

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

October 11, 2019
1:00 p.m. Central Time
Gold's Building, Room 534
1033 O Street, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 186, Chapter 5 of the Nebraska Administrative Code (NAC) – *Release of Medical Records and Health Information*. The regulation governs the release of medical record and health information for certain medical conditions that are required to be recorded and maintained in the state's registries, according to Neb. Rev. Stat. §§ 81-663 to 81-675. The regulations protect the identity and privacy of the individuals whose cases are in the health registries and affect those who apply to be an approved researcher. The proposed changes remove repetitive statutory language from the regulations and updates formatting.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at <http://www.sos.ne.gov>, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 186	Prepared by: Ashley Newmyer
Chapter: 5	Date prepared: 5/31/2019
Subject: Release of Medical Records & Health Information	Telephone: (402) 471-3489

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)
Increased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Increased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Indeterminable	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)

Provide an Estimated Cost & Description of Impact:

State Agency: [No fiscal impact](#)

Political Subdivision: [No fiscal impact](#)

Regulated Public: [No fiscal impact](#)

If indeterminable, explain why:

[Not applicable](#)

TITLE 186 _____ HEALTH REGISTRIES AND RELEASE OF INFORMATION

CHAPTER 5 _____ RELEASE OF MEDICAL RECORDS AND HEALTH INFORMATION

~~5-001 SCOPE AND AUTHORITY: This regulation governs the release of medical record and health information Neb. Rev. Stat. §§ 81-663 to 81-675 which are contained in the registries that record certain medical conditions occurring in this state, as prescribed by law. The information is recorded and reported from these registries and is maintained in order to achieve the goals of prevention, cure and control through research and education. These registries include the Birth Defects Registry established in Neb. Rev. Stat. §§ 71-646 to 71-649, the Cancer Registry established in Neb. Rev. Stat. §§ 81-642 to 81-650, the Brain Injury Registry established in Neb. Rev. Stat. §§ 81-653 to 81-661 and the Parkinson's Disease Registry established in Neb. Rev. Stat. §§ 81-681 to 81-696;~~

~~5-002 DEFINITIONS:~~

~~Aggregate Data means data contained in the medical record and health information registries maintained by the Department which is compiled in a statistical format and which does not include patient-identifying data.~~

~~Approved Researcher means an individual or entity which is approved by the Department pursuant to Neb. Rev. Stat. § 81-666 to obtain access to data contained in the medical record and health information registries maintained by the Department to assist in the scientific or medical research for the prevention, cure or control of a disease or injury process.~~

~~Case-Specific Data means data contained in the medical record and health information registries concerning a specific individual other than patient-identifying data.~~

~~Certain Diseases or Injuries means cancers, birth defects, head and brain injuries and Parkinson's disease or related movement disorders.~~

~~Department means the Nebraska Department of Health and Human Services Regulation and Licensure.~~

~~Medical Record and Health Information Registry means the system of reporting certain medical conditions occurring in this state, as prescribed by law, which are reported and recorded in order to achieve the goals of prevention, cure and control through research and education, and includes the Birth Defects Registry established in Neb. Rev. Stat. § 71-646, the Cancer Registry established in Neb. Rev. Stat. §§ 81-642 to 81-650, the Brain Injury Registry established in Neb. Rev. Stat. §§ 81-653 to 81-661 and the Parkinson's Disease Registry established in Neb. Rev. Stat. § 81-684.~~

~~Patient-Identifying Data means the patient's name, address, record number, symbol, or other identifying particular assigned to or related to an individual patient.~~

~~Permission means written consent or written authorization.~~

~~Research means study specific to the diseases or injuries for which access to data is requested and which is dedicated to the prevention, cure, or control of the diseases or injuries.~~

~~5-003 CLASSIFICATION OF MEDICAL RECORDS: Medical records provided to the Department for use in its medical record and health information registries must be classified for release according to the following categories:~~

- ~~1. Class I data is confidential with release only in aggregate data reports created by the Department on a periodic basis, usually specified in the statutes creating the registry. These reports are public documents;~~
- ~~2. Class II data is confidential with release only in aggregate data reports created by the Department at the request of an individual. These reports are public documents;~~
- ~~3. Class III data is confidential with release of patient-identifying data to approved researchers for specific research projects. The approved researcher must maintain the confidentiality of the information; and~~
- ~~4. Class IV data is confidential with release of case-specific data to approved researchers for specific research projects. The approved researcher must maintain the confidentiality of the data.~~

~~5-004 CONFIDENTIALITY AND RELEASE OF INFORMATION~~

~~5-004.01 All case-specific and patient-identifying data obtained from medical records of individual patients is for the confidential use of the Department, those reporting data to the Department, and public health agencies and approved researchers that the Department determines may view such records in order to carry out the intent of Neb. Rev. Stat. §§ 81-663 to 81-675.~~

~~5-004.01A The information is privileged and must not otherwise be divulged or made public so as to disclose the identity of an individual whose medical records and health information have been used for acquiring data.~~

~~5-004.01B Case-specific and patient-identifying data may be released to those individuals or entities who have reported information to the Department. The data may be released for the purpose of confirming the accuracy of the data provided and to coordinate information among sources.~~

~~5-004.01C All case-specific and patient-identifying data furnished and any findings or conclusions resulting from the data are privileged communications which may not~~

~~be used or offered or received in evidence at any legal proceeding of any kind, and any attempt to use or offer any such information, findings, conclusions, or any part thereof, unless waived by the interested parties, constitutes prejudicial error resulting in a mistrial in any such proceeding.~~

~~5-004.01D Any de-identified data (other than Class III data) asked for by and furnished to a researcher may not be intentionally re-identified in any manner. Should a recipient of de-identified information unintentionally or accidentally be able to identify any individual they must not use that information in any way. The recipient must also notify the Department of the means of accidental re-identification in order for the Department to consider additional procedures to safeguard against breaches in confidentiality.~~

~~5-004.02 Aggregate data collected must be open and accessible to the public and the statistical information will not be considered medical records pursuant to Neb. Rev. Stat. § 84-712.05.~~

~~5-004.03 The cost of data retrieved and data processing will be paid by the researchers and private or public entities or individuals requesting data from a certain disease or injury registry.~~

~~5-005 APPROVED RESEARCHER: The Department may approve individuals or entities who submit written application to obtain access to case-specific data or case-specific and patient-identifying data to assist in their research for the prevention, cure and control of certain diseases and injuries. These individuals or entities must show that the applicant is a qualified researcher, that the data requested will be used for bona fide scientific or medical research for prevention, cure, or control of certain diseases and injuries, and that the applicant will maintain the confidentiality and security of the data obtained. The application must contain, but is not limited to the following information:~~

- ~~1. Applicant's name and address;~~
- ~~2. The name of the entity, if any, which the applicant represents, its address and a brief description of the entity;~~
- ~~3. Name and address of the principal investigator, if other than the applicant;~~
- ~~4. The qualifications of the applicant and of the principal investigator, if other than the applicant, including education, experience, prior publications, and recommendations of professional colleagues who have knowledge and experience of scientific or medical research;~~
- ~~5. The purpose of the research project, a summary of the project and the anticipated time of the completion of such project;~~
- ~~6. The location where the research project will be conducted and the equipment, personnel, and other resources available to the applicant to carry out the projects;~~
- ~~7. The identity of the individual or entity funding the research project, a description of the availability of funds for the research project and any conditions on the receipt or continuation of such funding;~~

- ~~8. The specific data requested and a description of the use to be made of such data and, if patient-identifying data is requested, a substantiation of the need for access to such patient-identifying data;~~
- ~~9. A description of the measures to be taken to secure the data and maintain the confidentiality of such data during the research project, for disposal of the data upon completion of the study and to assure that the results of the study will not divulge or make public information that will disclose the identity of any individual patient;~~
- ~~10. If contact with patient or patient's family is planned, approved researcher must substantiate the need for such contact and describe the method to be used to obtain permission from the patient's physician for such contact; and~~
- ~~11. Such additional information as the Department determines to be necessary to assure that release of data to the applicant is appropriate and will further the purpose of Neb. Rev. Stat. §§ 81-663 to 81-650 or the laws governing the specific registry.~~

~~5-006 SUBMISSION OF REPORTS: The approved researcher must submit the reports or results of the research project to the Department at no cost. The Department reviews the reports or results and prohibits publication of confidential information or patient-identifying data. The approved researcher must acknowledge the Department and its medical record and health information registries in any publication in which information obtained from the medical record and health information registries is used.~~

~~5-007 RELEASE OF DATA TO GOVERNMENTAL HEALTH AGENCIES: Except as otherwise provided by the law governing a specific medical record and health information registry, the Department may release information contained in a registry to official public health departments and agencies as follows:~~

- ~~1. Upon request by an official local health department within the State of Nebraska, the Department may release the data to the requesting local health department. The official local health department must not contact patients using data received under Neb. Rev. Stat. §§ 81-663 to 81-675 without approval by the Department of an application made pursuant to Neb. Rev. Stat. § 81-666; and~~
- ~~2. Upon approval of an application by federal, state, or local official public health agencies made pursuant to Neb. Rev. Stat. § 81-666, the Department may release the data.~~
- ~~3. The information released by the Department will be limited to the minimum amount reasonably necessary to achieve the purposes for which disclosure is made.~~

~~5-007.01 The receiving agency, under 186 NAC 5-007, must not further disclose data to any third party but may publish aggregate statistical reports, except that no patient-identifying data will be divulged, made public, or released to any public or private person or entity. The receiving agency must comply with the patient contact provisions of Neb. Rev. Stat. §§ 81-663 to 81-675. The receiving agency must acknowledge the Department~~

~~and its medical record and health information registries in any publication in which information obtained from the medical record and health information registries is used.~~

~~5-007.02 The release and acknowledgment provisions of 186 NAC 5-007 do not apply to cancer registries located in another state which receive data through approved data exchange agreements.~~

~~5-008 PATIENT CONTACT PROVISIONS: No person who seeks information or obtains registry data pursuant to this regulation will contact a patient on the registry or the patient's family unless the registry has first obtained the permission of the patient or patient's family. The registry will coordinate its activities with the person desiring the contact and may authorize the person desiring the contact to perform these contacts under the direction of the registry.~~

~~5-009 IMMUNITY FOR RECEIPT AND RELEASE OF INFORMATION: Any person who receives or releases information in the form and manner prescribed by Neb. Rev. Stat. §§ 81-663 to 81-675 and 186 NAC 5 will not be civilly or criminally liable for the receipt or release unless the receipt or release is done with actual malice, fraudulent intent, or bad faith.~~

~~5-010 WRONGFUL DISCLOSURE OF INFORMATION: Any private or public entity, individual or approved researcher who wrongfully discloses confidential data obtained from the medical record and health information registries or uses the information with the intent to deceive will be guilty of a Class IV misdemeanor for each offense.~~

TITLE 186 HEALTH REGISTRIES AND RELEASE OF INFORMATION

CHAPTER 5 RELEASE OF MEDICAL RECORDS AND HEALTH INFORMATION

001. SCOPE AND AUTHORITY. This regulation governs the release of medical records and health information Neb. Rev. Stat. §§ 81-663 to 81-675 which are contained in the registries that record certain medical conditions occurring in this state, as prescribed by law. These registries include the Birth Defects Registry established in Neb. Rev. Stat. §§ 71-645 to 71-648, the Cancer Registry established in Neb. Rev. Stat. §§ 81-642 to 81-650, the Brain Injury Registry established in Neb. Rev. Stat. §§ 81-653 to 81-661 and the Parkinson's Disease Registry established in Neb. Rev. Stat. §§ 81-697 to 81-6,110.

002. DEFINITIONS. The definitions set in Neb. Rev. Stat. §§ 81-642 to 81-650, 81-653 to 81-675, 81-697 to 81-6,110 and the following definitions apply to this chapter.

002.01 CERTAIN DISEASES OR INJURIES. Certain diseases or injuries are cancers, birth defects, head and brain injuries and Parkinson's disease or related movement disorders.

002.02 PERMISSION. Permission is the written consent or written authorization for contact obtained by the approved researcher from such patient or patient's family.

003. CONFIDENTIALITY AND RELEASE OF INFORMATION. The data released must not be used in a manner to identify the individual and a data processing fee for the request will apply.

003.01 PROHIBITED RE-IDENTIFICATION. Any de-identified data (other than Class III data) furnished to a researcher may not be intentionally re-identified in any manner. Should a recipient of de-identified information unintentionally or accidentally be able to identify any individual they must not use that information in any way. The recipient must also notify the Department of the means of accidental re-identification in order for the Department to consider additional procedures to safeguard against breaches in confidentiality.

003.02 DATA PROCESSING FEE. The cost of data retrieved and data processing must be paid by the researchers, private or public entities, or individuals requesting data from a certain disease or injury registry.

004. APPROVED RESEARCHER. The Department may approve individuals or entities who submit written application to obtain access to case-specific data or case-specific and patient-identifying data to assist in their research for the prevention, cure and control of certain diseases and injuries. These individuals or entities must show that the applicant is a qualified researcher, that the data requested will be used for bona fide scientific or medical research for prevention,

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cure, or control of certain diseases and injuries, and that the applicant will maintain the confidentiality and security of the data obtained. The application must contain the information required by Neb. Rev. Stat. § 81-666 and the following information:

- (A) The applicant's name and address;
- (B) The name of the entity, if any, which the applicant represents and its address, and a brief description of the entity; and
- (C) The name and address of the principal investigator, if different from the applicant.