

Disclosure of Confidential Cancer Information

Effective date: 8/6/14

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Subdivision 4 of Section 225, and by Section 2402 of the Public Health Law, the section heading and subdivision (a) of Section 1.31 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

1.31 Disclosure of confidential cancer information [for research purposes].

(a) The identity of any person contained in a report of cancer made pursuant to the provisions of Section 2401 of the Public Health Law, or cancer data collected for other specific research studies, shall not be disclosed except [to governmental or government-sponsored research projects]:

(1) for the purpose of scientific studies and research when the State Commissioner of Health determines that substantial knowledge may be gained by such disclosure leading toward the reduction of morbidity and mortality[.]; or

(2) for surveillance or evaluation activities that are government sponsored at the federal, state or Canadian province level, when the State Commissioner of Health

determines that the proposed activity is of significant public health importance and that release of identifiable information is necessary for the proposed activity.

The recipient shall limit the use of such information to the specific [study or research] purpose for which such disclosure is made, shall not further disclose such information (except when the recipient is another cancer registry pursuant to laws applicable to such registry), and shall satisfy the State Commissioner of Health that the confidentiality of [the] patient['s] identity will be maintained.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of this regulation is contained in Public Health Law (“PHL”) Sections 225(4) and 2402. PHL 225(4) authorizes the Public Health and Health Planning Council (PHHPC) to establish, and from time to time, amend and repeal sanitary regulations, to be known as the sanitary code of the state of New York, subject to approval by the commissioner.

PHL 2402 specifies that “the reports of cancer cases made pursuant to the provisions of this article shall not be divulged or made public so as to disclose the identity of any person to whom they relate, by any person, except in so far as may be authorized in the sanitary code.”

Legislative Objectives:

To allow for the amendment of the State sanitary code in order to preserve the security of life or health or the preservation and improvement of public health in the state of New York. Also to provide for the confidential treatment of patient and medical data, specifically cancer patient identity, while recognizing the legitimacy of research.

Needs and Benefits:

The purpose of the proposed amendment to the existing regulation is to make it more consistent with current cancer surveillance, research, and evaluation needs as well as sponsorship practices: allowing greater access to the New York State Cancer

Registry's data and expanding use of confidential data for surveillance and evaluation activities while continuing to protect the privacy and security of any information that could be used to identify individual cancer patients. The proposed changes will bring the New York State Cancer Registry into conformance with standard cancer registry practices pertaining to use of confidential cancer information.

Much has changed in the cancer registration arena since the original regulation governing use of "confidential cancer information" was promulgated in 1979. The North American Association of Central Cancer Registries (NAACCR) was founded in 1987 through the joint efforts of the National Cancer Institute (NCI), the American College of Surgeons, the American Cancer Society, and the American Association of Cancer Institutes in response to the growing number of state cancer registries and the realization that the registry community needed to adopt consensus standards in order to maximize the usefulness of the data collected across all jurisdictions. In 1992, the U.S. Congress passed the Cancer Registries Amendment Act (PL 102-515) with the purpose of establishing a National Program of Cancer Registries (NPCR), administered through the Centers for Disease Control and Prevention (CDC) with a system of grants to states to support the operation of population-based statewide cancer registries. This federal legislation requires specific assurances that the funded states will "provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations." Among other provisions, the federal legislation specifically requires that State laws and regulations: a) address the protection of confidential cancer patient information (i.e., information that identifies or could lead to the identification of a cancer patient), with the specific exemption of disclosure to "other State cancer registries and

local and State Health officials,” and b) provide for the disclosure of confidential cancer data for research.

Currently all 50 states and the District of Columbia have cancer registries. All registries receive funding support from the CDC or NCI or from both federal institutions. The NPCR is a significant source of funding for the NYS Cancer Registry.

Over this same time period, significant shifts have occurred in the research environment. In 1979, 78.0% of research funding (not limited to cancer research) to academic and/or non-profit institutions came from federal or other governmental funding sources; by 2010 that percentage had declined to 65.3% (source: National Science Foundation). While the proportion of federal funding for research has decreased, the number of research applications, including cancer-related applications, has greatly increased. In 1997, the National Institutes for Health (NIH) reviewed about 18,000 new applications and funded 24.7% of these. In 2012, nearly 46,000 new applications were reviewed by NIH but only 15.3% were funded (source: NIH Research Portfolio Online Reporting Tools). Many of the unfunded research proposals were of scientific merit and it is highly likely that some were subsequently funded by non-governmental sources.

Another significant shift in the cancer research environment was brought about by the Food and Drug Administration Amendments Act of 2007 (FDAAA), which gives the FDA the authority to require drug companies to conduct post-marketing studies or clinical trials – known as post-marketing requirements (PMRs). For rare cancers, potential risk associated with drug use can only be assessed effectively through the participation of multiple state cancer registries. This avenue of research, typically

conducted by consulting firms on behalf of and sponsored by pharmaceutical companies, is expected to expand over time.

The New York State Cancer Registry (NYSCR) has been receiving funding through the CDC-NPCR since 1996. Although the NYSCR is compliant with the federal Cancer Registries Amendment Act (PL 102-515), the current regulation governing “disclosure of confidential cancer information” does not specifically address public health practice and is unnecessarily restrictive to research.

Part 1 of the State Sanitary Code 1.31(a) shall be amended to remove the requirement that research be governmental or government sponsored. An evaluation of state policies regarding cancer research conducted recently by CDC found that all state cancer registries have provisions for the release of confidential cancer information for research. The evaluation also found that no other state restricts research based on funding source (i.e., government-sponsored).

The proposed change to the regulation will permit greater use of NYSCR data for research. Specifically it will allow:

- Research conducted by or funded through private foundations such as the American Cancer Society, Susan G. Komen for the Cure, Howard Hughes Medical Institute, and the Leukemia and Lymphoma Society, which are significant sources of cancer research funding.
- Research sponsored by academic institutions.
- The conduct of pilot studies or proof-of-concept studies, which typically are not funded, but are required for most federal grant applications.
- FDA-required post-marketing surveillance studies.

Part 1 of the State Sanitary Code 1.31(a) shall be further amended to allow the release of identifiable cancer data for surveillance or evaluation activities that are government sponsored at the federal, state, or provincial level, when the State Commissioner of Health determines that the proposed activity is of significant public health importance and that release of identifiable information is necessary for the proposed activity. The concept of government sponsorship in the context of cancer surveillance and evaluation is still appropriate. This addition to the regulation addresses significant public health activities that require access to identifiable cancer data that do not fall in the realm of research. Specific examples include:

- Inter-state data exchange. In order for state cancer registries to be complete, i.e., to capture cancer surveillance data on all of their residents, confidential information must be exchanged by state cancer registries (e.g., a Connecticut resident treated for cancer in New York and reported to the NYSCR must be reported to the Connecticut state cancer registry and vice-versa). Both NAACCR and CDC-NPCR program standards specify that, at a minimum, state cancer registries must have agreements in place with all bordering states. [Note: NY PHL section 2401 paragraph 8 states “The department shall, meet cancer registry goals established by a nationally recognized central cancer registry organization unless any such goal is contrary to any provision of law.”] Currently, the NYSCR has 22 inter-state reporting agreements in place. These agreements have been reviewed by the Department of Health’s legal counsel and signed by the Health Commissioner or his/her designee

- Evaluation of an apparent cancer cluster tied to a potential environmental source, which may require the collection of additional information on specific cancer cases. These types of evaluations are frequently conducted by the Agency for Toxic Substances and Disease Registries (ATSDR). Similar evaluations in the context of occupational settings are conducted by the National Institute for Occupational Safety and Health (NIOSH).

The current specifications of Part 1 of the State Sanitary Code 1.31(a) regarding the limitation of the use of data for the specific purpose for which it was disclosed, the prohibition on disclosing the data further, and the requirement to ensure the confidentiality of the disclosed data shall be retained.

An exception to the “further disclosure” stipulation is the exchange of data with another state cancer registry; the confidentiality of that data shall be maintained pursuant to the laws applicable in that state. A review of state cancer registry policies regarding disclosure of confidential cancer data indicates that all states have laws and/or regulations in place to safeguard confidential cancer information. Additionally, all NPCR-funded state cancer registries are subject to the confidentiality provisions of the federal legislation. It is impractical for registries to treat data reported to them by another state cancer registry differently from data reported to them by in-state hospitals and physicians, since all the data become one population-based registry.

Although access to identifiable cancer data is being expanded, the Department of Health shall continue to apply a rigorous review process. All requests for identifiable cancer data will undergo administrative review as well as review by the New York State

Department of Health’s Institutional Review Board (IRB) to assure that the criteria of Part 1 of the State Sanitary Code 1.31(a) are met. Researchers must demonstrate that substantial knowledge leading to the reduction of morbidity or mortality may be gained; that they will only use the disclosed data for the specified purpose and will not re-disclose the data; and that they have procedures and safeguards in place to ensure the confidentiality of the disclosed data. In addition to submitting a formal application which describes how the researcher will meet the criteria stated above, the researcher is required to submit proof of human subject protection training and a copy of their own institution’s IRB approval of the proposed research.

Costs:

Other than a slight potential increase in research-funded employment, there is no cost to the state or increase in necessary state funds, and little significant change in operations. The amendment will not change any data reporting requirements; it will have no impact on regulated parties.

Local Government Mandates:

This rule imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The rule imposes no new reporting requirements, forms, or other paperwork upon regulated parties. All requestors will be required to submit the same “application for

research use of personal identifiable information” currently in use for researchers with governmental funding seeking access to identifiable data. This application includes, but is not limited to: a summary of the study proposal and project activities, including all sources of funding for the project, the type of data for which access is requested, documentation of Institutional Review Board approval of the project for the Protection of Human Subjects (in the case of research), documentation of informed consent (when appropriate); a detailed plan for ensuring the confidentiality of requested data; a detailed plan for securing specific and secure use of requested data; past and anticipated future requests for the study in question; and a signed, notarized affidavit verifying the data will be used only as specifically authorized and kept confidential.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

None. The original intent of this regulation was to protect the privacy and identities of cancer patients by severely limiting access to identifying information, while still making case information available for study and analysis, promoting the understanding and lessening of the burden of cancer in New York State. In recent years, important studies have been undertaken outside the province of the government. An increasing number of recognized contributors exist in the private sector. The current regulation limits access to Registry data for these non-government entities that support

research and make important contributions leading to the reduction of cancer morbidity and mortality, e.g., the American Cancer Society, the Robert Wood Johnson Foundation, and Susan G. Komen for the Cure. Additionally, the current regulations limit opportunities for exchange of information with other states, and with studies required by the FDA for Post-market Drug Safety Surveillance.

Federal Standards:

The rule does not exceed any minimum standards of the Federal government for the same or similar subject area. Rather, it brings us into closer alignment with federal requirements.

Compliance Schedule:

The amendment will take effect when the Notice of Adoption is published in the State Register.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

A Regulatory Flexibility Analysis is not being submitted with this rule because it will not impose any adverse impact on small businesses and local governments. The rule amendment and underlying provisions impose no new reporting requirements, forms, or other paperwork upon county, city, town, village, school district, fire district, or other special district, but apply universally throughout this State. The rule does not impose dissimilar reporting, recordkeeping, or other compliance requirements on public or private entities.

All requestors will be required to submit the same “application for research use of personal identifiable information” currently in use for governmental entities seeking access to identifiable data, and the rule does not distinguish between parties of dissimilar types. This application includes, but is not limited to: a summary of the study proposal and project activities, including all sources of funding for the project, the type of data for which access is requested, documentation of Institutional Review Board approval of the project for the Protection of Human Subjects (in the case of research), documentation of informed consent (when appropriate); a detailed plan for ensuring the confidentiality of requested data; a detailed plan for securing specific and secure use of requested data; past and anticipated future requests for the study in question; and a signed, notarized affidavit verifying the data will be used only as specifically authorized.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

**STATEMENT IN LIEU OF
A RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis is not being submitted with this rule because it will not impose any adverse impact on rural areas. The rule and underlying provisions of the law do not distinguish between regulated parties located in rural, suburban, or metropolitan areas of this New York State, but apply universally throughout this State. The rule does not impose dissimilar reporting, recordkeeping, or other compliance requirements on public or private entities in rural areas.

All requestors will be required to submit the same “application for research use of personal identifiable information” currently in use for governmental entities seeking access to identifiable data, and the rule does not distinguish between parties located in different geographical areas. This application includes, but is not limited to: a summary of the study proposal and project activities, including all sources of funding for the project, the type of data for which access is requested, documentation of Institutional Review Board approval of the project for the Protection of Human Subjects (in the case of research), documentation of informed consent (when appropriate); a detailed plan for ensuring the confidentiality of requested data; a detailed plan for securing specific and secure use of requested data; past and anticipated future requests for the study in question; and a signed, notarized affidavit verifying the data will be used only as specifically authorized.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have a substantial adverse impact on jobs and employment opportunities. The staffing status quo will remain unchanged by amending this regulation, both within the New York State Cancer Registry, and outside of it.

ASSESSMENT OF PUBLIC COMMENT

The Department received one public comment from New York City Department of Health and Mental Hygiene. The NYC Department of Health and Mental Hygiene was not opposed to the change but requested that the release of identifiable cancer data for surveillance or evaluation be further broadened to include government at the local level. The proposed regulation greatly expands access to identifiable data and the Department is not prepared to go beyond the scope of the proposed change at this time.