health care provider, and clinical laboratory shall have 30 business days after receipt of the Letter by certified mail or personal service in which to correct all deficiencies in its reporting that were discovered during the audit and cited in the Letter.

1. If a health care facility, physician, dentist, other health care provider, and clinical laboratory fails to correct deficiencies in its reporting that were discovered during the audit and cited in the Letter within 30 days, the Department, or its designee, will act as registrar and shall charge the facility, physician, dentist, other health care provider, and clinical laboratory for all costs related to these services, such as the retrieval of case information and the cost of the audit.
   ii. This fee shall be based upon the fair market value of such services.
   iii. All checks for fees for the Department's services shall be made payable to "Treasurer, State of New Jersey" or its designee, as provided in the Letter and forwarded to:

iv. Office of Cancer Epidemiology
New Jersey State Cancer Registry
New Jersey Department of Health
PO Box 369
Trenton, New Jersey 08625-0369

2. If a health care facility, physician, dentist or other health care provider fails to correct deficiencies in its reporting that were discovered during the audit and cited in the Letter within 30 days, the Department or its designee shall serve the entity or provider with a written Notice of Violation and Penalty Assessment.

(h) If a health care facility licensed by the Department pursuant to N.J.S.A. 26:2H-1 et seq., fails to correct deficiencies in its reporting that were discovered during the audit and cited in the Letter within 30 days, the Department, or its designee, shall report the facility to the Division of Health Facilities Evaluation and Licensing for non-compliance with these rules.

(i) If a physician, dentist, and other health care provider fails to correct deficiencies in its reporting that were discovered during the audit and cited in the Letter within 30 days, the Department, or its designee, shall report the provider to the appropriate New Jersey licensing board for non-compliance with this chapter.

(j) If a clinical laboratory fails to correct deficiencies in its reporting that were discovered during the audit and cited in the Letter within 30 days, the Department, or its designee, shall report the clinical laboratory to the Clinical Laboratory Improvement Service in the Division of Public Health and Environmental Laboratories for non-compliance with this chapter.

§ 8:57A-1.13 Civil monetary penalties

(a) Pursuant to N.J.S.A. 26:2-106f(3) and notwithstanding the provisions of N.J.A.C. 8:57A-1.12(f)1, the Commissioner may assess a penalty for violation of reporting requirements in accordance with the following standards:

1. For failure of a health care facility, physician, dentist or other health care provider to report pursuant to the provisions of this chapter, up to $ 500.00 per unreported case of cancer or other specified tumorous and precancerous disease; and/or
2. For failure of a health care facility to report electronically, up to $ 1,000 per business day.

(b) The Department or its designee may decrease the penalties in (a) above based upon compliance history, the number and frequency of the deficiencies, the measures taken to mitigate or prevent future deficiencies, the deterrent effect of the penalty and/or other specific circumstances of the facility, office or violation.

§ 8:57A-1.14 Failure to pay a penalty; remedies

(a) Upon receipt of a Notice of Violation and Penalty Assessment (Notice), a health care facility, physician, dentist or other health care provider has 30 days in which to notify the Department or its designee in writing of its, his or her answer to the Notice and request for a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

(b) The penalty becomes due and owing upon the 31st day from receipt of the Notice if the Department or its designee has not received a written answer and request for a hearing.

1. If the recipient of the Notice has requested a hearing, the penalty is due 45 days after the issuance of a Final Agency Decision by the Commissioner, if the Department or its designee has not withdrawn, rescinded or reversed its assessment, and an appeal has not been timely filed with the Appellate Division pursuant to Rule 2:2-3 of the New Jersey Court Rules.

(c) Failure to pay a penalty within 30 days of the date it is due and owing pursuant to (b) above may result in the institution of a summary civil proceeding by the Department or its designee pursuant to the Penalty Enforcement Law, N.J.S.A. 2A:58-10 et seq.

§ 8:57A-1.15 Hearings

(a) Upon request, a hearing shall be afforded to a health care facility, physician, dentist or other health care provider pursuant to N.J.A.C. 8:57A-1.14.

(b) A health care facility, physician, dentist or other health care provider shall notify the Department or its designee, in writing, of its request for a hearing within 30 days of receipt of a Notice of Violation and Penalty Assessment.

(c) The Department or its designee shall transmit the hearing request to the Office of Administrative Law, which will conduct the hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

§ 8:57A-1.16 Settlement of enforcement actions

(a) A health care facility, physician, dentist or other health care provider may request that the matter be settled in lieu of conducting an administrative hearing concerning an enforcement action.

(b) If the Department or its designee and the health care facility, physician, dentist or other health care provider agree on the terms of a settlement, a written agreement specifying these terms shall be executed.

(c) The Department or its designee may agree to accept payment of penalties over a schedule not exceeding 18 months where a health care facility, physician, dentist or other health care provider demonstrates financial hardship.

(d) All funds received in payment of penalties shall be recovered by and in the name of the Department and shall be dedicated to the New Jersey State Cancer Registry.