RULEMAKING NOTICE FORM

Notice Number **2015-193** Rule Number **He-P 304**

1. Agency Name & Address:

NH Depart. of Health and Human Services
Chronic Disease Section
Bureau of Population Health & Community Service
29 Hazen Drive
Concord, NH 03301

2. RSA Authority: **RSA 141-B:8, II and III**
3. Federal Authority:
4. Type of Action:
   - Adoption
   - Amendment
   - Repeal
   - Readoption
   - Readoption w/amendment **X**

5. Short Title: **Cancer Registry Rules**

6. (a) Summary of what the rule says and of any proposed amendments:

He-P 304 implements RSA 141-B, authorizing the establishment of the cancer registry in the Department of Health and Human Services (DHHS) for compilation and analysis of information relating to the incidence, diagnosis, and treatment of cancer. He-P 304 describes the rules for the state cancer registry (SCR). The rules describe who is required to report cases to SCR, what information should be reported, the time frame and format in which reports are required to be made, and how information reported will be maintained. The rules are scheduled to expire on December 5, 2015, but are subject to extension pursuant to RSA 541-A:14-a.

The proposed rules are being readopted with amendment to clarify and update definitions, including the term mutual agreement as used between facilities, physicians, hospice, and nursing care facilities as a means of facilitating reporting, and preventing missed or duplicate reporting. The proposed rules update reporting standards as required by the Centers for Disease Control (CDC) National Program of Central Cancer Registries (NPCR). Reporting requirements for physicians and clinics have been simplified, and the types of specialty clinics required to report to the SCR are listed. The proposed rules extend the time frame for medical laboratories to report from 45 to 180 days, and simplify reporting by allowing optional delegation of reporting to an affiliated hospital. The rules remove the requirement for an annual site visit. Site visits will occur only as needed to clarify or review the accuracy of reported information. The proposed rules continue to require facilities to provide copies of information during the site visit in order for SCR to ensure quality in reporting. The rules simplify release of aggregate data when numbers of cancers diagnosed or treated are small, while ensuring confidentiality.

6. (b) Brief description of the groups affected:

The rules are mandated by RSA 141-B, and any costs associated with the proposed rules are attributable to the statute. The state cancer registry is supported by some state general funds, approximately one fourth of its budget, and primarily supported by federal grant funds targeted at specific registry activities. The SCR provides a benefit to the public by providing accurate and up to date data and information about cancer diagnoses and treatments in the state.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	RSA of Federal Regulation Implemented
He-P 304.01	RSA 141-B:2
He-P 304.02	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.03	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.04	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.05	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.06	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.07	RSA 141-B:8, III; RSA 141-B:8, IV; RSA 141-B:9 42 USC 280e(c)(2)(D)(viii)
He-P 304.08	RSA-141-B:8, III; RSA 141-B:9; 45 CFR 164 45 CFR164.502; 45 CFR 164.506; 45 CFR 164.512
He-P 304.09	RSA 141-B:8, III; RSA 141-B:9
He-P 304.10	RSA 141-B:8, III; RSA 141-B:9

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Catherine Bernhard** Title: **Rules Coordinator**

Address: **Dept. of Health and Human Services**
Administrative Rules Unit
129 Pleasant St.
Concord, NH 03301

Phone #: **271-9374**

Fax#: **271-5590**

E-mail: **catherine.bernhard@dhhs.state.nh.us**

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:
http://www.dhhs.nh.gov/oos/aru/comment.htm

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **January 14, 2016**

☒Fax ☒E-mail ☐Other format (specify):

9. Public hearing scheduled for:

Date and Time: **January 7, 2016 at 1:00 PM**

Place: **DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH**

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **15:204**, dated **11/24/15**

1. **Comparison of the costs of the proposed rule(s) to the existing rule(s):**

   There is no difference in cost when comparing the proposed rules to the existing rules. Any cost difference is attributable RSA 141-B.

2. **Cite the Federal mandate. Identify the impact of state funds:**

   The State of New Hampshire participates in the Centers for Disease Control's (CDC) National Program of Central Cancer Registries (NPCR), which was established in 1992 by the Cancer Registries Amendment Act (Act) and was amended in 1998. Under the Act, the CDC is authorized to fund the activities of state cancer registries, set standards and provide training for registry personnel. In order to qualify for funding, a state registry is required to maintain compliance with the CDC requirements. The NPCR provides direct funding for the operation of the state cancer registry and requires that New Hampshire have rules and statutes for cancer reporting. The federal mandate does not affect state funds.

3. **Cost and benefits of the proposed rule(s):**

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

None.

C. To Independently owned businesses:

None.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rule modifies an existing program or responsibility, but does not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.

Readopt with amendment, He-P 304 effective 12-5-07 (Document 9046), to read as follows:

PART He-P 304 CANCER REGISTRY RULES

He-P 304.01 Definitions.

(a) "Clinic" means a health care facility licensed by the state of New Hampshire, where a physician, nurse practitioner, or other health care professional provides cancer diagnosis and treatment or both, and that is not an operational entity of and not affiliated with a hospital. Such facilities include urology clinics, dermatology clinics, out-patient surgical centers, ambulatory oncology treatment centers, ambulatory radiation treatment centers, and physician group practices devoted to oncology.

~~(a)~~(b) "Commissioner" means ~~"commissioner" as defined in RSA 141-B:3, I namely~~ "the commissioner of the department of health and human services."

~~(b)~~(c) "Confidence interval" means an estimated range of values, which is likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data.

~~(c)~~(d) "Courier service" means a mail delivery service that provides guaranteed delivery of documents or packages by using a reliable tracking system.

~~(d)~~(e) "Definitive report" means information or data in the format of an electronic or paper document, or report, ~~that~~ describing~~es~~ a reportable cancer, including the information described in He-P 304.02 ~~(b)~~(e), that ~~and~~ is submitted to the state cancer registry (SCR) as follows: ~~in accordance with the following:~~

(1) No sooner than 90 days and no later than 180 days of an initial diagnosis or treatment; or

(2) In cases where the patient has died, or is transferred to hospice care, within 90 days of death and transfer.

~~(e)~~(f) "Department" means the New Hampshire department of health and human services.

~~(f)~~(g) "Facility" means "facility" as defined in RSA 141-B:3, VI, namely, "a governmental or private agency, department, institution, clinic, laboratory, hospital, health maintenance organization, association, physician, ~~hospice,~~ or other similar unit ~~that~~ diagnose~~s~~ing or provide~~s~~ing treatment for cancer."

(h) "Medical Laboratory" means a facility performing tests or analyses of human samples from patients suspected to have cancer.

~~(g)~~(i) "~~Formal~~ Mutual agreement" means an ~~mutual~~ understanding, arrangement, or stipulation which establishes the responsible reporter to the SCR as made between 2 facilities, clinics, or physicians, ~~organizations, such as the SCR and a reporting facility or 2 separate reporting facilities,~~ which may be confirmed in writing, but for which written documentation is not required. ~~which is to be made through the exchange of letters filed with the SCR.~~

~~(h) "Oncology clinic" means a health care facility where a physician, nurse practitioner, or other health care professional provides cancer diagnosis and treatment or both, and that is not an operational entity of and not affiliated with a hospital.. Such facilities include urology clinics, out-patient surgical~~

~~centers, ambulatory oncology treatment centers, ambulatory radiation treatment centers, and physician group practices devoted to oncology.~~

~~(i)~~(j) "Pathology report" means ~~a written~~ electronic or paper report(s) prepared by a pathologist ~~that~~ providing~~es~~ a description of laboratory test results, and an evaluation of cells, ~~and~~ tissues, and organs based on ~~microscopic~~ evidence from a sample ~~piece~~ of body tissue, and ~~sometimes~~ used to ~~make a~~ diagnos~~e~~is ~~of a~~ and characterize disease.

~~(j)~~(k) "Protected health information" means protected health information as defined in 45 CFR 160.103.

~~(k)~~(l) "Rapid report" means ~~an electronic or paper~~ information or data in an electronic or paper document or report,~~document~~ ~~that~~ describing~~es~~ a reportable cancer, including the information described in He-P 304.02 ~~(c)~~(d), ~~and~~ that is submitted to the SCR within 45 days of diagnosis.

~~(l)~~(m) "Reportable cancer" means any syndrome, condition, or disease ~~which is~~ listed in ~~the~~ "Table 2 "NAACCR Layout Version 15: Comparison of Reportable Cancers" (Thornton ML, (ed.)) "Standards and Registry Operations/Volume II/Data Standards and Data Dictionary", Version 15, 19th ed. (Posted October 2014, Revised February 27, 2015)/Chapter III, "Standards for Tumor Inclusion and Reportability" "Table 2 NPCR Requirements." Springfield, Ill.: North American Association of Central Cancer Registries. Available as a free electronic document at http://www.naaccr.org.

~~/Applications/ContentReader/Default.aspx?c=3 www.naaccr.org. 9th Revision of the "International Classification of Diseases," ICD-9-CM codes 140-239, published by Centers for Disease Control and Prevention (CDC), available at the CDC website www.cdc.gov/nchs/icd9.htm or comparable ICD-O codes listed in the "International Classification of Diseases for Oncology," 3rd Edition published by the World Health Organization (WHO), available at the WHO website www.who.int/classifications/icd/adaptations/oncology/en/ but excluding:~~

~~(1) Carcinoma in situ of skin, ICD code 232, and other malignant neoplasms of the skin, ICD code 173 with histology 8000-8110;~~

~~(2) Benign neoplasms, ICD codes 210-219; and~~

~~(3) Carcinoma in situ of the cervix, ICD code 233.1.~~

~~(m)~~(n) "State cancer registry (SCR)" means the department or, if the department meets its statutory obligations by contract, an organization, system, or individual contracted by the department to collect, manage and store information on cases of reportable cancer pursuant to RSA 141:B:5 and RSA 141-B:10.

He-P 304.02 Reporting Requirements.

(a) In accordance with RSA 141-B:7, all facilities shall ~~provide a~~ report diagnosis or treatment of a reportable cancer to the SCR ~~regarding any diagnosis or treatment of a reportable cancer~~ in accordance with these rules. ~~and as required by the CDC National Program of Cancer Registries (NPCR), as available from the reporting facility.~~

(b) Pursuant to (a) above, all facilities shall include information and data in each report describing ~~of~~ cancer diagnosis or treatment ~~shall~~according to one of the following standards, as applicable: ~~include items with the following elements listed in~~

(1) ~~t~~The North American Association of Central Cancer Registries (NAACCR), "Standards for Cancer Registries, Volume II"/"Data Standards and Data Dictionary, 19th Edition, Record Layout Version 15." (January 1, 2015) Edited by Monica Thornton, Revised (February, 27, 2015.). Available as a free document at www.naccr.org. and incorporated by reference as listed in Appendix A; ~~or Case Record Layout (Version 11). {Havener L, Hultstrom D, editors. Standards for Cancer Registries Volume II: Data Standards and Data Dictionary, Tenth Edition, Version 11. Springfield, IL: North American Association of Central Cancer Registries, November 2004}, and, on or after January 1, 2008, the 12th Edition, Version 11.2 at the NAACCR website www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=133~~

(2) The North American Association of Central Cancer Registries (NAACCR), "Standards for Cancer Registries/Volume V: "Pathology Laboratory Electronic Reporting, Version 4.0." Klein Wt., Havener L (eds.), Springfield (IL); North American Association of Central Cancer Registries, Inc., April, 2011. Available as a free electronic document at www.naaccr.org and incorporated by reference as listed in Appendix A; ~~a~~nd or

(3) The National Center for Chronic Disease Prevention and Health Promotion Division of Cancer Prevention and Control, "Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries HL7 Clinical Document Architecture (CDA) Release 1.1" (March, 2014). Available as a free electronic document in PDF format at http://cdc.gov/cancer/npcr/ehrmeaningfuluse/cancer.htm, and incorporated by reference as listed in Appendix A.

(c) Each report shall contain information or data required by the appropriate standard in (b) above, as listed in elements (1)-(10) below, and shall include any supporting information, as follows:

(1) Item numbers defining demographics;

(2) Item numbers defining cancer identification;

(3) Item numbers defining hospital-specific information;

(4) Item numbers defining stage prognostic factors;

(5) Item numbers defining the first course of treatment;

(6) Item numbers defining follow-up, recurrence, and death;

(7) Item numbers defining confidential patient information;

(8) Item numbers defining confidential hospital information;

(9) Item numbers defining other confidential information; and

(10) Item numbers defining diagnosis.

~~(c)~~(d) Of the item numbers specified in (b) and (c) above, the following shall require rapid reporting as defined in He-P 304.01(l)~~(k)~~ and described in He-P 304.03(b) and (c)~~, 304.04(a), 304.05.(a) and 304.06(a) and (b)~~:

(1) Item numbers defining demographics;

(2) Item numbers defining cancer identification;

(3) Item numbers defining hospital-specific information;

(4) Item numbers defining confidential patient information; and

(5) Item numbers defining other confidential information.

~~(d)~~(e) The items listed in (c) above shall require definitive reporting as defined in He-P 304.01(e), and described in He-P 304.03(a), He-P 304.03(d), He-P 304.04(a), and He-P 304.06(a) and (b). ~~With the exception of (c) above, all items specified in (b) above shall require definitive reporting as defined in He-P 304.01(d) and described in 304.03(b) and (d) and 304.06(c).~~

~~(e) All reports required under this part shall be in a format secure from inadvertent and unwarranted intrusion.~~

(f) All ~~F~~facilities making an electronic report to the SCR ~~using an electronic system for reporting data to the SCR~~ in accordance with (a) above, shall submit through a secure internet-based encrypted mechanism, such as a direct file transfer, or a web-based reporting form supported by the SCR. ~~reports using one of the following methods:~~

~~(1) Through a secure internet based encrypted mechanism such as direct file transfer or, web-based reporting form supported by the SCR, or~~

~~(2) Through encrypted computer disk mailed to the SCR via regular mail or a courier service.~~

(g) All facilities reporting electronically ~~filings~~ shall format reports ~~be written in a format~~ as specified by one of the following standards, as applicable: ~~following the requirements in this section.~~

(1) The North American Association of Central Cancer Registries (NAACCR), "Standards for Cancer Registries, Volume II/Data Standards and Data Dictionary, 19th Edition, Record Layout Version 15." (January 1, 2015) Edited by Monica Thornton, Revised (February, 27, 2015). Available as a free document at www.naccr.org. and incorporated by reference as listed in Appendix A;

(2) The North American Association of Central Cancer Registries (NAACCR), "Standards for Cancer Registries/Volume V: Pathology Laboratory Electronic Reporting, Version 4.0." Klein Wt., Havener L. (eds.) Springfield (IL); North American Association of Central Cancer Registries, Inc., April, 2011. Available as a free electronic document at www.naaccr.org and incorporated by reference as listed in Appendix A; or

(3) The National Center for Chronic Disease Prevention and Health Promotion Division of Cancer Prevention and Control, "Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries HL7 Clinical Document Architecture (CDA) Release 1.1" (March, 2014). Available as a free electronic document in PDF format at http://cdc.gov/cancer/npcr/ehrmeaningfuluse/cancer.htm, and incorporated by reference as listed in Appendix A.

~~at www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx#~~

~~www.naaccr.org/StandardsandRegistryOperations/VolumeV.aspx#.~~

~~(h) All facilities that diagnose or treat at least 105 new reportable cancer cases per year shall report those cases to the SCR in an electronic format in accordance with (e)-(g) above.~~

~~(i) All facilities that diagnose or treat less than 105 new reportable cancer cases per year shall report those cases to the SCR in one of the following formats:~~

(h) Where electronic reporting is not feasible, facilities shall complete and file the New Hampshire State Cancer Registry (NHSCR) "Cancer Report Form" (July, 2015) provided by the SCR and faxed or mailed by the facilities to the SCR, via regular mail or a courier service.

~~(1) Electronic format in accordance with (e)-(g) above; or~~

~~(2) Paper reporting form as provided by the department, and faxed or mailed by the facilities to the SCR, via regular mail or a courier service.~~

He-P 304.03 Reporting of Information by Hospitals Licensed by the State of New Hampshire.

(a) Hospitals licensed by the state of New Hampshire that diagnose or treat at least 105 new reportable cancer cases per year shall employ a cancer registrar to abstract the definitive report.

(b) Hospitals licensed by the state of New Hampshire that diagnose or treat at least 105 new reportable cancer cases per year shall provide a rapid report to SCR in accordance with He-P 304.01~~(k)~~(l) and a definitive report in accordance with He-P 304.01~~(d)~~(e). ~~and transmit the case to SCR~~.

(c) Hospitals licensed by the state of New Hampshire that diagnose or treat fewer than 105 reportable cancer cases per year shall provide a rapid report to SCR in accordance with He-P 304.01~~(k)~~(l), and a paper or electronic report ~~transmit the case~~ to SCR in accordance with He-P 304.02.

(d) Hospitals licensed by the state of New Hampshire that diagnose or treat fewer than 105 reportable cancer cases per year shall make available to SCR the medical records of all patients with a reportable cancer for the creation of the definitive report in accordance with He-P 304.01(e). ~~The hospital shall make available the medical records of all patients with a reportable cancer to the SCR annually for creation of the definitive report in accordance with He-P 304.01(d).~~

~~(e) Hospitals licensed by the state of New Hampshire who employ providers to diagnose or treat reportable cancer cases outside the primary hospital setting in a clinic that is an operational entity or affiliate of such hospital, shall be responsible for the submission of all cancer reports to the SCR for those providers according to the rules above.~~

(e) Facilities ~~Hospitals~~ owned by a hospital licensed by the state of New Hampshire shall have met the reporting requirements of this rule, if reports are submitted to SCR on their behalf by the hospital. ~~may by mutual agreementwith their staff be responsible for the submission of all cancer reports to the SCR according to the rules above, for providers in their employ who diagnose or treat patients with reportable cancer outside the primary hospital setting in a clinic that is an operational entity or affiliate of such hospital.~~

He-P 304.04 Reporting of Information by a Physician Licensed by the State of New Hampshire.

(a) A physician, surgeon, or other licensed health care practitioner ~~that~~who diagnoses or treats cancer patients shall complete and provide~~transmit~~ a ~~rapid~~ definitive report in accordance with He-P

304.01~~(k)~~(d) for each newly diagnosed cancer case when that patient will not be immediately referred to a hospital or other treatment center for additional diagnosis or treatment.

(b) A physician, surgeon, or other licensed health care practitioner shall ~~be contacted by the SCR if~~ provide additional information to SCR regarding a patient as is considered necessary for abstraction of required cancer incidence data in accordance with He-P 304.07(a).

(c) A physician, surgeon, or other licensed health care practitioner may fulfill his or her responsibility for cancer reporting for a cancer patient, through a mutual agreement allowing cases to be reported by a hospice or other facility that provided medical or nursing care to that cancer patient.

(d) A physician, surgeon or other licensed health care practitioner shall make available to the SCR the medical records of all patients with a reportable cancer for creation of the definitive report in accordance with He-P 304.01(e).

He-P 304.05 Reporting of Information by a Medical Laboratory Licensed by the State of New Hampshire.

(a) A medical laboratory licensed by the state of New Hampshire that obtains a specimen of human tissue which, upon examination, shows evidence of cancer, shall:

(1) Within ~~45~~180 days after that pathology report is complete, provide information concerning its findings to the SCR;

(2) Fax, mail, or electronically transmit a copy of the pathology report using procedures described in this section;

(b)~~(3)~~ A medical laboratory may fulfill its responsibility for cancer reporting ~~Submit the pathology report to the SCR~~ through a ~~formal~~ mutual agreement allowing cases to be submitted by the cancer registrar at an affiliated hospital or other facility; ~~and~~

~~(4) In the absence of a formal agreement referenced in (3) above, the laboratory shall be responsible for the submission of all pathology reports to the SCR.~~

(c)~~(b)~~ The SCR shall be granted access to ~~all cancer~~ pathology reports used to confirm or rule out a diagnosis of cancer by medical laboratories for the purpose of case finding and quality assurance; and

(d)~~(c)~~ The SCR shall be authorized to identify cancer cases from the pathology reports and request information about missing cancer reports from the reporting facility.

~~(d) A medical laboratory that reports fewer than 500 cases per year to the SCR shall request a less frequent reporting timeline to report cases as described in (a) above through a formal agreement with the SCR.~~

~~(e) Medical laboratories shall provide information about current reporting practices annually upon request by the SCR.~~

He-P 304.06 Reporting of Information by ~~Oncology~~ Clinics that Diagnose or Treat Patients With Cancer.~~Licensed by the State of New Hampshire~~.

(a) An oncology clinic licensed by the state of New Hampshire shall provide a rapid reportdefinitive report for each case as defined in accordance with He-P 304.01 (k) (e).

(b) An oncology clinic licensed by the state of New Hampshire shall:

(1) Develop a formal agreement with the SCR for the submission of a rapid report to the SCR by utilizing a cancer registrar at a hospital or other facility; or

(2) In the absence of such a formal agreement, the oncology clinic shall be responsible for the submission of all rapid reports to the SCR.
submitted

(b) An oncology clinic licensed by the state of New Hampshire shall:

(1) Develop a mutual agreement with a cancer registrar at a hospital or other affiliated facility for the submission of a definitive report to the SCR; or

(2) In the absence of reporting by an affiliated cancer registrar, the oncology clinic shall
(1) Be responsible for the submission of all definitive reports to the SCR.; or

(2) Develop a mutual agreement with a cancer registrar at a hospital or other affiliated facility for the submission of a definitive report to the SCR.

(c) An oncology clinic licensed by the state of New Hampshire that diagnoses or treats more than 105 reportable cancer cases per year shall provide additional information to SCR regarding a cancer patient as necessary for abstraction of required cancer incidence data in accordance with He-P 304.07(a).:

(1) Develop a formal agreement with the SCR for the submission of a definitive report; or

(2) In the absence of such an agreement, the oncology clinic shall be required by the SCR to use the services of a cancer registrar to create and submit a definitive report.

He-P 304.07 Quality Assurance, Verification, and Confidentiality.

(a) All Reporting facilities shall respond to SCR requests for case information pursuant to He-P 304.02(b) and (c) within 14 working days of receipt of such requests.

(b) All facilities shall respond to SCR requests to perform a site visit. SCR shall perform a site visit at each facility in order to:

(1) Audit pathology reports and other information to ensure that no cancer cases are overlooked in reporting; and

(2) Monitor the completeness and accuracy of the cancer reports.

(b) In order to monitor the completeness and accuracy of submitted reports, the SCR shall perform a site visit to all facilities annuallyat least quarterly to review and copy reports and records as described in (d) below.

(c) Reporting facilities shall make personnel available to the SCR during site visits to assist with questions that arise from the quality assurance review.

(c) ~~(d) Upon request of the SCR, each~~ Each facility shall make available for reviewing and copying all paper or electronically stored information including the following:

(1) Laboratory analyses including tissue, cytology, and pathology reports;

(2) Records regarding radiological examinations, in relation to cancer diagnoses or treatment;

(3) Reports of diagnoses of malignant disease, and notations of the reasons for such diagnoses, including both primary clinicians' reports and consultants' reports;

(4) Pharmacy records;

(5) Reports regarding any operations or an autopsy;

(6) Discharge plans and abstracts regarding cancer diagnoses; and

(7) A ~~L~~list of ~~disease indices based on~~ the applicable discharge diagnoses or treatment as identified in the "Casefinding Lists, Current Lists/Code List" available as a free electronic document at http://seer.cancer.gov/tools/casefinding/case2016-icd10cm.html as listed in Appendix A. ~~in relation to cancer diagnoses or treatment; and~~

~~(8) Consult notes in relation to cancer diagnoses or treatment.~~

~~(e)~~(d) Pursuant to 42 USC 280e(c)(2)(D)(viii), ~~for~~ individuals complying with the law, ~~no person~~ shall not be held liable in any civil action with respect to a report of cancer ~~case report~~ provided to the SCR, or with respect to access to ~~cancer case~~data or information provided to the SCR.

He-P 304.08 Procedures for Disclosure of Protected Health Information.

(a) The SCR shall use and disclose protected health information in accordance with RSA 141-B:9 and the provisions of 45 CFR 164 generally, and specifically, 45 CFR 164.502, 164.506 and 164.512.

(b) The department shall maintain the confidentiality of reports submitted to the SCR pursuant to RSA 141-B:9 except in accordance with (c) below.

(c) A report submitted to the SCR concerning an individual, and any other information maintained by the SCR, which, because of a personal identifier, can be readily associated with an individual, shall only be released:

(1) To the individual upon:

a. Receipt of a written request which shall be signed by the individual; and

b. Presentation of identification, such as a driver's license, by the individual;

(2) If the individual is a minor, to a parent of the individual upon:

a. Receipt of a written request, which shall be signed by the parent;

b. Receipt of a certified copy of the birth certificate of the individual; and

c. Receipt of a copy of the parent's identification, such as a driver's license of the parent;

(3) If the individual has a court-appointed guardian or if the individual is deceased, to the court-appointed guardian or to the executor or administrator of the individual's estate upon:

a. Receipt of a written request, which shall be signed by the court-appointed guardian, executor, or administrator of the estate;

b. Receipt of a certified copy of the order or decree which appoints the guardian, executor, or administrator; and

c. Receipt of a copy of identification, such as a driver's license, by the guardian, executor, or administrator;

(4) To an attorney or other person designated by the individual upon receipt of a written medical release request which shall be signed by the individual;

(5) To persons conducting health related research, upon receipt and approval pursuant to He-P 304.09 of a written application to the department, which shall be signed by the applicant and includes:

a. The following information about the principal investigator:

1. Name, address, and phone number;

2. Organizational affiliation;

3. Professional qualification; and

4. Name and phone number of principal investigator's contact person, if any;

b. The following information about the data or record copies being requested:

1. Type of event or record copies;

2. Time period of the data or record copies;

3. Specific data items required, if applicable;

4. Medium in which the data or record copies are to be supplied by the bureau; and

5. Any special format or layout of data required by the principal investigator;

c. A research protocol which shall contain:

1. A summary of background and origin of the research;

2. A statement of the health-related problem or issue to be addressed by the research;

3. The primary research hypothesis to be tested;

4. The research design, which shall include:

(i) Case definition;

(ii) Method of case selection; and

(iii) Method of data analysis;

5. The research methodology, which shall include:

(i) The way in which the requested data will be used; and

(ii) The procedures for follow-back to any persons or facilities named in records, if applicable;

6. Procedures to obtain informed consent from the research participants, if applicable;

7. The procedures that ~~will~~shall be followed to maintain the confidentiality of any data or copies of records provided to the requester; and

8. The intended completion date;

d. A statement signed by the principal investigator agreeing to the following:

1. The investigator shall acknowledge the department as the source of the data in any and all public reports, publications, or presentations generated by the requester from these data;

2. The investigator shall specify that the analyses, conclusions, and recommendations drawn from such data are solely those of the requester and are not necessarily those of the department;

3. Any data or record copies provided shall not be used for any purpose other than that described in the application;

4. The principal investigator and the research staff shall not disclose the identity of individuals revealed in the data or record copies to any persons except as is necessary to perform the research described in the application;

5. The data record shall not be further released to any other person or organization without the written consent of the commissioner or his designee; and

6. No form of information derived from the data or record copies that identify any individuals shall be made public;

e. A written statement ensuring that the investigator shall hold all information confidential; and

f. When contact with patients will occur, submission of an Institutional Review Board (IRB) approval for the study by an IRB formed in accordance with the requirements of the U.S. Department of Health and Human Services Code of Federal Regulations for Protection of Human Subjects, 45 CFR 46, June 23, 2005; or

(6) In association with an audit as required under Title III of Public Health Services Act, 42 U.S.C. 241 et seq.

(d) Persons fraudulently requesting data or information shall be subject to penalty for unsworn falsifications pursuant to ~~in accordance with~~ RSA 641:3.

He-P 304.09 Approval Criteria for Release of Confidential Data for Research Purposes.

(a) The commissioner shall review applications for the use of confidential SCR data, by based on the following criteria:

(1) Completeness of application, pursuant to He-P 304.08(b)(5);

(2) Documentation of adequate measures to insure confidentiality of patients, pursuant to He-P 304.08(b)(5);

(3) Determination of whether the study, if carried out according to the application submitted pursuant to He-P 304.08(b)(5), will be able to answer the research hypothesis as stated in this application; and

(4) Qualifications of investigator(s) and research staff, as indicated by:

a. Documentation of training and previous research, such as peer reviewed publications, in the proposed or related area; and

b. Affiliation with a university, medical center or other institution, which will provide sufficient research resources.

(b) The commissioner shall deny an application in accordance with RSA 541-A: 29, II (a) when it has been determined that one or more of the requirements of He-P 304.08(b)(5) or He-P 304.09(a) have not been met.

He-P 304.10 Aggregate Data.

(a) The number of cancer cases shall not be released in any document where the numbers of cancer cases are between 1 and 4. ~~Statistics derived from the SCR data shall be considered to be aggregate data if published by towns with a population of 5,500 or more.~~

~~(b) Population estimates shall be derived from the most recent decennial census.~~

~~(c) If the numbers of cases are between 1 and 4 for towns with population less than 5,500, then the data at the town level shall not be released, to prevent constructive identification of individuals.~~

~~(d) The age-adjusted rates and age-specific rates shall:~~

~~(1) Not be calculated for cases fewer than 10; and~~

~~(2) Be provided with confidence intervals.~~

Appendix A

Rule	Title	Publisher, How to Obtain, Cost
He-P 304.01(m)	"Chapter III, Standards for Tumor Inclusion and Reportability" Table 2. "NAACCR Layout Version 15: "Comparison of Reportable Cancers" "NPCR Requirements." (Thornton ML, (ed)). "Standards for Cancer Registry Operations"/Volume II: "Data Standards and Data Dictionary, Record Layout" Version 15, 19th ed. (Posted October 2014, Revised February 27, 2015), Springfield, Ill.: North American Association of Central Cancer Registries, (NAACCR).	Available online at no cost at www.naaccr.org.
He-M 304.02(b) and (g)	North American Association of Central Cancer Registries (NAACCR), "Standards for Cancer Registries, Volume II"/"Data Standards and Data Dictionary", 19th (ed.), "Record Layout Version 15", Implementation: January 1, 2015, Edited by Monica Thornton, Revised February 2015.	Available online at no cost at www.naccr.org.
He-M 304.02(b) and (g)	"Standards for Cancer Registries" Volume V: "Pathology Laboratory Electronic Reporting, Version 4.0."Klein Wt., Havener L. (eds.) Springfield (IL); North American Association of Central Cancer Registries, Inc., April, 2011.	Available online at no cost at www.naaccr.org.
He-M 304.02(b) and (g)	National Center for Chronic Disease Prevention and Health Promotion Division of Cancer Prevention and Control, "Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries" HL7 Clinical Document Architecture (CDA) Release 1.1 (March, 2014).	Available online at no cost at http://cdc.gov/cancer/npcr/meaningful_use.htm.
He-M 304.07(d)	Surveillance, Epidemiology and End Results Program (SEER) "Case Finding List, Current List", ICD-10-CM-(FY 2015-October 1, 2015-September 30, 2016.	Available online at no coast at http://seer.cancer.gov/tools/casefinding.

Appendix B

Rule	RSA of Federal Regulation Implemented
He-P 304.01	RSA 141-B:2
He-P 304.02	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.03	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.04	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.05	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.06	RSA 141-B:7; RSA 141-B:8, II; RSA 141-B:10
He-P 304.07	RSA 141-B:8, III; RSA 141-B:8, IV; RSA 141-B:9 42 USC 280e(c)(2)(D)(viii)
He-P 304.08	RSA-141-B:8, III; RSA 141-B:9; 45 CFR 164 45 CFR164.502; 45 CFR 164.506; 45 CFR 164.512
He-P 304.09	RSA 141-B:8, III; RSA 141-B:9
He-P 304.10	RSA 141-B:8, III; RSA 141-B:9