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**HEALTH**

**PUBLIC HEALTH SERVICES BRANCH**

**DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL AND OCCUPATIONAL HEALTH**

**CANCER EPIDEMIOLOGY SERVICES**

**Cancer Registry**

**Proposed Readoption with Amendments: N.J.A.C. 8:57A**

**Proposed Repeals: N.J.A.C. 8:57A Appendices A through M**

Authorized By: Shareef Elnahal, MD, MBA, Acting Commissioner, Department of Health (in consultation with the Public Health Council).

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

Calendar Reference: See Summary below for an explanation of exception to calendar requirement.

Proposal Number: PRN 2018-035.

Submit written comments by June 15, 2018, electronically to www.nj.gov/health/legal/ecomments.shtml or on paper by regular mail to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

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The agency proposal follows:

**Summary**

The Department of Health (Department) proposes the readoption with amendments of N.J.A.C. 8:57A, Cancer Registry, and proposed repeal of N.J.A.C. 8:57A Appendices A through M. Pursuant to N.J.S.A. 52:14B-5.1, the chapter was scheduled to expire on March 10, 2018. However, the agency filed this notice with the Office of Administrative Law prior to the expiration date, which extended the expiration of N.J.A.C. 8:57A by 180 days to September 6, 2018, in accordance with N.J.S.A. 52:14B-5.1.c(2).

N.J.A.C. 8:57A implements The Cancer Registry Act, N.J.S.A. 26:2-104 et seq., which requires the Department to maintain the New Jersey State Cancer Registry (NJSCR) and the disease conditions that must be reported thereto. The chapter applies to mandated reporters, identified in the existing rules as administrative officers of health care facilities, physicians, dentists, and other health care providers, health care insurers and other third-party health care payers, and directors of clinical laboratories, which requires them to report certain data concerning New Jersey residents diagnosed with particular types of cancer and specified cases of tumorous or precancerous disease.

The Acting Commissioner reviewed N.J.A.C. 8:57A and determined that the existing rules remain necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which they were originally promulgated. In addition, the Acting Commissioner recommends proposing certain amendments to the existing rules to reflect changes in the reporting of cancer related data required by the Federal government. Specifically, the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services, through its National Program of Cancer Registries (NPCR) Program Standards aims to achieve electronic reporting

benchmarks of 100 percent for hospitals and 80 percent for non-hospital facilities by 2022. As a grantee of the CDC's Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations (DP17-1701), the NJSCR is required to adhere to these standards. Other proposed amendments would support electronic submission by utilizing a software system and coding manual for the most up-to-date list of reportable diseases and conditions in the classification of cancerous and pre-cancerous diagnoses issued by the National Cancer Institute (NCI) of the National Institutes of Health (NIH) and CDC.

The following is a summary of the regulatory history of N.J.A.C. 8:57A:

On November 18, 1977, P.L. 1977, c.266, directed the Department to establish a cancer registry based on statistics that showed New Jersey had "the highest overall mortality rates for cancer in the Nation." N.J.S.A. 26:2-104. The Department is responsible for maintaining "an up-to-date registry which shall include a record of cases of cancer and specified cases of tumorous or precancerous disease that occur in New Jersey, and such information concerning these cases as it shall deem necessary and appropriate in order to conduct thorough and complete epidemiologic surveys of cancer and cancer-related diseases in this State and to apply appropriate preventive and control measures." N.J.S.A. 26:2-105.

On December 13, 1977, the Department adopted N.J.A.C. 8:57-1.19 as an emergency rule requiring the reporting of bladder cancer to assist the Department in an emergency investigation. 10 N.J.R. 12(a).

In response to statutory amendments at N.J.S.A. 26:2-104 through 109, the Department promulgated a new rule at N.J.A.C. 8:57-1.20, which established the

NJSCR and the timely, mandatory reporting thereto of cancer and other tumorous and precancerous diseases by administrative officers of every licensed health care facility in the State, physicians and dentists on initial diagnosis, and directors of every independent clinical laboratory licensed in the State. 10 N.J.R. 30(a); 385(b). Initially, the NJSCR focused on determining correlations between cancer and environmental factors that, if controlled, could reduce the incidence of cancer in the State. N.J.S.A. 26:2-104.

N.J.A.C. 8:57-1.19 and 1.20 expired October 30, 1985, pursuant to Executive Order No. 66 (1978). The Department repealed N.J.A.C. 8:57-1.19 and 1.20, inasmuch as the emergency investigation into bladder cancer was complete and the focus of the rule had changed pursuant to statutory amendment, and N.J.A.C. 8:57-1.20 was relocated as a new rule with amendments at N.J.A.C. 8:57-6, to accomplish the following reporting objectives: maintain a population-based cancer reporting system for New Jersey; provide annual New Jersey cancer incidence data using demographic data for prevention and control activities; promote studies related to high risk groups and occupational occurrence of cancer; expand cancer registry programs in New Jersey health care facilities; and provide education and outcome data to physicians and hospitals. 17 N.J.R. 2836(b); 18 N.J.R. 1283(a).

In 1990, the Department recodified N.J.A.C. 8:57-6 with amendments as N.J.A.C. 8:57A, which expanded the list of reportable diseases to the NJSCR, clarified ambiguous terms used in the interpretation of final cancer diagnoses, and provided the Department access to cancer data from a variety of sources for research related to cancer prevention and control. 21 N.J.R. 3909(a); 22 N.J.R. 1596(a).

In 1995, the Department readopted N.J.A.C. 8:57A with amendments that required hospitals, and provided an option for health care providers, physicians, and dentists, to submit machine-readable data that meet criteria and standards specified by the Department to address the changing health care practices of increased outpatient diagnosis. 27 N.J.R. 629(a); 1988(a).

In 1998, the Department adopted amendments to N.J.A.C. 8:57A to implement statutory amendments that require abstracting work for a health care facility to be performed by a certified tumor registrar; permit the Department to contract out its registry services to those health care facilities that lack the capability to timely comply with reporting mandates; allow the Department to conduct registry services at facilities that fail to correct deficiencies discovered on audit; require all health care facilities to report cases electronically; require health insurers and third party health care payers to report cancer cases to the NJSCR; permit the imposition of civil monetary penalties against any health facility, health care provider, or health insurer that fails to report cancer cases in a timely manner; and provide necessary funding to bring the NJSCR up-to-date, pursuant to N.J.S.A. 26:2-106, effective July 22, 1996. 29 N.J.R. 2759(a); 30 N.J.R. 2903(b).

In 2000, the Department readopted N.J.A.C. 8:57A. 32 N.J.R. 214(a); 1790(a).

In 2005, the Department readopted N.J.A.C. 8:57A with amendments to the list of reportable diseases and conditions at N.J.A.C. 8:57A-1.8(g). 37 N.J.R. 1666(a); 4257(a).

In 2011, the Department readopted N.J.A.C. 8:57A with amendments, new rules, and a repeal, which effectively recast the role of the Public Health Council from advisory

to consultative and vested in the Commissioner of Health the responsibility to establish standards and promulgate rules to maintain an up-to-date registry. 42 N.J.R. 2529(a); 43 N.J.R. 850(a).

The following is a summary of the rules proposed for readoption with amendments:

The Department makes technical changes throughout the chapter to implement a statutory amendment at N.J.S.A. 26:2A-2.1 that renames the agency the "Department of Health," updates manual references, and corrects contact information for reference materials.

N.J.A.C. 8:57A-1.1, Purpose and scope, describes the purpose and scope of the subchapter, the purpose of the NJSCR, and the stakeholders to which the chapter applies.

N.J.A.C. 8:57A-1.2, Incorporated and referenced documents, identifies the documents incorporated and referenced by the chapter. The Department proposes to delete existing N.J.A.C. 8:57A-1.2(c) and (d) by deleting existing language that refers to the reporting forms at N.J.A.C. 8:57A Appendices A through M because the NJSCR no longer will support paper-based reporting in accordance with the terms and conditions of Federal cancer data reporting agencies and would require all cancer data to be submitted electronically.

N.J.A.C. 8:57A-1.3, Definitions, defines words and terms used in the chapter. Proposed amendments to N.J.A.C. 8:57A-1.3 would add definitions for "certified tumor registrar" and "clinical laboratory." Proposed definition of the term "certified tumor registrar (CTR)" anticipates the changes to be made by the National Cancer Registrars

Association, which governs the education and certification of the data information specialists who capture the complete history, diagnosis, treatment, and health status for every cancer patient in the U.S. This amendment would permit CTRs with the new credential to perform reporting and abstracting work for health care facilities and enable those facilities to remain in compliance with N.J.A.C. 8:57A.

N.J.A.C. 8:57A-1.4, Reporting of cancer; general requirements, establishes the general requirements for reporting cancer data to the Department. Proposed amendments to N.J.A.C. 8:57A-1.4(a) and (b) would remove the qualifying term "independent" before the term "clinical laboratories" to maintain consistency with N.J.A.C. 8:57A-1.1(c), which refers to clinical laboratories in general. Proposed amendments to N.J.A.C. 8:57A-1.4(b) would redefine the existing reporting timeframe to align with industry standards. "Date of first contact" is a data element required by the NAACCR Data Standards for Cancer Registries and is defined as "date of first patient contact, as inpatient or outpatient, with the reporting facility for the diagnosis and/or treatment of the tumor." The existing requirement at N.J.A.C. 8:57A-1.4(b) as written is within six months after diagnosis or three months of discharge, whichever is sooner, which presents difficulties in measurement because diagnosis may not have occurred at the reporting facility and may not capture all patients who are not admitted for cancer treatment. Proposed amendments to N.J.A.C. 8:57A-1.4(c) would allow the NJSCR to define the most appropriate format of follow-up reporting on a case-by case basis. Multiple potential formats exist for reporting follow-up data and may vary by reporting facility type. Electronic reporting of follow-up data in the form of a NAACCR-modified abstract is preferred, but not all software programs have the capability of producing

such an abstract. The Department proposes to amend N.J.A.C. 8:57A-1.4(e) that would redefine health care facilities', physicians', dentists', other health care providers', and clinical laboratories' options for applying for no-cost registry software because the Rocky Mountain software is no longer used. Health care facilities, physicians, dentists, and other health care providers may contact the NJSCR at njscrdat@doh.nj.gov to obtain Registry Plus™ Web Plus or Abstract Plus software through CDC at no cost. Laboratories may contact the NJSCR to receive electronic laboratory software provided by NIH or CDC at no cost to the facility.

N.J.A.C. 8:57A-1.5, Health care facility reporting, addresses cancer reporting requirements specific to health care facilities. Proposed amendments to N.J.A.C. 8:57A-1.5(b) through (f), would require health care facilities with greater than 100 cancer cases to be required to employ or have under contract a CTR or other equivalent certified professional to oversee case-finding activities, inform the NJSCR of any change in the name and contact information of the CTR, and ensure abstracting services adhere to New Jersey State cancer-reporting rules, as these services may be performed remotely in other states where rules differ from those in New Jersey. The Department expects these amendments would improve completeness of case capture, allow the Department to more easily obtain supplemental information, monitor compliance with reporting, and provide support to the reporting facility. The amendments also would allow the Department to offer facilities the option of contracting with the Department, or the Department's designee, to perform abstracting services. The Department authorized the Rutgers, Cancer Institute of New Jersey as its designee.

N.J.A.C. 8:57A-1.6, Physician, dentist, and other health care provider reporting, addresses cancer reporting requirements for physicians, dentists, and other health care providers. N.J.A.C. 8:57A-1.6(a) proposed for amendment would simplify the reporting requirements for physicians by removing the qualification for physicians to report only patients who were not seen at another facility. Increasingly, cancer is being treated in the physician office setting, and this treatment is not often captured by other health care facilities. Accurate physician office reporting of these cases would improve the completeness of treatment information reported to the NJSCR. In addition, it is not always possible for the NJSCR or the physician to confirm whether a patient has been seen in another facility. N.J.A.C. 8:57A-1.6(b), as proposed for amendment, would define acceptable electronic reporting formats for physicians, dentists, and other health care providers. To replace paper-based reporting, NPCR Program Standards require a shift to electronic reporting by physicians and other health care facilities using the free cancer-reporting software provided at proposed N.J.A.C. 8:57A-1.4. The Department proposes to allow electronic reporting in the NAACCR data standard format for cancer registries or in other industry-accepted standard reporting formats that are currently in the process of implementation. These formats would include reporting under the Centers for Medicare and Medicaid Meaningful Use (MU) program and medical claims billing data. Allowing these reporting formats would eliminate the need for duplicate reporting by the physician.

N.J.A.C. 8:57A-1.7, Clinical laboratory reporting, addresses cancer reporting requirements for clinical laboratories. N.J.A.C. 8:57A-1.7(a), as proposed for amendment, would define acceptable electronic reporting formats for clinical

laboratories to replace paper-based reporting because CDC's NPCR Program Standards favor electronic reporting by laboratories and other health care facilities and such cancer reporting software is available at no cost to these providers as set forth at proposed N.J.A.C. 8:57A-1.4.

N.J.A.C. 8:57A-1.8, Health care insurer reporting, addresses cancer reporting requirements for health care insurers.

N.J.A.C. 8:57A-1.9, Supplemental information, establishes the requirement for health care facilities, physicians, dentists, and other health care provers and clinical laboratories to provide the Department supplemental information upon request. N.J.A.C. 8:57A-1.9, as proposed for amendment, would delete the forms that no longer will be used for submitting supplemental information and establishes that the NJSCR would contact the reporter for the supplemental information and direct the manner of submission at the time of the request.

N.J.A.C. 8:57A-1.10, Access to information and records, addresses the obligation of every health care facility, clinical laboratory, physician, dentist, or other health care provider and health care payers to allow the Department or its designee access to records related to cancer cases. Proposed amendments to N.J.A.C. 8:57A-1.10(a) and (b) would remove the qualifying term "independent" from clinical laboratories to maintain consistency within the subchapter, particularly with N.J.A.C. 8:57A-1.1(c), which refers to clinical laboratories in general. Proposed amendments to N.J.A.C. 8:57A-1.10(a) would allow remote, electronic access to records, where available, to reduce costs to the Department associated with travel to and from health care facilities and may reduce the expenditure of health care facility resources by eliminating the need to provide

space on-site for NJSCR staff. Proposed new N.J.A.C. 8:57A-1.10(f)2 would allow the Department to release limited summary information to the patient or next-of-kin, with written authorization, for the purposes of the health or welfare of the patient or their descendants. Proposed new N.J.A.C. 8:57A-1.10(f)3 would permit healthcare providers to make written requests to the Department for release of pertinent patient cancer information for treatment purposes.

Existing N.J.A.C. 8:57A-1.11 identifies reportable diseases and conditions. The lists of reportable conditions at subsections (a) and (g) are subject to rapid obsolescence as the science of oncology progresses. To avoid this, the Department proposes to amend this section to delete existing subsections (a) and (g), recodify existing subsection (b) as new subsection (a), add new subsection (b), which would identify reportable diagnoses by histology and behavior as specified in the ICD-O, recodify, reorganize, and combine existing subsections (c) and (d), which contain exceptions to reportability, as new subsection (c), and recodify existing subsections (e) and (f) as new (d) and (e).

N.J.A.C. 8:57A-1.12, Audit, letter and notice of violations and enforcement actions, defines the procedure for the Department to conduct audits of regulated entities and to issue enforcement action for failure to comply with the reporting requirements of the chapter. The Department proposes to amend N.J.A.C. 8:57A-1.12(a) and (b) to remove the qualifying term “independent” from clinical laboratories to eliminate confusion on the requirement of hospital-based clinical laboratories to report to NJSCR and to maintain consistency within the subchapter, particularly with N.J.A.C. 8:57A-1.1(c), which refers to clinical laboratories in general. The Department proposes to

amend N.J.A.C. 8:57A-1.12(f) to enable the NJSCR to report non-compliant mandated reporters to the appropriate State licensing authorities that could subject such entities to potential enforcement actions that affect licensure status, as provided by statute and regulation. The previously existing civil monetary penalties for noncompliance have not been changed.

N.J.A.C. 8:57A-1.13, Civil monetary penalties, sets forth the process for assessing a per day fine for health care facilities with violations for unreported cancer cases and failure to report electronically to the NJSCR, as well as providing the Department discretion for mitigation of penalties on a fact-specific basis.

N.J.A.C. 8:57A-1.14, Failure to pay a penalty; remedies, establishes the process mandated reporters must follow to pay a Notice of Violation and Penalty Assessment and identifies enforcement actions available to the Department for non-payment pursuant to the Penalty Enforcement Law at N.J.S.A. 2A:58-10.

N.J.A.C. 8:57A-1.15, Hearings, sets forth the rights of mandated reporters to request a hearing upon receipt of a Notice of Violation and Penalty Assessment, whereby the Department transmits the request for a hearing to the Office of Administrative Law pursuant to the Administrative Procedure Act at N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq.

N.J.A.C. 8:57A-1.16, Settlement of enforcement actions, provides a process by which mandated reporters may request the Department settle an enforcement action in lieu of conducting an administrative hearing, whereby funds recovered by the Department are dedicated to the NJSCR.

The Department proposes to repeal the following appendices that contain reporting formats that are no longer acceptable by the Federal government, as discussed above.

N.J.A.C. 8:57A APPENDIX A is the “Radiation Therapy Facility Report Form.”

N.J.A.C. 8:57A APPENDIX B is the “Ambulatory Surgery Center Report Form.”

N.J.A.C. 8:57A APPENDIX C is the “Physician Report Form.”

N.J.A.C. 8:57A APPENDIX D is the “Dentist Report Form.”

N.J.A.C. 8:57A APPENDIX E is the “Laboratory Report Form.”

N.J.A.C. 8:57A APPENDIX F is the “Hospice Program Report Form.”

N.J.A.C. 8:57A APPENDIX G is the “Hematology/Oncology Physician Report.”

N.J.A.C. 8:57A APPENDIX H is the “Hematology/Oncology Information Request.”

N.J.A.C. 8:57A APPENDIX I is the “Cancer Registry Survey.”

N.J.A.C. 8:57A APPENDIX J is the “Diagnostic Laboratory Information Request.”

N.J.A.C. 8:57A APPENDIX K is the “Rocky Mountain Cancer Data Software (RMCDS) Information Request.”

N.J.A.C. 8:57A APPENDIX L is the “Death Certificate Follow-Back Report.”

N.J.A.C. 8:57A APPENDIX M is the “NJSCR Follow-Back Physician Form.”

The Department has provided a 60-day public comment period on this notice of proposal; therefore, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

**Social Impact**

In 2018, the NJSCR expects to receive over 300,000 reports of cancer among New Jersey residents. Health care facilities are the primary source of reporting cancer

cases. However, as cancer care patterns trend toward the ambulatory setting, non-hospital health care providers are becoming an increasingly critical source of information for the NJSCR. Physicians, dentists, clinical laboratories, and other health care providers report treatment performed outside the hospital setting as well as cancer cases in patients who do not require hospitalization. Because of this trend, and owing to the importance of ensuring that all cases of cancer among New Jersey residents, including complete treatment information, are documented in the NJSCR, the CDC has established program standards requiring the NJSCR to ensure electronic reporting from 80 percent of non-hospitals facilities by 2022.

The NJSCR's database contains nearly 1.8 million cases of cancer diagnosed since October 1, 1978. Data collected include but are not limited to demographic information (name, date of birth, gender, race, ethnicity, and address at diagnosis) and medical information (primary site, histological type, stage of disease at diagnosis and treatment, and survival). The Department uses these data to monitor cancer trends, make comparisons to national data, plan and evaluate cancer prevention and control initiatives, investigate community cancer concerns, and conduct epidemiological studies of cancer causes and treatment outcomes.

Over 400 scientific papers and reports have been produced using the NJSCR data, thereby contributing to the understanding of cancer in New Jersey. The NJSCR has been recognized nationally for excellence by the NCI, CDC, and the North American Association of Central Cancer Registries (NAACCR). NCI’s Surveillance, Epidemiology and End Results (NCI/SEER) program has awarded the NJSCR with first-place recognition for meeting all 14 data quality measures for the last three years.

NJSCR has been recognized as a Registry of Excellence by the CDC's National Program of Cancer Registries. The NJSCR has earned the NAACCR gold certification 19 out of the 20 years since the inception of the award (the one exception being a silver certification in 2014). See http://www.naaccr.org.

New Jersey's diverse, multi-ethnic population and unique environmental factors make the State an excellent place to study cancer differences and similarities in comparative populations. Population-based data are essential in assisting in the research and development of treatment protocols that combat cancer. The data inform health care planners and policy makers of trends that aid in activating plans and policies regarding cancer. A number of research programs use these data for the control and prevention of cancer and for special investigations of cancer etiology and treatment outcomes.

The rules proposed for readoption with amendments and repeals would continue to have a beneficial social impact since cancer remains a leading cause of morbidity and mortality in this State, as well as in the entire nation. The increased focus on electronic reporting proposed in these rules would expedite the mechanism for reporting cancer and pre-cancerous conditions to the NJSCR and improve the timely availability of complete cancer data and statistics to researchers, policy makers, and the public.

Non-substantive changes to the rules may positively impact among members of the regulated community by providing a greater understanding of the meaning of the rules, and therefore, may improve compliance. Other positive outcomes from the proposed amendments could be significant reduction in paper-based reporting, shifting toward more electronic reporting by utilizing existing IT systems and infrastructure, thus

ensuring data integrity and improving the timely availability of complete cancer data to researchers, policy makers, and the public.

The proposed amendment at N.J.A.C. 8:57A-1.4(b) would simplify timing of reporting for the regulated community and bring it into alignment with industry standards. Date of first contact is a well-defined date specific to each reporting facility, while date of diagnosis and date of discharge may be unknown to or vary by facility. This proposed amendment also would facilitate the ability of the Department to assess the compliance of reporting facilities with timing requirements of N.J.A.C. 8:57A-1.4 to identify delinquent reporters and improve the timely availability of complete cancer data to researchers, policy makers, and the public. Proposed amendments to N.J.A.C. 8:57A-1.4(e) would provide health care facilities, physicians, dentists, clinical laboratories, and other health care providers instructions for accessing no-cost software to facilitate electronic cancer reporting to the NJSCR.

The proposed amendments to N.J.A.C. 8:57A-1.5(b) would anticipate potential changes in the name of the Certified Tumor Registrar (CTR) credential by the NCRA. This proposed amendment would allow reporting facilities to utilize staff with the expected new credential and remain in compliance with N.J.A.C. 8:57A. An additional proposed amendment to N.J.A.C. 8:57A-1.5(b) would require hospitals that contract with outside agencies for cancer registry reporting ensure that these agencies follow New Jersey cancer reporting rules and standards, which the Department anticipates would improve the quality of the data that is reported to NJSCR and that would be available to researchers, policy makers, and the public.

Proposed amendments at N.J.A.C. 8:57A-1.6(b) would allow physician reporting under the Centers for Medicare and Medicaid Meaningful Use (MU) program and other innovative reporting mechanisms currently in development at NCI and NJSCR (that is, medical billing claims data) to satisfy the cancer reporting requirements of N.J.A.C. 8:57A. The current rule creates redundant reporting for physicians, requiring reporting under both MU and N.J.A.C. 8:57A. This amendment would eliminate the need for physicians to dual report, thus easing the burden on these providers. These electronic reporting mechanisms replace the need for paper-based reporting forms. The proposed amendment at N.J.A.C. 8:57A-1.6(c) eliminates the need for providers to complete the paper Cancer Registry Survey, which is redundant with their registration for reporting electronically under amended N.J.A.C. 8:57A-1.4 and 1.6.

The Department believes the proposed amendments to N.J.A.C. 8:57A-1.7 would improve the electronic case capture of cancer from clinical laboratories providing services for New Jersey residents, which likely would ensure data integrity and provide more timely availability of complete cancer data to researchers, policy makers, and the public. Currently, 32 hospital-based and 34 independent clinical laboratories report to NJSCR electronically via software provided by the National Cancer Institute and at no cost to the reporting facility. No-cost software also is available now from the CDC that would allow all laboratories to report electronically to the NJSCR via the Public Health Information Messaging System (PHIN MS). Currently, eight independent clinical laboratories report to NJSCR vis PHIN MS. The proposed amendment would allow all laboratories to determine the reporting mechanism that best meets their needs.

Proposed amendments to N.J.A.C. 8:57A-1.10 would allow the Department to release limited cancer record summaries to the patient or their next-of-kin, with the positive social impact of improving individuals access to cancer registry information that are no longer available from the physician or hospital due to record retention and destruction policies, hospital or clinic closures, physician retirements, or natural disasters. Better understanding of personal and familial history of cancer improves the individual's ability to make informed decisions around health care and cancer screening. Additional proposed amendments to N.J.A.C. 8:57A-1.10 would allow the Department to release diagnostic, treatment, or follow-up information about a patient to a physician or medical facility involved in the patient's care. This may aid providers in ensuring patients receive appropriate care during and after their initial treatment and may help providers to assess outcomes and make improvements in their own practice.

The proposed amendments to N.J.A.C. 8:57A-1.11 remove the list of reportable conditions and incorporate by reference the reporting requirements published by the NCI/SEER Program, which would allow the regulated community to maintain the most up-to-date list of reportable diseases and conditions.

**Economic Impact**

The rules proposed for readoption with amendments and repeals impose requirements on health care facilities, independent and hospital-based clinical laboratories, physicians, dentists and other health care providers, and health care insurers and other third-party payers. The information required for reporting is information that regulated entities, subject to the chapter's reporting requirements, routinely collect in the ordinary course of health care practice.

Existing N.J.A.C. 8:57A-1.5(b) requires health care facilities that diagnose or treat 100 or more cancer cases per year to either employ or retain the services of a Certified Tumor Registrar to perform abstracting for the purpose of reporting of cancer data. These facilities have incurred and would continue to incur costs associated with the employment or retention of a registrar.

Some entities subject to the chapter's reporting requirements elect to purchase reporting software as part of their existing cancer practices. All hospitals have the capacity to report data electronically. However, upon request, the Department provides the necessary cancer-reporting software and associated training in the use of the software at no cost to entities subject to the chapter. The rules proposed for readoption with amendments and repeals have required and would continue to require entities to incur administrative expenses associated with the time needed to train employees in use of the system and the time needed to enter the information into the system and transmit it to the Department.

Under existing N.J.A.C. 8:57A-1.6(b) and 1.7(c), physicians, dentists, other health care providers, and clinical laboratories that report through submission of paper reports incur administrative expenses associated with form completion and postage as well as a certain level of risk to confidentiality when paper-based reports are generated and mailed to the registry. Proposed amendments to N.J.A.C. 8:57A-1.6 and 1.7 provide mechanisms for physicians, dentists, other health care providers, and clinical laboratories to report electronically, eliminating the burden associated with paper reporting, enhancing data integrity, and significantly decreasing risks to confidentiality. The rules proposed for readoption with amendments and repeals would require

reporting entities to incur administrative expenses associated with the time needed to train employees in the use of the system and to enter information into the system to transmit to the Department. When available, the Department may provide cancer-reporting software and associated training in the use of the software at no cost to the reporting entities subject to the chapter. The time and cost associated with submitting electronically is not anticipated to be significantly greater than reporting on paper and may be less in the long term. The NJSCR funding sources include monies from Federal, State, and collaborating researchers, such as universities and private companies.

Proposed amendments to N.J.A.C. 8:57A-1.7 and 1.12 may result in penalties imposed by the Department or other actions pursuant to the appropriate State licensing authorities for failure to comply with the provisions of N.J.A.C. 8:57A. The previously existing civil monetary penalties for noncompliance have not been changed.

The provision of timely and accurate cancer data is essential for developing a complete picture of cancer in New Jersey. In the long term, the reporting of cancer data benefits the public through the provision of important information that public and private health care agencies and governmental authorities use in the planning and funding of cancer prevention and control activities. Identifying high-risk populations, trends, and disparities specific to this State result in the economically efficient allocation of public health resources.

In terms of cost efficiency studies of the NJSCR, Dr. Hannah K. Weir and colleagues analyzed state variations in average cost per case of cancer reported by 43 state cancer registries and the cancer registry for the District of Columbia in their article entitled "The National Program of Cancer Registries: Explaining State Variations in

Average Cost per Case Reported," published in the journal Preventing Chronic Disease in July 2005. The authors reported that the average cost per case of cancer reported tended to decrease with increasing total number of cases reported by the state, and that the cost per case reported tended to increase in areas with higher costs of living. New Jersey is among the states that reports a higher number of cancer cases each year, due to the State's large population. The cost per case in New Jersey was found to be $11.01, nearly 67 percent lower than the national average of $29.20. The Department is not aware of any more recent cost analyses of state cancer registries in the United States. The Department believes that the benefits of the NJSCR in reducing the burden of cancer among the residents of this State outweigh the associated costs.

Existing N.J.A.C. 8:57A-1.10 required reporting entities to provide Department personnel, or their designee, with access to all records pertinent to its cancer cases as necessary for fulfilling the functions of the NJSCR. Proposed amendments to N.J.A.C. 8:57A-1.10 would leverage existing information technology infrastructure to provide NJSCR staff access to these records without the expense of physical travel to the facility, thereby further reducing the cost per case of cancer data collection in New Jersey. Additionally, the fact that patients and next-of-kin would now be allowed to access records previously filed with the Cancer Registry and now no longer available elsewhere can be expected to improve treatment outcomes.

**Federal Standards Analysis**

The Department proposes to readopt the rules at N.J.A.C. 8:57A with amendments and repeals pursuant to the authority of N.J.S.A. 26:2-104 et seq.,

particularly 26:2-106b. Nevertheless, there are Federal laws and standards that are applicable to cancer registries and the rules at N.J.A.C. 8:57A.

The Cancer Registries Amendment Act (Pub. L. 102-515, enacted October 24, 1992) authorizes the Secretary of the U.S. Department of Health and Human Services to make grants to states to support the collection of cancer data by the operation of statewide cancer registries. Section 3 of the Act, codified at 42 U.S.C. § 280e, specifically conditions grant eligibility on a state's promulgation of statutes and regulations implementing its cancer registry. 42 U.S.C. § 280e(c)(2)(D) provides a state's regulations must: 1) require reporting of newly diagnosed cancer cases by hospitals and other health-care facilities; 2) require reporting of cancer cases by physicians and other health-care practitioners; 3) guarantee access by the statewide cancer registry to all records of medical status of persons with cancer; 4) require the use of standardized reporting formats; 5) ensure confidentiality of cancer case data; 6) allow use of confidential case data by certain researchers; 7) authorize the conduct of studies using cancer registry data; and 8) ensure protection of persons complying with the law from liability.

The rules proposed for readoption with amendments and repeals meet and do not exceed these requirements, thereby making the Cancer Registry eligible for Federal funding under the National Program of Cancer Registries (NPCR) funded by the Centers for Disease Control and Prevention. The NPCR Program Standards, 2017 to 2022, require the NJSCR, as a recipient of Federal funding, to increase the percentage of non-hospital facilities reporting to the NJSCR to at least 80 percent by 2022.

The Benign Brain Tumor Cancer Registries Amendment Act, Pub. L. 107-260, signed on October 29, 2002, requires state cancer registries participating in the NPCR to collect data on benign and borderline tumors of the central nervous system in addition to the previously required data on malignant tumors. The rules proposed for readoption with amendments meet, but do not exceed, this Federal standard.

**Jobs Impact**

The rules proposed for readoption with amendments and repeals may have created, and may continue to create, a demand for personnel in positions requiring specialized training in the use of cancer reporting systems.

Except as described above, the rules proposed for readoption with amendments and repeals would have no impact in the creation or loss of jobs.

**Agriculture Industry Impact**

The rules proposed for readoption with amendments and repeals have not had an impact on the agriculture industry, and the Department does not anticipate that the rules proposed for readoption with amendments and repeals would have an impact on the agriculture industry.

**Regulatory Flexibility Analysis**

The rules proposed for readoption with amendments and repeals would continue to impose reporting requirements on health care facilities (hospitals), which are the primary source of reporting cancer cases. In addition, the rules proposed for readoption with amendments and repeals would continue to require physicians, dentists, other

health care providers, and clinical laboratories to report cancer cases treated on an outpatient basis. Hospitals and health care insurers are not small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Physicians, dentists, other health care providers, and clinical laboratories may be small businesses within the meaning of the Regulatory Flexibility Act.

The rules proposed for readoption with amendments and repeals would continue to require small businesses subject to the chapter to report cancer data. The proposed amendment at N.J.A.C. 8:57A-1.6(a) may result in a small increase in the number of cases required to be reported by small business. Although the Department has no statistics quantifying the number of such cases that have been reported to the NJSCR, the Department does not expect the proposed amendments and repeals to have any significant impact on the burden of cancer reporting on these entities. Information on whether or not a patient has been referred to or previously diagnosed in a health care facility may not be readily available or clear to the reporting physician, dentist, or other health care provider, thus resulting in an unclear determination of the reportability of the case to the NJSCR. This proposed amendment removes the ambiguity and eliminates the need for the reporting entity to research the patient's hospitalization history. In addition, the act of referring a patient to a health care facility does not confirm that the patient was seen at and reported by the health care facility. For these reasons and the ability of physicians, dentists, and other health care providers who treat cancer patients in the outpatient setting to provide essential information on this treatment to the NJSCR, the potential small economic impact on reporting entities is justified. As described in the Economic Impact above, the rules proposed for readoption with amendments and

repeals have required and would continue to require these small businesses to obtain reporting software and associated training services either from an outside vendor or free of charge from the Department and to incur administrative expenses associated with the time needed to train employees in the use of the software and to enter the required cancer data. Also, as noted above, the Department has and will continue to assist health care providers in obtaining free software and training, which, in the long run, may reduce the administrative costs associated with reporting to the registry.

The rules proposed for readoption with amendments and repeals do not require small businesses subject to the chapter to retain the services of professionals in order to comply. The Department has made no provision for lesser or differing standards to minimize the burden of the rules on small businesses. The Department has determined that the rules proposed for readoption with amendments and repeals impose the minimum standards necessary to implement the statutory mandate to establish a thorough and complete cancer registry, to provide thereby an accurate picture of the incidence of cancer in New Jersey. These data are essential for public health policy and planning for cancer control and prevention. The provision of exclusions, exemptions, or variations in data reporting from small businesses would skew the accuracy and completeness of the NJSCR. Moreover, to require less than complete reporting on New Jersey cancer cases from small businesses subject to the chapter potentially would be inconsistent with the requirements of and conflict with the Federal standards described in the Federal Standards Statement above, thereby jeopardizing the NJSCR's eligibility for Federal funding to support its efforts.

**Housing Affordability Impact Analysis**

The rules proposed for readoption with amendments and repeals would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing. The rules have concerned and would continue to concern the reporting of cases of cancer and specified cases of tumorous or precancerous disease to the NJSCR.

**Smart Growth Development Impact Analysis**

The rules proposed for readoption with amendments and repeals would have an insignificant impact on smart growth, and there is an extreme unlikelihood that the rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey. The rules proposed for readoption with amendments and repeals have concerned and would continue to concern the reporting of cases of cancer and specified cases of tumorous or precancerous disease to the NJSCR.

**Full text** of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:57A.

**Full text** of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:57A Appendices A through M.

**Full text** of the proposed amendments follows (additions indicated in boldface **thus**; deletions in brackets [thus]):

SUBCHAPTER 1. CANCER REGISTRY

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 [and Senior Services] 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. – 3. (No change.)

(b) - (c) (No change.)

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. [The e-path Reporting Site Information Checklist (based on the National Cancer Institute's Surveillance Epidemiology End Results (SEER) Program Case Finding List, effective January 2010), developed by the] Artificial Intelligence in Medicine Incorporated[, 2 Berkeley Street, Suite 403, Toronto, Ontario, Canada M5A 2W3,]**. "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 [SEER Program Code Manual 2007, developed by the Surveillance Epidemiology and End Results (SEER) Program of the] National Cancer Institute, Division of Cancer Control and Population Sciences, Surveillance Research Program, Cancer Statistics Branch/SEER Program[, 6116 Executive Boulevard, Suite 504, MSC 8316, Bethesda, MD 20892-8316, Telephone: (301) 496-8510,]**. "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 [NAACCR Data Standards for Cancer Registries - Data Standards and Data Dictionary (Volume II – Version 12), developed by the] North American Association of Central Cancer Registries (NAACCR), [Executive Office, 2121 West White Oaks Drive, Suite B, Springfield, IL 62704-6495, Telephone: (217) 698-0800,] **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**; [and]

4. The [NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting, Version 2.1 (effective January 1, 2008), developed by

the] North American Association of Central Cancer Registries (NAACCR), [Executive Office, 2121 West White Oaks Drive, Suite B, Springfield, IL 62704-6495, Telephone: (217) 698-0800,] **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 [2.3.1] **2.5.1** standard protocol that [independent or hospital-based] clinical laboratories [must] **may** use [if they chose] to make reports to the Department electronically and is available online at: [http://www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx.] **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**,"** [written and published by the New Jersey Department of Health and Senior Services, Cancer Epidemiology Services to] **which**

provide**s** guidance to health care facilities on the electronic transmission of data to the Department and [to provide] information from Federal programs that establish standards for cancer registries and which is available online at:

[http://nj.gov/health/ces/cancer_reporting_hos.shtml]

**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 [2008] **2017,"** [written and published by the New Jersey Department of Health and Senior Services, Cancer Epidemiology Services to] **which** provide**s** guidance to physicians, ambulatory care centers (ACCs)**,** and radiation treatment facilities (RTFs) on the electronic [or written] transmission of data to the Department and which is available online at: [http://nj.gov/health/ces/cancer_reporting_phy.shtml]

**http://www.nj.gov/health/ces/reporting-entites/non-hospital/**.

[(c) The Department incorporates by reference the following forms in this subchapter:

1. The Radiation Therapy Facility Report Form (N.J.A.C. 8:57A Appendix A), which is a form required of radiation facilities to report radiotherapy treatment information for cases of cancer to the NJSCR;

2. The Ambulatory Surgery Center Report Form (N.J.A.C. 8:57A Appendix B), which is a form required of ambulatory care centers to report surgical cancer diagnosis and cancer treatment to the NJSCR;

3. The Physician Report Form (N.J.A.C. 8:57A Appendix C), which is a form required of physicians to report information on cancer diagnosis or treatment at their respective practices to the NJSCR;

4. The Dentist Report Form (N.J.A.C. 8:57A Appendix D), which is a form required of dentists to report information on non-hospitalized cases of cancer to the NJSCR;

5. The Laboratory Report Form (N.J.A.C. 8:57A Appendix E), which is a form required of laboratories to report cancer diagnoses to the NJSCR;

6. The Hospice Program Report Form (N.J.A.C. 8:57A Appendix F), which is a form required of hospice providers to report patients diagnosed with cancer to the NJSCR;

7. The Hematology/Oncology Physician Report (N.J.A.C. 8:57A Appendix G), which is a form required of physicians to report information on cases of hematopoietic cancer to the NJSCR;

8. The Hematology/Oncology Information Request (N.J.A.C. 8:57A Appendix H), which is a form that physicians shall use to report information about their practice to the NJSCR, upon request;

9. The Cancer Registry Survey (N.J.A.C. 8:57A Appendix I), which is a form required of physicians, dentists, or health care providers to report information on their practice when they report cases of cancer to the NJSCR the first time or if they have just opened their practice in New Jersey;

10. The Diagnostic Laboratory Information Request form (N.J.A.C. 8:57A Appendix J), which is a form that clinical laboratories located in New Jersey shall use to

report information about their laboratory to the NJSCR, upon request, and to request software in order to implement electronic cancer case-finding and pathology data gathering for the NJSCR;

11. The Rocky Mountain Cancer Data Software (RMCDS) Information Request (N.J.A.C. 8:57A Appendix K), which is a form required of health care facilities and providers if they choose to apply for a no- cost software program to report information on cases of cancer electronically to the NJSCR;

12. The Death Certificate Follow-Back Form (N.J.A.C. 8:57A Appendix L), which is a form used to obtain information on New Jersey residents who died with a cancer diagnosis and is only required when the NJSCR determines that there is a need for more information on a specific cancer case, which is based on cancer related cause of death information from the death certificate;

i. If the NJSCR determines that more information is needed, NJSCR staff will mail the appropriate form to the physician or health care facility; and

13.The NJSCR Follow-Back Physician Form (N.J.A.C. 8:57A Appendix M), which is a form used to obtain information on living patients with a cancer diagnosis and is only required when the NJSCR receives insufficient information and needs further details in order to complete abstraction of the case.

i. If the NJSCR determines that more information is needed, NJSCR staff will mail the appropriate form to the physician.

(d) All of the forms in (c) above are available by written request to the NJSCR mailing address.

1. The forms in (c)1 through 13 above are available online through the NJSCR webpage or the Department's Forms webpage at http://web.doh.state.nj.us/forms/]

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:

…

**"Certified tumor registrar" means a person who has been certified as such, or certified with an equivalent credential, by the National Cancer Registrars Association's (NCRA) Council on Certification, pursuant to N.J.A.C. 8:57A-1.5(b), 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 [and Senior Services], or his or her designee.

"Department" means the New Jersey Department of Health [and Senior Services].

…

"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 [and Senior Services], PO Box 369, Trenton, New Jersey 08625-0369.

"NJSCR webpage" means the webpage of the New Jersey State Cancer Registry available at [www.state.nj.us/health/ces/index.shtml] **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 [independent] clinical laboratory shall report [all cases of cancer and other specified tumorous and precancerous diseases] to the Department [in accordance with] the [list of] 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 [independent] clinical laboratory shall submit all case reports within six months of the date of [diagnosis or within three months of the date of discharge from the reporting facility, whichever is sooner] **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 [reports] **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 [Code] **Coding and Staging** Manual [2007] **2016** when abstracting and coding cancer data.

(e) [If health care facilities and physicians choose to] **A health care facility, physician, dentist, other health care provider**, **or clinical laboratory may** apply for a no-cost software program [, which would be used] to report information on cases of cancer **electronically** to the NJSCR [, they shall use the Rocky Mountain Cancer Data Software Information Request, available at N.J.A.C. 8:57A Appendix K] **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**,** [or] when the patient is first admitted or treated for any reason in that facility[.

1. The administrative officer of the health care facility shall also submit to the Department a report for each]**, including admissions and discharges to inpatient or outpatient services, and when** subsequent primary cancer **is** diagnosed in that patient.

(b) A [certified tumor registrar] **certified tumor registrar** shall perform all abstracting work [from] **and oversee all case-finding for** a health care facility that diagnoses [ o r ] **and/or** treats 100 or more cancer cases per year.

[1. The certified tumor registrar shall be certified by the National Cancer Registrars Association's Council on Certification, 1340 Braddock Place, Suite 203, Alexandria, VA 22314, http://www.ctrexam.org, telephone: (703) 299-6640; telefacsimile: (703) 299-6620, e-mail: ctrexam@ncra-usa.org;]

[2.] **1. [**The certified tumor registrar shall be either employed by] **Either** the health care facility or [employed by] an abstract-coding service under contract [by] **with** the health care facility **shall employ the certified tumor registrar**; and

[3.] **2.** [The] **A** health care facility shall [have until August 3, 2000 to comply with the provisions of (b) above.] **notify the NJSCR by e-mail to ops.njscr@doh.nj.gov of the name and contact information for the certified tumor registrar, and of any changes to registry staff or contact information; and**

**3. 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, [shall:

1. Be] **is** submitted electronically using the NAACCR Data Standards for Cancer Registries - Data Standards and Data Dictionary (Volume II - Version [12] **16**)[;]**, as amended and supplemented,** and

[2. Include] **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 [which] **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[, which] **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 [not referred to or previously diagnosed in a health care facility in the State of New Jersey.

1. The physician, dentist or health care provider shall also submit to the Department a report for] **and for** each subsequent primary cancer diagnosed in that [individual.

(b) The information to be reported in (a) above shall:

1. Be submitted electronically] **person,** using **either** the NAACCR Data Standards for Cancer Registries - Data Standards and Data Dictionary (Volume II - Version [12] **16**) **or another standard electronic reporting format approved by the Department**[;

2. Be submitted using the following forms:

i. Physicians shall use the Physician Report Form, available at N.J.A.C. 8:57A Appendix C;

ii. Dentists shall use the Dentist Report Form, available at N.J.A.C. 8:57A Appendix D; and

iii. Other health care providers shall use the forms set forth at N.J.A.C. 8:57A-1.2(c) 1 and 2 and 6 and 7, as appropriate for the type of health care provider; and

3. Include] **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.

[(c) The physician, dentist or health care provider shall report information on their practice when they report cases of cancer to the NJSCR the first time or if they have just opened their practice in New Jersey using the Cancer Registry Survey, available at N.J.A.C. 8:57A Appendix I.

i. If applicable, physicians shall use the Hematology/Oncology Information Request, available at N.J.A.C.8:57A Appendix H, to provide information to the Department upon request.]

[(d)] **(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 [2008] **2017," incorporated herein by reference, as amended and supplemented,** as guidance when reporting.

[(e)] **(c)** A physician, dentist, or other health care provider who fails to [comply with the provisions of this subchapter] **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 [of cancer or other specified tumorous and precancerous disease] **for violation of the Cancer Registry Act**.

8:57A-1.7 Clinical laboratory reporting

(a) The director of every [independent or hospital-based] 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 [not previously reported from that laboratory.

(b) The information to be reported shall:

1. Be submitted using the Laboratory Report Form, available at N.J.A.C. 8:57A Appendix E; and

2. Include] **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.

[(c) The director of the independent or hospital-based clinical laboratory may submit the reports electronically in accordance with:

1. The e-path Reporting Site Information Checklist; and

2. The HL-7 standard protocol set forth in the NAACR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting, Version 2.1.

(d) The director of the independent or hospital-based clinical laboratory shall use the Diagnostic Laboratory Information Request Form, available at N.J.A.C. 8:57A Appendix J, to report information about the laboratory to the NJSCR, upon request, and to request software in order to implement electronic cancer case-finding and pathology data gathering for the NJSCR.]

[(e)] **(b)** A [hospital-based] clinical laboratory[, which] **that** fails to [comply with the provisions of this subchapter] **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 [of cancer or other specified tumorous and precancerous disease].

8:57A-1.8 Health care insurer reporting

[(a)] 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[.

(b) The information shall:

1. Be submitted electronically] in the format specified by the Department in the request set forth in [(a) above] **this section**; and

[2. Include] **that includes** patient identifying information and medical information, [including but not limited to,] **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 [independent] clinical laboratory shall [supply] **report supplemental** information necessary to clarify medical or demographic data upon request of the Department[.

1. This supplemental information shall include, but not be limited to:]**, 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 [mail one of the following forms] **contact**, as appropriate, [to] the [physician or] 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.**

[1. The Death Certificate Follow-Back Report form, available at N.J.A.C. 8:57A Appendix L; or

2. The NJSCR Follow-Back Physician Form, available at N.J.A.C. 8:57A Appendix M.]

8:57A-1.10 Access to information and records

(a) Every health care facility, [independent] clinical laboratory, physician, dentist**,** [or] **and** other health care provider [who diagnoses or provides] **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, [independent] clinical laboratory, physician, dentist**,** [or] **and** other health care provider [who diagnoses or provides] **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. - 2. (No change.)

(c) Representatives of the Department shall:

1. (No change.)

2. Present valid identification at the time of access, including[, but not limited to], Department or designee issued identification, if on-site access to patient records is necessary.

(d) - (e) (No change.)

(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. (No change.)

**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) – (h) (No change.)

8:57A-1.11 [List of reportable] **Reportable** diseases and conditions

[(a) If a diagnosis includes any of the following words, every New Jersey health care facility, physician, dentist, other health care provider or independent clinical laboratory

shall report the case to the Department in accordance with the provisions of this subchapter:

Cancer;

Carcinoma;

Leukemia;

Lymphoma;

Malignant; and/or

Sarcoma.]

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

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:**

**i. "/0" benign disease;**

**ii. "/1" disease of uncertain malignant potential;**

**iii. "/2" *in situ* disease; or**

**iv. "/3" malignant disease.**

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

**1.** Basal cell carcinomas of the skin [shall not be reported to the Department], except when they are diagnosed in the labia, clitoris, vulva, prepuce, penis**,** or scrotum[.]**; or**

[(d)] **2.** Carcinoma *in situ* of the cervix and/or cervical squamous intraepithelial neoplasia III (CIN III) [shall not be reported to the Department].

[(e)] **(d)** (No change in text.)

[(f)] **(e)** If any uncertainty regarding the reporting of a particular case exists, the health care facility, physician, dentist, other health care provider**,** or [independent] clinical laboratory shall contact the Department for guidance at (609) [588-3500] **633-0500** or view information on the following website**:** http://www.nj.gov/health/ces/njscr.shtml.

[(g) Every New Jersey health care facility, physician, dentist, other health care provider or independent clinical laboratory shall report the following conditions to the Department in accordance with the provisions of this subchapter:

ADRENAL

Adrenal cortical carcinoma

Ganglioneuroblastoma

Neuroblastoma

Neuroendocrine carcinoma

Neuroepithelioma

Paraganglioma (+)

Pheochromocytoma, malignant only

Sympathicoblastoma

ANUS (see G-I tract)

APPENDIX (see G-I tract)

BILE DUCTS (see gall bladder and bile ducts)

BLOOD (see Hematopoietic/Lymphoid)

BLOOD VESSELS (see soft tissues)

BONE AND JOINTS

Adamantinoma

Ameloblastoma, malignant

Angioblastoma (+)

Angiosarcoma

Chondrosarcoma

Chordoma

Ewing's Sarcoma

Fibrosarcoma (medullary, periosteal, central, endosteal)

Giant cell tumor of bone (+)

Giant cell tumor, malignant

Hemangioendothelioma, malignant

Mesenchymal chondrosarcoma

Myeloma

Osteoclastoma (+)

Osteogenic Sarcoma

Osteosarcoma

Parosteal osteoma

Plasmacytoma

BONE MARROW (see Hematopoietic/Lymphoid)

BRAIN, SPINAL CORD, CRANIAL NERVES, MENINGES, AND CENTRAL NERVOUS SYSTEM

Acoustic neuroma (O)

Angiolipoma (O)

Angiomatous meningioma (O)

Astroblastoma

Astrocytoma, any type

Atypical choroid plexus papiloma (+)

Atypical lipoma (+)

Atypical meningioma (+)

Capillary hemangioma (O)

Cavernous hemangioma (O)

Central neurocytoma (+)

Chordoid glioma (+)

Choroid plexus papilloma, malignant

Choroid plexus papilloma (O)

Clear cell meningioma (+)

Dermoid cyst (O)

Demoplastic infantile astrocytoma (+)

Diffuse melanocytosis (O)

Dysembryoplastic neuroepithelial tumor (O)

Dyplastic gangliocytoma of cerebellum (O) (Lhermitte-Duclos)

Ependymoblastoma

Ependymoma

Fibrolipoma (O)

Fibroma (O)

Fibrous meningioma (O)

Gangliocytoma (O)

Ganglioglioma (+)

Ganglioneuroblastoma

Ganglioneuroma (O)

Germinoma

Glioblastoma multiforme

Gliofibroma (+)

Glioma, all types

Gliomatosis cerebri (+)

Hemangioblastoma (+)

Hemangioendothelioma, benign (O)

Hemangioendothelioma (+)

Hemangioma (O)

Hemangiopericytoma, benign (O)

Hemangiopericytoma (+)

Hemangiopericytoma, malignant

Leiomyoma (O)

Leiomyomatosis (+)

Lipoma (O)

Medulloblastoma

Medulloepithelioma

Melanotic neurofibroma (O)

Meningeal melanocytoma (+)

Meningioma, malignant

Meningioma (O)

Meningiomatosis (+)

Meningiotheliomatous meningioma (O)

Meningiothelial meningioma (O)

Myxopapillary ependymoma (+)

Neoplasm, benign (O)

Neoplasm, uncertain whether benign or malignant (+)

Neurilemoma (O)

Neurinomatosis (+)

Neuroblastoma

Neurofibroma (O)

Neurofibromatosis (+)

Neuroma (O)

Neurothekeoma (O)

Oligodendrocytoma or oligodendroblastoma

Oligodendroglioma

Papillary meningioma

Paraganglioma (+)

Perineurioma (O)

Pinealoma

Pineal teratoma, malignant

Pineoblastoma

Pineocytoma

Plexiform neurofibroma (O)

Polarespongioblastoma

Psammomatous meningioma (O)

Rhabdomyoma (O)

Schwannoma (any)

Smooth muscle tumor (+)

Soft tissue tumor, benign (O)

Solitary fibrous tumor (O)

Spongioblastoma

Subependymal astrocytoma

Subependymal giant cell astrocytoma (+)

Supependymoma (+)

Teratoma, benign (O)

Teratoma (+)

Transitional meningioma (O)

Tumor cells, benign (O)

Tumor cells, malignant

Venous hemangioma (O)

BREAST

Adenocarcinoma

Apocrine carcinoma

Colloid carcinoma

Comedocarcinoma

Cribiform carcinoma

Cystosarcoma phyllodes, malignant only

Ductal carcinoma, in situ

Fibroadenoma, malignant only

Glycogen rich carcinoma

Infiltrating carcinoma of the breast such as:

Carcinoma, NOS

Duct adenocarcinoma

Duct and lobular

Duct carcinoma

Duct and Paget's disease

Ductular

Lobular

Lipid-rich carcinoma

Lobular carcinoma, in situ

Lobular and intraductal, in situ

Lobular neoplasia

Medullary carcinoma

Papillary carcinoma, in situ

Paget's disease

Phyllodes tumor, malignant

Stromal sarcoma of breast

Tubular carcinoma

BRONCHUS (see lung)

CERVIX (see uterus)

COLON (see G-I tract)

EAR (see skin, soft tissue)

ENDOMETRIUM (see uterus)

ESOPHAGUS (see G-I tract)

EYE

Epidermoid carcinoma

Melanoma, malignant

Retinoblastoma

Squamous cell carcinoma

Squamous cell epithelioma

(Tumors of the orbit: See soft tissues and Hematopoietic/Lymphoid)

EXTRA-ADRENAL PARAGANGLIA (see adrenal)

FALLOPIAN TUBE (see uterus)

GALL BLADDER AND BILE DUCTS

Adenocarcinoma

Carcinoma (other)

GASTRO-INTESTINAL TRACT (esophagus, stomach, intestine, appendix, colon, anus)

Adenoacanthoma

Adenocarcinoma

Adenoidcystic carcinoma

(Adeno) carcinoma in Adenomatus polyp with or without invasion of stalk

Adenosarcoma

Anal intraepithelial neoplasia (AIN III)

Apudoma (+)

Argentaffinoma (+)

Bowen's disease of anus

Carcinoid (except benign—e.g. appendix)

Carcinosarcoma

Cloacogenic carcinoma

Epidermoid carcinoma

Gastrinoma (+)

Immunoproliferative disease, small intestinal

Kaposi's Sarcoma

Leiomyosarcoma, malignant only

Linitis plastica

Lymphoma

Mixed tumor of esophagus, malignant only

Neuroendocrine carcinoma

Paget's disease of anus

Polypoid adenoma, malignant only

Signet ring cell carcinoma

Squamous cell carcinoma

Squamous cell epithelioma

Transitional cell carcinoma

HEMATOPOIETIC/LYMPHOID (Including blood, bone marrow, lymph nodes, spleen and tumors of hematopoietic or lymphoid histogenesis found in other sites.)

Acute erythremic myelosis

Acute megakaryocytic myelosis

Blastic plasmacytoid dendritic cell neoplasm

Chronic lymphoproliferative disorder of NK cells

Dendritic cell sarcoma

DiGuglielmo syndrome

Erythroleukemia

Essential thrombocythemia

Extraosseous plasmacytoma

Fibroblastic reticular cell tumor

Heavy chain disease, all such as:

Alpha

Gamma (Franklin's Disease)

Mu

Not otherwise specified

Histiocytic medullary reticulosis

Histiocytosis, malignant

Histiocytosis-X, malignant only

Hodgkin's Disease, all such as:

Histiocyte predominant

Lymphocyte depleted

Lymphocyte predominant

Mixed cellularity

Nodular sclerosing

Hypereosinophilic syndrome

Idiopathic thrombocythemia

Immunoproliferative Disease, NOS

Letterer-Siwe's Disease

Leukemia, all

Leukemic reticuloendotheliosis

Lymphoid neoplasm

Lymphoma, all

Lymphosarcoma

Lymphoreticular process, malignant

Megakaryocytosis, malignant

Multiple myeloma

Mycosis fungoides

Myelodysplastic neoplasm, unclassifiable

Myelodysplastic syndrome

Myelofibrosis with myeloid metaplasia, malignant only

Myeloid neoplasm

Myeloma

Myeloproliferative disease (+)

Myelosclerosis

Panmyelosis, acute

Primary myelofibrosis

Polycythemia Vera

Refractory anemia

Refractory neutropenia

Refractory thrombocytopenia

Reticulosis, malignant

Reticulum cell sarcoma/tumor

Sezary's disease or syndrome

Systemic mastocytosis

Therapy related myelodysplastic syndrome

Waldenstrom's macroglobulinemia or syndrome

HYPOPHARYNX (see oral cavity)

KIDNEY

Adenocarcinoma

Adenomyosarcoma

Clear cell carcinoma

Hypernephroma

Nephroblastoma

Renal cell carcinoma

Squamous cell carcinoma

Transitional cell carcinoma

Tubular adenoma, borderline or malignant only

Wilms's Tumor

LARYNX AND TRACHEA

Adenocarcinoma

Adenocystic carcinoma

Cylindroma

Squamous cell carcinoma

LIP (see oral cavity)

LIVER

Angiosarcoma

Bile duct carcinoma

Cholangiocarcinoma

Hepatoblastoma

Hepatocellular carcinoma

Hepatoma, malignant only

LUNG AND BRONCHUS

Adenocarcinoma

Adenoid cystic carcinoma

Apudoma (+)

Argentaffinoma (+)

Bronchial adenoma (+)

Bronchial adenoma (carcinoid type)

Cylindroma

Epidermoid carcinoma

Intravascular bronchial alveolar tumor

Large cell (anaplastic) carcinoma

Neuroendocrine carcinoma

Oat cell carcinoma

Pulmonary blastoma

Small cell (anaplastic) carcinoma

Squamous cell carcinoma

Undifferentiated carcinoma

LYMPH NODE (see Hematopoietic/Lymphoid)

MEDIASTINUM (see Hematopoietic/Lymphoid, soft tissue, or thymus)

MENINGES (see brain)

MUSCLE (see soft tissue)

NERVE (see soft tissue)

NOSE (Nasal cavity, Para-nasal sinus and Nasopharynx)

Adenocarcinoma

Epidermoid carcinoma

Esthesioneuroblastoma

Lymphoepithelioma

Mesenchymoma, malignant

Neuroblastoma

Rhabdomyosarcoma

Sarcoma botryoides

Squamous cell carcinoma

ORAL CAVITY AND SALIVARY GLANDS

Adenocarcinoma

Adenoid cystic carcinoma

Acinic cell carcinoma

Acinic cell tumor (+)

Cylindroma

Epidermoid carcinoma

Lymphoepithelioma

Melanoma

Mixed tumor, salivary gland type, malignant only

Mucoepidermoid carcinoma

Mucoepidermoid tumor (+)

Pleomorphic adenoma, malignant only

Squamous cell carcinoma

Transitional cell carcinoma

Undifferentiated carcinoma

Verrucous carcinoma

OROPHARYNX (see oral cavity)

OVARY

Adenocarcinoma, NOS

Arrhenoblastoma, malignant

Brenner tumor, malignant only

Choriocarcinoma

Clear cell carcinoma

Dysgerminoma

Embryonal carcinoma

Endodermal sinus tumor

Endometrioid carcinoma

Granulosa cell carcinoma

Granulosa cell tumor, malignant

Leydig cell tumor, malignant

Mesonephroid carcinoma

Mucinous cystadenocarcinoma

Papillary serous cystadenocarcinoma

Pseudomucinous cystadenocarcinoma

Seminoma

Serous papillary cystadenocarcinoma

Sertoli-leydig cell carcinoma

Teratoma, malignant

Yolk-sac tumor

PANCREAS

Adenocarcinoma

Cystoadenocarcinoma

Gastrinoma (+)

Glucagonoma, malignant only

Islet cell adenoma (+)

Islet cell carcinoma

Pancreatoblastoma

Papillary cystic tumor (+)

Squamous cell carcinoma

PARAGANGLIA

Non-chromaffin paraganglioma (+)

(see also adrenal gland)

PARATHYROID

Carcinoma, all

PARANASAL SINUSES (see nose)

PENIS

Basal cell carcinoma of Penis and Prepuce (skin of)

Bowen's disease

Erythroplasia of Queyrat

Squamous cell carcinoma

Verrucous carcinoma

PERICARDIUM (see pleura)

PERITONEUM (see pleura)

PHARYNX (see oral cavity)

PINEAL

Demoid cyst (O)

Epithelial tumor, benign (O)

Gangliocytoma (O)

Ganglioglioma (+)

Neoplasm, benign (O)

Pinealoma (+)

Pineoblastoma

Pineocytoma (+)

Teratoma, benign (O)

Teratoma (+)

PITUITARY AND CRANIOPHARYNGEAL DUCT

Acidophil adenoma (O)

Adamanthinomatous craniopharyngioma (+)

Adenoma (O)

Basophil adenoma (O)

Chromophobe adenoma (O)

Clear cell adenoma (O)

Clear cell tumor (O)

Craniopharyngioma (any type) (+)

Craniopharyngioma, malignant

Epithelial tumor, benign (O)

Granular cell tumor (O)

Lipoma (O)

Mixed acidophil-basophil adenoma (O)

Mixed cell adenoma (O)

Monomorphic adenoma (O)

Neoplasm, uncertain (+)

Neoplasm, benign (O)

Oxyphilic adenoma (O)

Papillary adenoma (O)

Papillary craniopharyngioma (+)

Pituitary adenoma (O)

Prolactinoma (O)

Rathke Pouch tumor (+)

Soft tissue tumor, benign (O)

Teratoma, benign (O)

Teratoma (+)

Tumor cells, benign or uncertain

PLACENTA

Choriocarcinoma

Chorioepithelioma

Hydatiform mole, malignant (+)

Invasive mole (+)

PLEURA, PERITONEUM, PERICARDIUM

Fibrosarcoma

Mesothelioma

Sarcoma

PROSTATE AND SEMINAL VESICLE

- Adenocarcinoma
- Adenoid cystic carcinoma
- Alveolar rhabdomyosarcoma
- Carcinosarcoma
- Endometrioid carcinoma
- Rhabdomyosarcoma

RECTUM (see G-I Tract)

SALIVARY GLANDS (see oral cavity)

SKIN

- Amelanotic melonama
- Basal cell carcinoma of labia, clitoris, vulva, prepuce, penis and scrotum
- Bowen's disease of anus and penis
- Hutchinson's melanotic freckle
- Lentigo maligna
- Melanocarcinoma
- Melanoma
- Melansarcoma
- Merkle cell tumor
- Mycosis Fungoides
- Pilomatrix carcinoma
- Superficial spreading melanoma
- Sweat gland carcinoma

SOFT TISSUE (including retroperitoneum, peripheral nerve)

Alveolar rhabdomyosarcoma

Alveolar soft parts sarcoma

Angiofibrosarcoma

Angiosarcoma

Angiomyxoma (+)

Chondrosarcoma

Clear cell sarcoma of tendons

Dermatofibrosarcoma protuberans

Embryonal rhabdomyosarcoma

Fibromyxosarcoma

Fibrosarcoma

Fibrous histiocytoma, malignant

Granular cell tumor, malignant

Hemangioendothelial sarcoma

Hemangioendothelioma, malignant only

Hemangiopericytoma, malignant only

Juvenile rhabdomyosarcoma

Kaposi's sarcoma

Leiomyosarcoma

Liposarcoma

Lymphangioendothelioma, malignant

Lymphangiosarcoma

Mesenchymoma, malignant

Metastasizing leiomyoma

Myosarcoma

Myxosarcoma

Neuroblastoma

Neurogenic sarcoma

Neurilemmoma, malignant

Neurilemmosarcoma

Osteosarcoma

Paraganglioma, malignant

Pigmented dermatofibrosarcoma protuberans bednar tumor

Reticulum cell sarcoma

Rhabdomyoma, malignant

Rhabdomyosarcoma

Sarcoma botryoides

Schwannoma, malignant

Schwannoma, malignant with rhabdomyoblastomatous differentiation

Synovial sarcoma

Xanthofibroma, malignant

SPINAL CORD (see brain)

SPLEEN (see Hematopoietic/Lymphoid)

STOMACH (G-I Tract)

TESTIS

Carcinoid tumor (+)

Choriocarcinoma

Chorioepithelioma

Embryoma

Embryonal carcinoma

Embryonal teratoma

Endodermal sinus tumor

Germ cell carcinoma

Gonadal stromal tumor, malignant only

Gonadoblastoma (+)

Interstitial cell carcinoma

Leydig cell carcinoma

Mesonephric adenocarcinoma (infantile, juvenile embryonal carcinoma)

Polyembryoma

Seminoma

Sertoli cell carcinoma

Spermatoblastoma

Spermatocytic seminoma

Spermatocytoma

Teratoblastoma

Teratocarcinoma

Teratoma (+)

Vitelline tumor

Yolk sac tumor

THYMUS

Epithelioid thymoma, malignant only

Lymphocytic thymoma, malignant only

Seminoma

Spindle cell thymoma, malignant only

Thymic carcinoid

Thymoma, malignant

THYROID

Adenocarcinoma

Anaplastic carcinoma

Follicular carcinoma

Giant cell carcinoma

Hurthle cell adenoma, malignant only

Hurthle cell tumor, malignant only

Medullary carcinoma

Occult sclerosing carcinoma

Papillary carcinoma

Undifferentiated carcinoma

TRACHEA (see Larynx)

URINARY BLADDER, URETER, URETHRA

Adenocarcinoma

Adenosarcoma

Carcinosarcoma

Chemodectoma, malignant only

Mullerian mixed tumors

Papillary transitional cell carcinoma

Paraganglioma (+)

Pheochromocytoma, malignant only

Rhabdomyosarcoma

Squamous cell carcinoma

Transitional cell carcinoma

UTERUS, UTERINE TUBES, CERVIX

Adenoacanthoma

Adenocarcinoma

Adenosarcoma

Adenosquamous carcinoma

Endolymphatic stromal myosis (low grade sarcoma)

Endometrial stromal sarcoma

Endometrioid carcinoma

Leiomyosarcoma

Mesonephric carcinoma

Mixed mesodermal tumor

Squamous cell carcinoma

VULVA AND VAGINA

Basal cell carcinoma of vulva, clitoris, and labia

Clear cell carcinoma

Mesonephroid carcinoma

Paget's disease

Squamous cell carcinoma

Vaginal intraepithelial neoplasia (VAIN III)

Vulvar intraepithelial neoplasia (VIN III)

NOTE: The following superscript indicates the nature of other than overtly malignant reportable tumors listed:

(+) Borderline, reportable

(O) Benign, reportable]

8:57A-1.12 Audit, [letter] **Letter,** and notice of violations and enforcement actions

(a) A health care facility, physician's, dentist's, other health care provider's office, [or independent] **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 [including, but not be limited to, the following:]**, such as** medical records, diagnostic indices[, such as] **of** radiation, laboratory, cytology and/or pathology reports**,** and discharge records.

(c) (No change.)

(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**,** [or independent] **and** clinical laboratory does not comply with the reporting requirements established in this subchapter.

(e) (No change.)

(f) A health care facility, physician, dentist, other health care provider**,** [or independent] **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**,** [or independent] **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**,** [or independent] **and** clinical laboratory for all costs related to these services, [including, but not limited to,] **such as** the retrieval of case information and the cost of the audit.

i. (No change.)

ii. All checks for fees for the Department's [audit] services shall be made payable to "Treasurer, State of New Jersey" **or its designee, as provided in the Letter** and forwarded to:

Office of Cancer Epidemiology

New Jersey State Cancer Registry

New Jersey Department of Health [and Senior Services]

PO Box 369

Trenton, New Jersey 08625-0369

2. (No change.)

3. If [an independent clinical laboratory] **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 [deficiency] **facility** to the [Department's Clinical Laboratory Improvement Service, which may initiate enforcement actions] **Division of Health Facilities Evaluation and Licensing for non-compliance with these rules**.

**4. 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.**

**5. 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.**