

March 31, 2009

VIA FIRST CLASS MAIL

Mr. David P. Lawton
Public Health Informatics Manager
Nebraska Department of Health
301 Centennial Mall South
PO Box 950097
Lincoln, NE 68509

Re: Preemption Update

Dear David:

Enclosed you will find the report of our review of the existing Nebraska regulations, statutes and laws governing behavioral health information and predictive genetic testing information that affects the use of electronic formats and electronic health information exchanges to retrieve, store or transmit such information. Per our discussion, we did not review laws of general applicability to medical records and health information generally that could have an impact on electronic health information exchanges, with one exception you will see from the report.

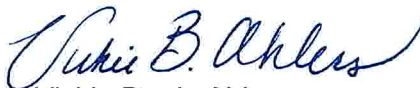
We set forth each area of review in a table that outlines the relevant statutory or regulatory text and the context within which the text is included. We then discussed the effect of such language on implementation of electronic health records and the recommendation for change, if any.

We appreciate the opportunity to conduct this review on behalf of the Department. We are certainly willing to respond to any questions or concerns you may have regarding the information contained in this report.

Very truly yours,



Alex M. Clarke
FOR THE FIRM



Vickie Brady Ahlers
FOR THE FIRM

AMC/VBA/cmk
Enclosure
DOCS/907181.1

CITATIONS AND TEXT:

- **Neb. Rev. Stat. § 71-551 (2008) Physician; genetic tests; written informed consent; requirements; Department of Health and Human Services; duty**
- **Nebraska Admin. Code Title 181, Ch. 2 (2008) Screening of infants for metabolic diseases**
- **Nebraska Admin. Code Title 181, Ch. 5 (2008) Consent for Predictive Genetic Testing**

71-551(1) Except as provided in section 71-519 and except for newborn screening tests ordered by physicians to comply with the law of the state in which the infant was born, a physician or individual to whom the physician has delegated authority to perform a selected act, task, or function shall not order a predictive genetic test without first obtaining written informed consent of the patient to be tested. Written informed consent consists of a signed writing executed by the patient or the representative of the patient lacking decisional capacity that confirms that the physician or individual acting under the delegated authority of the physician has explained, and the patient or his or her representative understands:

(d) The future uses of the sample taken to conduct the predictive genetic test **and the genetic information** obtained from the predictive genetic test;

...

(f) Who will have access to the sample taken to conduct the predictive genetic test and the genetic information obtained from the predictive genetic test, **and the patient's right to confidential treatment of the sample and the genetic information.**

71-551(6) For purposes of this section:

(a) **Genetic information** means information about a gene, gene product, or inherited characteristic derived from a genetic test;

(b) **Genetic test** means the analysis of human DNA, RNA, chromosomes, epigenetic status, and those tissues, proteins, and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. Tests of tissues, proteins, and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition. Genetic test does not include a physical examination or imaging study. Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46, as such regulations existed on January 1, 2003.

(c) **Predictive Genetic Test** means a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype. Predictive genetic test does not include diagnostic testing conducted on a person exhibiting clinical signs or symptoms of a possible genetic condition. Predictive genetic testing does not include prenatal genetic diagnosis, unless the prenatal testing is conducted for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority.

5-003.03 and .04 – Proper completion of [Attachments A, B and C – Model Informed Consent Forms] will satisfy this obligation for all predictive genetic tests [for newborn screenings, prenatal genetic testing for adult-onset, and all other predictive genetic testing, respectively].

Model consent language (Schedule B and C) – Genetic test results, like all confidential medical information, **can be released only with your written consent.** However, if a potential employer or insurer demands that you release your medical records and you refuse, you can be turned down for the job or the insurance. If you have health insurance your contract allows the insurer access to your own medical records and those of your dependents, even for the medical care it doesn't cover.

5-003.04 The written informed consent requirement only relates to tests to predict an asymptomatic individual's risk of developing a genetically related disease or disability.

CONTEXT:

Providers across the state, particularly hospitals, run thousands of tests per day for diagnostic and treatment purposes, many of which yield results that would be covered by the rule if performed as a covered test. Providers generally interpret the rule so as not to apply to tests ordered for diagnostic and treatment purposes. This is significant because these test results are scattered throughout and incorporated into the patient's general medical record, and providers would likely have no means to flag or hold back these tests in an electronic health information exchange ("HIE") environment.

It is believed that only a small number of programs perform covered predictive genetic tests. These may be conducted and maintained separate from the individual's general record or they may be conducted in a separate program or care setting that facilitates flagging.

EFFECT:

Based on common understanding of the narrow scope of the rule, most providers (including hospitals) do not view themselves as performing predictive genetic testing. The rule should not have adverse effect on the electronic retrieval, storage or transmission of these providers' records.

Providers or programs that conduct covered predictive genetic testing have four options:

- (1) Obtain broad informed consent to electronic retrieval, storage or transmission of such records at the time services are rendered or thereafter (but see our later discussion of section 71-8403); or
- (2) Not merge or combine such test results into general medical records that the provider does submit to electronic retrieval, maintenance or transmission through an HIE; or
- (3) Develop a means to flag and hold such records back from an edge server or common record when submitting or making available through an HIE other records of the provider; or
- (4) If unable to keep separate or flag and hold back covered predictive genetic testing records, not participate in an HIE.

It is believed the rule has very limited effect statewide because there are so few providers performing covered tests and because providers that do perform covered tests should already keep such records out of the general medical record or have a means to flag them and hold them back.

The primary effect would be on laboratory providers who conduct testing and furnish test results to providers. To the extent these testing laboratories participate in an HIE, their test results would be posted and available for electronic retrieval or transmission to the same extent as all other laboratory test results that do not receive special protection. However, it is probably the provider responsible for obtaining informed consent that is principally at risk for disclosures that exceed the scope of informed consent. Providers performing covered tests, therefore, should insist on a means whereby they can flag a test request or requisition as subject to special protections when ordered or requisitioned and the performing lab can withhold such test results from retrieval or transmission through an HIE.

RECOMMENDATION:

None.

CROSS REFERENCES:

Neb. Rev. Stat. § 77-5519 Genetic test defined similarly for purposes of Invest Nebraska Act.
Neb. Rev. Stat. § 44-7,100 Genetic test defined similarly for purposes of Insurance Code.
Neb. Rev. Stat. § 48-236 Genetic test defined similarly for purposes of Labor laws.

These laws generally prohibit requiring an individual to submit to genetic testing or furnish genetic information, and prohibit discrimination based on genetic information.

CITATION AND TEXT:

- **Neb. Rev. Stat. §§ 29-401 to 29-4115 DNA Identification Information Act**

29-4105 – Except for records and samples expunged under section 29-4109, the Nebraska State Patrol shall permanently retain DNA samples and records of an individual obtained under section 29-4106.

The Nebraska State Patrol may contract with the University of Nebraska Medical Center to establish the State DNA Sample Bank at the medical center and for DNA typing tests.

29-4108 – All DNA samples and DNA records submitted to the State DNA Sample Bank or the State DNA Data Base are confidential except as otherwise provided in the DNA Identification Information Act. Permitted disclosures are specified in the statute.

29-4109 - The Nebraska State patrol shall purge all DNA records and identifiable information in the data base pertaining to the person and destroy al DNA samples form the person upon receipt of a written request for expungement pursuant to this section and a certified copy of the final court order reversing and dismissing the conviction.

CONTEXT:

Regulates laboratories who perform and submit DNA tests and records to the State DNA Data Base. Law authorizes the University of Nebraska Medical Center to establish the State DNA Sample Bank at the Medical Center and to perform DNA typing tests. DNA tests may be genetic tests if the test is performed for a clinical purpose.

EFFECT:

These records receive separate treatment regardless of the medium in which maintained or transmitted.

Tests covered by the Act are not of the type maintained or shared via an HIE for treatment, payment or health care operations purposes.

A laboratory would need to identify all tests conducted pursuant to the Act and maintain results in a separate database. A lab participating in an HIE could not make test results conducted pursuant to the Act available to other participants in such an exchange.

RECOMMENDATION:

None.

CITATION AND TEXT:

- **Neb. Rev. Stat. § 43-4414 Genetic testing; procedure; confidentiality; violation; penalty**

(2) In any proceeding to establish paternity, the Department of Health and Human Services, county attorneys, and authorized attorneys have the authority to require the child, the mother and the alleged father to submit to genetic testing to be performed on blood or any other appropriate genetic testing material. All genetic testing shall be performed by a laboratory accredited by the College of American Pathologists or any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the college.

...

(4) If an alleged father who is tested as part of an action under such sections is found to be the child's father, the testing laboratory shall retain the genetic testing material of the alleged father, mother and child for no longer than the period of years prescribed by the national standards under which the laboratory is accredited. If a man is found not to be the child's father, the testing laboratory shall destroy the man's genetic testing material in the presence of a witness after such material is used in the paternity action. The witness may be an individual who is a party to the destruction of the genetic testing material. After the man's genetic testing material is destroyed, the testing laboratory shall make and keep a written record of the destruction and have the individual who witnessed the destruction sign the record. The testing laboratory shall also expunge its records regarding the genetic paternity testing performed on the genetic testing material in accordance with the national standards under which the laboratory is accredited.

(5) A testing laboratory is required to protect the confidentiality of genetic testing material, except as required for a paternity determination. The court and its officers shall not use or disclose genetic testing material for a purpose other than the paternity determination.

- **Neb. Rev. Stat. § 43-3327 Support orders and genetic testing; access to information without court or administrative order; fee authorized; confidentiality; violation; penalty**

(2) The Department of Health and Human Services, county attorney, or an authorized attorney may (a) compel by subpoena . . . (ii) genetic testing of an individual relevant to establishing, modifying, or enforcing a support order. . . . (b) Obtain access to information contained in the records including automated data bases, of any state or local agency which is relevant to establishing, modifying, or enforcing a support order or to ordering genetic testing.

...

(4) All information acquired pursuant to this section is confidential and cannot be disclosed or released except to other agencies which have a legitimate and official interest in the information for carrying out the purposes of this section.

CONTEXT:

Regulates laboratories who perform genetic tests for purposes of determining paternity.

EFFECT:

The Act requires special protection for covered records regardless of whether retrieved, maintained or transmitted in an electronic or other medium.

Tests covered by the statute are not of the type maintained or shared via an HIE for treatment, payment or health care operations purposes.

A laboratory would need to identify all tests conducted pursuant to this statute and maintain results in a separate database. A lab participating in an HIE could not make test results conducted pursuant to the Act available to other participants in such an exchange.

RECOMMENDATION:

None.

CITATION AND TEXT:

- **Nebraska Admin. Code Title 205, Ch. 4 Regulations for Certification of a Developmental Disabilities Service Provider.**

011 Confidentiality. The provider shall maintain confidentiality of information that pertains to the identity, diagnosis, or habilitation of any person receiving services.

011.01 – Information can be disclosed only with the written informed consent of the person or his/her legal representative, pursuant to a court order, or in a review by a state or federal agency for purposes of certification, accreditation, audit, monitoring, or interagency cooperative agreements.

011.02 – The provider shall have policies and procedures to govern confidentiality which must include: . . .

011.02D – Procedures for securing informed consent from the person receiving services and/or the person's legal representative to release information.

CONTEXT:

These regulations govern certification of providers of developmental disabilities services. These regulations are essentially conditions of participation for maintaining certification, and directly address release of behavioral health/mental health information.

EFFECT:

This regulation may be aimed at creating special protection for records related to the diagnosis and treatment of individuals for developmental disability issues, but the effect is broader. It would appear to limit disclosure of even medical diagnosis or treatment, allergies, prescription history, etc., in connection with referral or request for medical services. The text is significantly more limiting than HIPAA, which would permit disclosure without consent for treatment purposes, for example. The effect is to create a different standard of privacy for individuals cared for by a covered developmental disabilities service provider, even when the exchange of information relates to medical care. Medical information related to medical condition or treatment, prescriptions, health history, etc., is the type of information often retrieved, stored or transmitted via an HIE. We would anticipate covered developmental disabilities service providers or physicians and practitioners associated with them will want to participate in an HIE in the future. The rule could thus significantly limit retrieval, storage and transmittal of health information via an electronic exchange.

RECOMMENDATION:

We recommend revising the language governing disclosure of medical records of developmental disabilities service providers as follows:

011.01 – Information can be disclosed only with the written informed consent of the person or his/her legal representative, pursuant to a court order, or in a review by a state or federal agency for purposes of certification, accreditation, audit, monitoring, or interagency cooperative agreements, or as permitted by law.

CITATION AND TEXT:

- **Nebraska Admin. Code Title 471, Ch. 20 Psychiatric Services for Individuals Age 21-and Older.**

20-001.18 Transition and Discharge Planning: Providers shall meet the following standards regarding transition and discharge planning:

6. The current provider shall arrange for prompt transfer of appropriate records and information to ensure continuity of care during transition into the next level of care; and
7. A written transition and discharge summary must be provided as part of the medical record.

20-001.19 Clinical Records: Clinical records must be arranged in a logical order such that the clinical information can be easily reviewed, audited, and copied. Each provider shall maintain accurate, complete, and timely records and shall always adhere to procedures that ensure the confidentiality of clinical data.

CONTEXT:

These regulations are contained within the Medicaid regulations governing the provision of and payment for psychiatric services for individuals age 21 and older. A condition of coverage for such psychiatric services includes the requirement that providers carry out appropriate transition and discharge planning when a client is transferred from one level of care to another.

EFFECT:

In the absence of more stringent standards in state or federal law, the reference to confidentiality should default to the HIPAA standard, which permits retrieval, storage and transmittal for treatment, payment and certain health care operations with various safeguards. The typical HIE will operate under the HIPAA standard. The existing rule should not require different treatment of records of psychiatric services for individuals 21 years of age or older than other medical records.

RECOMMENDATION:

None.

CITATION AND TEXT:

- **Neb. Rev. Stat. § 81-653 The Brain Injury Registry Act.**
- **Nebraska Admin. Code Title 186, Ch. 5 Health Registries and Release of Information.**

81-657 Brain Injury Registry; Physician, Psychologist, Hospital, and Rehabilitation Center; Report Required; Contents.

(1) If a person with brain or head injury is treated in this state in the office of a physician or psychologist licensed to practice in this state but is not admitted to a hospital within this state, the treating physician or psychologist shall provide a report of such injury to the department within thirty days after such treatment and identification of the person sustaining such injury.

(2) If a person with brain or head injury is admitted to or treated at a hospital or a rehabilitation center located within a hospital in this state, such hospital or rehabilitation center shall provide a report of such injury to the department within thirty days after the discharge of such person from the hospital or rehabilitation center.

81-659 Brain Injury Registry; Certain Data; Confidential; Access; When.

No patient-identifying data as defined in section 81-664 shall be disclosed, made public, or released by the department to any public or private person or entity. All other data obtained from medical records of persons sustaining brain or head injury is for the confidential use as Class I, Class II, or Class IV data of the department and the private or public persons or entities that the department determines may view such records as provided in sections 81-663 to 81-675.

81-667 Medical Records; Classification.

Medical records provided to the department for use in its medical record and health information registries shall be classified for release according to the following categories:

(1) Class I data shall be 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 shall be public documents;

(2) Class II data shall be confidential with release only in aggregate data reports created by the department at the request of an individual. These reports shall be public documents;

(3) Class III data shall be confidential with release of patient-identifying data to approved researchers for specific research projects. The approved researcher shall maintain the confidentiality of the information; and

(4) Class IV data shall be confidential with release of case-specific data to approved researchers for specific research projects. The approved researcher shall maintain the confidentiality of the data.

81-668 Case-Specific and Patient-Identifying Data; Confidentiality; Aggregate Data; Cost.

All case-specific and patient-identifying data obtained from medical records of individual patients shall be for the confidential use of the department, those reporting data to the department, and the public health agencies and approved researchers that the department determines may view such records in order to carry out the intent of sections 81-663 to 81-675. Such information shall be privileged and shall 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 such data. Aggregate data collected shall be open and accessible to the public, and such information shall not be considered medical records pursuant to section 84-712.05. The cost of data retrieval and data processing shall be paid by the data requester. Case-specific and patient-identifying data may be released to those individuals or entities who have

reported information to the department. Such data may be released for the purpose of confirming the accuracy of the data provided and to coordinate information among sources.

81-671 Release of Information to Public Health Departments and Agencies; Requirements.

(1) 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:

(a) Upon request by an official local health department within the State of Nebraska, the department may release such data to the requesting local health department. The official local health department shall not contact patients using data received under sections 81-663 to 81-675 without approval by the department of an application made pursuant to section 81-666; and

(b) Upon approval of an application by federal, state, or local official public health agencies made pursuant to section 81-666, the department may release such data.

(2) Except as provided in subsection (3) of this section, the receiving agency shall not further disclose such data to any third party but may publish aggregate statistical reports, except that no patient-identifying data shall be divulged, made public, or released to any public or private person or entity. The receiving agency shall comply with the patient contact provisions of sections 81-663 to 81-675. The receiving agency shall 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.

(3) The release and acknowledgment provisions of this section do not apply to the Centers for Disease Control and Prevention of the United States Public Health Service of the United States Department of Health and Human Services, the North American Association of Central Cancer Registries, or cancer registries located outside Nebraska which receive data through approved data exchange agreements.

CONTEXT:

The statute requires the state to establish a data repository for reports. This data repository or database is not for sharing with providers for treatment, payment or health care operations purposes. The statute establishes a separate confidentiality standard for reported data and authorizes access and use for certain research purposes. The confidentiality standard is more stringent than HIPAA.

EFFECT:

These records receive separate treatment regardless of the medium in which maintained or transmitted.

Registry information is not of the type maintained or shared via an HIE for treatment, payment or health care operations. The state would need to maintain this registry information in a separate database and not make the data available to other participants in an HIE. The state will need to make data in the registry available following case-by-case determination of authority and safeguards.

RECOMMENDATION:

None.

CITATION AND TEXT:

- **Neb. Rev. Stat. §§ 71-901 to 71-962 Nebraska Mental Health Commitment Act**

71-949 – Counsel for Subject; Rights; Enumerated; Discovery; Appeal from Denial of Discovery; When

Counsel for a subject, upon request made to the county attorney at any time after the subject has been taken into emergency protective custody under the Nebraska Mental Health Commitment Act or the Sex Offender Commitment Act, or after the filing of a petition under section 71-921 or 71-1205, whichever occurs first, shall have the right to be provided with . . . (2) knowledge of the location and access at reasonable times for review or copying of all written documents including reports of peace officers, law enforcement agencies, and mental health professionals, . . . and (4) written records of any treatment facility or mental health professional which or who has at any time treated the subject for mental illness, substance dependence, or a personality disorder, which records are relevant to the issues of whether the subject is mentally ill and dangerous or a dangerous sex offender and, if so, what treatment disposition should be ordered by the mental health board.

71-961 – Subject's Records; Confidential; Exceptions.

(1) All records kept on any subject shall remain confidential except as otherwise provided by law. Such records shall be accessible to (a) the subject, except as otherwise provided in subsection (2) of this section, (b) the subject's legal counsel, (c) the subject's guardian or conservator, if any, (d) the mental health board having jurisdiction over the subject, (e) persons authorized by an order of a judge or court, (f) persons authorized by written permission of the subject, (g) agents or employees of the Department of Health and Human Services upon delivery of a subpoena from the department in connection with a licensing or licensure investigation by the department, (h) individuals authorized to receive notice of the release of a sex offender pursuant to section 83-174, (i) the Nebraska State Patrol or the department pursuant to section 69-2409.01, or (j) the Office of Parole Administration if the subject meets the requirements for lifetime community supervision pursuant to section 83-174.03.

71-962 – Violations; Penalty.

Any person who willfully (3) breaches the confidentiality of records required by section 71-961 shall be guilty of a Class II misdemeanor in addition to any civil liability which he or she may incur for such actions.

CONTEXT:

This is a statutory scheme for confidentiality of records created or maintained for EPC purposes. Section 71-961 creates a more stringent standard of privacy than exists for medical records, including mental health records, generally. This statute permits disclosure only as otherwise provided by law, and then enumerates a list of exceptions. We would read this as an inclusive list and would prohibit a provider from defaulting to the HIPAA list of exceptions. It is a more stringent or narrow list than HIPAA provides. For many health care providers, this information would be limited to referrals to law enforcement for emergency protective custody. Others could be medical facilities providing treatment during the mental health commitment process. The statute expressly requires authorization by the patient unless disclosure is to a limited category of identified recipients.

Importantly, there is no clear definition of which records are covered. It is fairly clear that those records created for the purpose of EPC or mental health commitment are covered. Less clear (and the biggest issue) is whether records with dual purpose – for example, created as part of an ER, ICU or med/surgical consult for diagnosis or treatment purposes, but also for the purpose of (or eventually used for) EPC or mental health commitment purposes are covered. Potentially broad application – could reach any hospital.

EFFECT:

The effect is to leave providers unclear with respect to the scope of duty owed to their *medical records* created in connection with or following or as a result of EPC proceedings. Medical and mental health information that may follow or be related to EPC proceedings, but be created for diagnosis and treatment purposes, is typically integrated into and spread throughout the entire medical record, making it impossible or very difficult to flag and withhold such records from retrieval, storage or transmittal in an HIE.

RECOMMENDATION:

1. Amend § 71-961 to only apply to records created and used for the purpose of conducting EPC proceedings; and
2. Amend § 71-961 to except from coverage records subject to the more stringent rule under recommendation #1, above, to the extent they are integrated into the provider's medical or clinical record and used for diagnosis or treatment purposes by the provider.

The excepted records would still come under the HIPAA standard of confidentiality.

CITATION AND TEXT:

- **Nebraska State Statute**

69-2409.01 – Mental Health Treatment Data Base; Created; Disclosure: Limitation; Liability; Prohibited Act; Violation; Penalty.

(1) For purposes of sections 69-2401 to 69-2425, the Nebraska State Patrol shall be furnished upon the patrol's request with only such information as may be necessary for the sole purpose of determining whether an individual is disqualified from purchasing or possessing a handgun pursuant to state or federal law. Such information shall be furnished by the Department of Health and Human Services. The clerks of the various courts shall furnish to the Department of Health and Human Services, within thirty days after the order of commitment or finding and the discharge, all information necessary to set up and maintain the data base required by this section. *This information shall include (a) information regarding those persons who are currently receiving mental health treatment pursuant to a commitment order of a mental health board or who have been discharged and (b) information regarding those persons who have been committed to treatment pursuant to section 29-3702. The Department of Health and Human Services shall also maintain in the data base a listing of persons committed to treatment pursuant to section 29-3702.* Information regarding mental health board commitments and commitments pursuant to section 29-3702 shall not be retained in the data base maintained by the department on persons who have been discharged from those commitments more than five years previously. Any such information maintained or disclosed under this subsection shall remain privileged and confidential and shall not be redisclosed or utilized for any other purpose. The procedures for furnishing such information shall guarantee that no information is released beyond what is necessary for purposes of this section.

CONTEXT:

The information, and the purpose for gathering and maintaining it, are outside of the scope of an HIE.

EFFECT:

The statute requires the state to create and manage a separate database subject to separate, more stringent privacy rules. To the extent the state participates in one or more HIEs, it must have the means to segregate and not make this information available to other participants in the HIE.

RECOMMENDATION:

None.

CITATION AND TEXT:

- **Neb. Rev. Stat. §§ 71-8401 – 71-8407**

71-8402 – Terms, Defined

(2) *Mental health medical records* means medical records or parts thereof created by or under the direction or supervision of a licensed psychiatrist, a licensed psychologist, or a mental health practitioner licensed or certified pursuant to the Mental Health Practice Act;

71-8403 – Access to Medical Records.

(1) A patient may request a copy of the patient's medical records or may request to examine such records. Access to such records shall be provided upon request pursuant to sections 71-8401 to 71-8407, except that mental health medical records may be withheld if any treating physician, psychologist, or mental health practitioner determines in his or her professional opinion that release of the records would not be in the best interest of the patient unless the release is required by court order. The request and any authorization shall be in writing and shall be valid for one hundred eighty days after the date of execution by the patient.

CONTEXT:

Defines mental health information for purposes of the individual's right of access and establishes a limitation on the length of time a patient's authorization for disclosure of medical records is valid.

EFFECT:

1. To the extent the HIE extends to a community model whereby patients can access their own record, the HIE needs to have the functionality to carry out the physician's determination to withhold access to mental health medical records. We note that the basis for withholding access is inconsistent with HIPAA's more stringent requirements governing when a provider may deny an individual access to information, including mental health information, contained in a medical record. The effect is partial pre-emption of this provision of the statute.

2. The effect of the 180-day duration of an authorization to disclose health records is to prevent HIEs in Nebraska from using a "consent" or "opt-in" approach whereby individuals affirmatively consent to having other records available for sharing through an HIE. The authority expires every 180 days. Some HIEs prefer this approach, even though consent is not required for sharing for treatment, payment and certain health care operations purposes.

RECOMMENDATION:

1. Revise the second sentence of 71-8401 to 71-8407 as follows: Access to such records shall be provided upon request pursuant to sections 71-8401 to 71-8407 unless access is denied as permitted under the Health Insurance Portability and Accountability Act of 1996, and any amendments thereto, and the regulations issued thereunder as amended from time to time, presently codified at 45 CFR Parts 160, 162 and 164.

2. Delete the text in section 71-8403 " . . . and shall be valid for one hundred eighty days after the date of execution by the patient.

3. We also believe further revision of this statute provides an opportunity to clarify interpretation of the phrase "permitted by law" which is used frequently in statutory and regulatory text governing disclosure of medical records. While providers generally interpret "permitted by law" to encompass the permitted uses and disclosure of protected health information described in HIPAA, it would significantly benefit all providers to have a state law that established a common standard for use and disclosure of information that specifically encompasses the rules on use and disclosure established by HIPAA by cross-reference to the current HIPAA standards. More stringent state or federal rules could apply in

specific cases. This benefits current paper exchange as well as any future HIE adoption. Significant guidance has been provided by CMS regarding establishing HIEs within the context of HIPAA's rules. If state law deferred to HIPAA on disclosure of medical records, there would be a common basis for developing rules regarding HIE adoption within the state that would more easily connect in the future with other states. We recommend the following language to be added at the end of section 71-8403(1), building on our recommended revision in #2 above.

"Any authorization shall be in writing. Unless a more stringent standard is established for a particular medical record, medical records may be used and disclosed as permitted by law which includes, but is not limited to, uses and disclosure of protected health information permitted under the Health Insurance Portability and Accountability Act of 1996, as amended from time to time, and the implementing regulations presently codified at 45 CFR Parts 160, 162 and 164 and amendments thereto."

CITATION AND TEXT:

- **Nebraska Admin. Code Title 175, Ch. 19 Mental Health Centers**

19-006.18B2 – Confidentiality: The facility must keep records confidential unless medically contraindicated. Records are subject to inspection by authorized representatives of the Department.

19-006.18B4 – Access: Client information and/or records may be released only with the consent of the client or client's designee or as *required* by law. When a client is transferred to another facility or service, appropriate information must be sent to the receiving facility or service.

19-006.18B5 – Administrative Changes: If a facility changes ownership or administrator, all client records must remain in the facility. Prior to the dissolution of any facility, the Administrator must notify the Department in writing as to the location and storage of client records.

19-006.19D – Transfer: The facility must ensure the timely transfer of appropriate client record information as authorized by the client or designee by a signed release of information.

CONTEXT:

These requirements are contained within the standards of operation, care and treatment of mental health centers. They implicate not only strict requirements for disclosure, but also storage of the records and transfers of records.

EFFECT:

This language permits disclosure only in narrow circumstances or as "required by law," and is more restrictive than presently permitted under HIPAA. Other classes of facility and individual licensees may release as "permitted" by law, which HIPAA expands to mean for treatment, payment and certain health care operations purposes. There is no overriding rule requiring mental health centers to disclose for treatment, payment and health care operations purposes. Therefore, they would be prevented from participating in an HIE absent express authorization (see discussion of section 71-8403 and the issue created by 180-day limitation on effectiveness of an authorization). This puts them on a distinctly different footing than other providers.

To the extent a covered mental health center is part of a larger provider, there would need to be a means to segregate and withhold mental health center records from provider records generally.

RECOMMENDATION:

We recommend revising the language governing disclosure of medical records to substitute "permitted by law" in place of "required by law" in 19-006.18B4.

CITATION AND TEXT:

- **Nebraska Admin. Code Title 204, Ch. 5 – Regulations for Certifying Community Mental Health Programs**

5-004.05A6 – Written policies and procedures which govern the disposal of consumer service records. These policies and procedures contain the following provisions.

5-004.05A6b Methods of disposal which are designed to assure the confidentiality of information.

5-004.05A7 – Written policies, procedures and documentation of the implementation of the maintenance of records at the site where the person is served to ensure that the records are directly accessible to the staff providing services.

5-004.06 – Confidentiality. Records of the identity, diagnosis, prognosis or treatment of any consumers are confidential and *must be disclosed only with the written consent of the individual, the consumer's legal guardian, by order of a court of competent jurisdiction, or as otherwise required by law.*

5-004.06A – The program shall have policies and procedures designed to ensure confidentiality of the service records. These policies must include:

5-004.06A1 The conditions under which information on consumers may be disclosed and the procedures for releasing such information.

5-004.06A2 Provisions for consumers or their authorized representative may consent to the release of information provided that written consent is given on a form containing the following information:

004.06A2a The name of the person or organization to which the information is to be disclosed;

004.06A2b The specific information to be disclosed;

004.06A2c The purpose of the disclosure;

004.06A2d The date the consent was signed and the signature of the individual witnessing the consent; and

004.06A2e Specification of the period of time the consent is valid.

5-004.06B – Forms for release and receipt of consumer information must appear as an addendum in the policies and procedures manual.

5-004.06C – Documentation of the signed release of information form(s) must be present in the consumer's service record.

004.06C1 A copy of each signed release is in the service record.

004.06C2 There is documentation in the progress notes of the signing of the release of information form.

5-004.06D – All aspects of confidentiality are addressed in the program's quality improvement function.

004.09B3 Procedures to ensure that pertinent portions of records and other relevant information are readily transferred, with consumer consent, between organizations.

CONTEXT:

These provisions are contained within the regulations that establish the treatment requirements along with required management policies and procedures for community mental health programs.

EFFECT:

The language regarding disclosure of the identity, diagnosis, prognosis or treatment of any client information is limited to disclosures with the client's written consent or disclosures required by law. This language prohibits disclosures even for purposes of further treatment without the clients' written consent. This is more restrictive than presently permitted under HIPAA. For providers with a community mental health center component, the rule requires that certain records be segregated and withheld before sharing through an HIE. This may be functionally difficult depending on the extent to which covered records are integrated into and scattered throughout a provider's medical record. For providers that are community mental health programs and covered by the rule, the rule effectively bars participation in an HIE, except on a consent or opt-in basis (but note discussion of section 71-8403 and the limited duration of consent).

RECOMMENDATION:

We recommend revising the restrictions on disclosure to substitute "permitted by law" in place of "required by law" so as to come under the same HIPAA-based standard applicable to other providers and records.

CITATION AND TEXT:

- **83-109 – Patients and Residents; admission to state institutions; records; to whom accessible; transfers; investigations; appeals**

The Department of Health & Human Services shall have general control over the admission of patients and residents to institutions over which it has jurisdiction. Each individual shall be assigned to the institution best adapted to care for him or her. A record of every patient or resident of every institution shall be kept complete from the date of his or her entrance to the date of his or her discharge or death, such records to be accessible only (1) to the department, a legislative committee, the Governor, any federal agency requiring medical records to adjudicate claims for federal benefits, and any public or private agency under contract to provide facilities, programs, and patient services; (2) upon order of a judge or court; (3) in accordance with sections 20-161 to 20-166; (4) to the Nebraska State patrol pursuant to section 69-2409.01; or (5) to those portions of the record required to be released to a victim as defined in sections 29-119 in order to comply with the victim notification requirements pursuant to subsections (4) and (5) of sections 81-1850. In addition, a patient or resident or his or her legally authorized representative may authorize the specific release of his or her records, or portions thereof, by filing with the department a signed written consent.

CONTEXT:

Institutions under the control of DHHS include the regional centers and the Beatrice State Developmental Center.

EFFECT:

State institutions into which individuals are placed under this statute will not be able to participate in HIEs, given the more stringent level of privacy required. They cannot disclose through an HIE for treatment, payment and health care operations. For these institutions, this more stringent rule overrides the rule for community mental health centers at 175 NAC 19-006.18B4 and our recommendation to modify that rule.

RECOMMENDATION:

If the state wishes to permit these state institutions to participate in an HIE with sharing of records for treatment, payment and certain health care operations, it will need to amend the restrictive scope of this statute.

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