CHIEF MEDICAL OFFICER, NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

November 28, 2023
7:00 a.m. – 7:00 p.m. Central Time
Lancaster Event Center – Lincoln Room
4100 N 84th St., Lincoln, NE 68507

The purpose of this hearing is to receive comments on the adoption of Title 181, Chapter 8 of the Nebraska Administrative Code (NAC) – *Nonsurgical Pharmaceutical Gender Altering Treatments.* The adoption of this new regulation chapter will outline the requirements for health care professionals to prescribe approved puberty-blocking drugs, cross-sex hormones, or both to individuals with a long-lasting and intense pattern of gender nonconformity or gender dysphoria. These prerequisites include the minimum number of gender-identity-focused contact hours, elements of informed patient consent, patient medical record documentation requirements, and a minimum waiting period between informed consent and administration, prescribing, or delivery of such drugs.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7), § 71-7305(1), and § 71-7305(2).

Interested persons are encouraged to provide written comments via mail, fax, or email, no later than 11:59 p.m. the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 (fax) or dhhs.regulations@nebraska.gov, respectively. All written comments received prior to that deadline will be fully reviewed and considered by the Chief Medical Officer, Nebraska Department of Health and Human Services.

Alternatively, interested persons may attend the hearing and provide verbal or written comments, or both. The hearing will start at 7:00 a.m. and run until 7:00 p.m. or until there are no additional speakers, whichever comes first. Please note, oral comments will be limited in duration to 3 minutes to allow the maximum number of speakers to provide comments based on the anticipated public participation in the hearing. In order to maximize the number of speakers in the time allotted, the Chief Medical Officer, Nebraska Department of Health and Human Services reserves the right to decrease the allotted time to 2 minutes. Participants are strongly encouraged to bring a written copy of all oral comments as to ensure the Chief Medical Officer, Nebraska Department of Health and Human Services can fully consider all comments adequately, regardless of duration of testimony or opportunity to provide comments. Please also note that all written and oral comments will be equally reviewed and considered by the Chief Medical Officer, Nebraska Department of Health and Human Services.

Due to limited capacity, oral commenters are respectfully asked to consider vacating the premise upon completion of their testimony as to provide space for all who wish to comment.

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 who are deaf or hard of hearing may call DHHS via 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: 181	Prepared by: Ryan Daly
Chapter: 8	Date prepared: 10/16/2023
Subject: Nonsurgical Pharmaceutical Gender Altering Treatments	Telephone: 402-471-2012

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☐)
Increased Costs	(☐)	(☐)	(☒)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency: No anticipated cost.

Political Subdivision: No anticipated cost.

Regulated Public: The proposed regulation requires 40 contact hours of therapeutic treatment prior to nonsurgical pharmaceutical gender-altering treatments, which may require increased co-payments or out-of-pocket expenses related to therapeutic sessions for the minor patient and parent/guardian. Injectable cross-sex hormone and puberty blocking therapies must be administered in a prescriber's office by credentialed staff, which may require increased co-payments or out-of-pocket expenses related to office visits for the minor patient and parent/guardian. The proposed regulation would require one therapeutic contact hour every 90 days while the patient is administered puberty blocking drugs or cross-sex hormones, which may require increased co-payments or out-of-pocket expenses for the minor patient and parent/guardian. Additionally, the proposed regulation would require 3 hours of Category 1 Continuing Competency Education for providers prior to prescribing cross-sex hormones or puberty blocking drugs to a patient under 19 years of age. The proposed regulation requires the individual taking receipt of puberty blocking drugs or cross-sex hormones to display a valid driver's or operator's license, a state identification card, or military identification card, an alien registration card, or a passport as proof of identification to the pharmacist. This may result in an added expense if the individual does not already possess one of these forms of identification.

If indeterminable, explain why: The exact cost to the minor patient and parent is unknown and is likely contingent on the medical insurance available to the patient.

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 8 NONSURGICAL PHARMACEUTICAL GENDER ALTERING TREATMENTS

001. SCOPE AND AUTHORITY. This regulation governs the use of nonsurgical pharmaceutical gender altering treatments under the Let Them Grow Act, Nebraska Revised Statutes (Neb. Rev. Stat.) §§ 71-7301 to 71-7307.

002. DEFINITIONS. Definitions are set out in the Let Them Grow Act, and this chapter.

002.01 GENDER DYSPHORIA. A marked incongruence between a person's experienced or expressed gender and the biological sex at birth for at least six months as manifested by the criteria set out in in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text-Revisions as published in March 2022.

002.02 GENDER NONCONFORMITY. For purposes of this chapter, gender nonconformity is a pattern of sexual identity different from the biological sex at birth expressed through observable behaviors as determined by a credentialed health care practitioner or mental health care practitioner.

002.03 LONG-LASTING AND INTENSE PATTERN OF GENDER NONCONFORMITY OR GENDER DYSPHORIA. A pattern of gender nonconformity being observed or treated for more than six continuous months or a diagnosis of gender dysphoria.

002.04 PRESCRIBED MEDICATIONS. For the purposes of this chapter, prescribed medications mean puberty blocking drugs or cross-sex hormones for the treatment of gender nonconformity or gender dysphoria.

002.05 TANNER SCALE OF PUBERTY. Also known as Sexual Maturity Rating is an objective classification system used to determine the development and sequence of secondary sex characteristics of children during puberty.

003. PUBERTY BLOCKING DRUGS. Prior to prescribing, dispensing, or administering puberty blocking drugs for the treatment of gender nonconformity or gender dysphoria to a patient who has not reached the age of majority, the prescribing practitioner must meet the following:

(A) Obtain three hours of Category 1 Continuing Competency Education for prescribing drugs for the purpose of treating gender nonconformity or gender dysphoria within the most recent biennial renewal period;

(B) Determine or document:

(i) That gender nonconformity or gender dysphoria is driving the patient's distress and not other mental or physical health conditions, that there is no reasonable expectation of natural resolution of gender nonconformity, and that there has been a long-lasting and intense pattern of gender nonconformity or gender dysphoria which began or worsened at the start of puberty;
(ii) The severity of other mental or physical health conditions is being properly addressed and treated, and will not negatively impact treatment;
(iii) Puberty blocking treatment is not likely to negatively impact, or exacerbate other mental or physical health conditions;
(iv) The patient has received at least 40 contact hours of therapeutic treatment as required by this chapter;
(v) The patient has at least six consecutive months of living primarily as the preferred gender;
(vi) For individuals not suffering from gender dysphoria or for whom a clinical diagnosis of gender dysphoria is not available, that without puberty blocking treatment the patient will experience harm;
(vii) Tanner stage of puberty development and if puberty blockers would be effective; and
(viii) The appropriate supports are in place for the patient including appropriate social, and familial supports prior to initiating puberty blocking treatment;

(C) Discuss the following with the patient and parent or legal guardian or the patient, if the patient is an emancipated minor:
(i) The recommended dosage and route of treatment for the puberty blockers; and
(ii) The minimum waiting period of seven calendar days as required by this chapter;

(D) Obtain signed informed consent and patient assent as required by this chapter; and
(E) Document all the foregoing in the patient's medical record.

004. CONTACT HOURS OF THERAPEUTIC TREATMENT. A patient who has not reached the age of majority must receive a minimum of 40 gender-identity-focused contact hours of therapeutic treatment prior to receiving prescribed medications subject to the following restrictions:

(A) The following may count toward the contact hours:
(i) An initial assessment of up to four consecutive hours; and
(ii) Following an initial assessment, up to two hours per week;

(B) The therapeutic hours must:
(i) Be clinically objective and non-biased;
(ii) Assess factors contributing to the patient's presenting emotions, actions, and beliefs; and
(iii) Not merely affirm the patient's beliefs; and

(C) For an unemancipated minor, the therapeutic hours must include sufficient parental or legal guardian involvement to ensure adequate familial support during and post treatment.

005. ONGOING CONTACT HOURS OF THERAPEUTIC TREATMENT. A patient who has not reached the age of majority must receive at least one therapeutic contact hour every 90 days while puberty blocking drugs or cross-sex hormones are being administered to evaluate ongoing effects on the patient's mental health.

006. ATTESTATION REQUIREMENTS FOR PRACTITIONERS.

006.01 PRESCRIBING PRACTITIONER. If the prescribing practitioner provided all or some of the contact hours of therapeutic treatment required by this chapter, the prescribing practitioner must sign an attestation as part of the documentation required by this chapter.

006.02 NON-PRESCRIBING PRACTITIONER. For contact hours of therapeutic treatment required by this chapter not provided by the prescribing practitioner, the prescribing practitioner must obtain an attestation from the other practitioner or practitioners as part of the documentation required by this chapter.

006.03 INITIAL 40 HOUR ATTESTATION REQUIREMENTS. The initial 40 gender-identity-focused contact hours attestation must include at least the following:

(A) Name of patient;
(B) Patient date of birth;
(C) Statement from the practitioner providing therapy detailing their training and experience with gender-identify-focused issues;
(D) Number of all contact hours of therapeutic treatment spent with the patient;
(E) Detailing the duration and frequency of those contact hours of therapeutic treatment;
(F) The duration and frequency of gender nonconformity;
(G) Any diagnosis of gender dysphoria;
(H) Any other co-occurring psychiatric diagnosis as required in this chapter;
(I) Appropriate support or referrals for the patient;
(J) Patient level of engagement in the therapy;
(K) Parental or legal guardian consent to therapy and their level of engagement in the therapy, or the consent of the patient, if the patient is an emancipated minor;
(L) Any other relevant information regarding the patient; and
(M) When the patient is an unemancipated minor, the ability of the patient to assent to therapy.

007. PATIENT INFORMED CONSENT FOR PUBERTY BLOCKING TREATMENT. A patient consent form must be obtained by the prescribing practitioner and include the following, in addition to information otherwise required in a consent form:

(A) Discussion of appropriateness of care has taken place;
(B) All the known side effects of puberty blockers, the risks associated with taking them and the risks associated with discontinuing the treatment including, but not limited to, long-term effects on bone density, brain development, impact on fertility, sexual side effects including, but not limited to, loss of sexual gratification, and effects upon physical growth and development;
(C) List of alternatives to treatment including, but not limited to, social, behavioral, and physical alternatives, and that these alternatives have been discussed with the patient and parent or legal guardian or the patient, if the patient is an emancipated minor;
(D) Signed consent of a parent or legal guardian or the signed consent of the patient, if the patient is an emancipated minor;
(E) When the patient is an unemancipated minor, patient assent to treatment; and
(F) Whether the medication is being prescribed for off-label use or otherwise not approved by the Food and Drug Administration.

008. PUBERTY BLOCKING DRUG PRESCRIPTIONS. The following restrictions apply for a patient who has not reached the age of majority in addition to all other applicable laws relating to the administration, prescribing, delivery, sale, or use of puberty blocking drugs:

(A) Prescriptions must identify the drugs being prescribed are for the treatment of gender nonconformity or gender dysphoria;

(B) Prescriptions must identify the patient's parent or legal guardian or if the patient is an emancipated minor;

(C) Prescribed medications picked up from a pharmacy are required to be picked up by the patient's parent, legal guardian, or the patient if the patient is an emancipated minor;

(D) Injectable prescribed medications must be administered either in the prescribing practitioner's office or in the office of the patient's primary care provider, by staff who are properly credentialed to administer drugs by injection;

(E) The prescribing practitioner must document no adverse effects on the patient's mental health during the course of treatment and that continued treatment is still medically appropriate as required by the chapter; and

(F) The prescribing practitioner must document the ongoing contact hours of therapeutic treatment as required by this chapter.

009. PHARMACIST REQUIREMENTS. A pharmacist dispensing puberty blocking drugs, as defined in the Let Them Grow Act, to a patient under the age of 19 shall comply with the following restrictions:

(A) Prescribed medications picked up from a pharmacy are required to be picked up by the patient's parent, legal guardian, or the patient if the patient is an emancipated minor;

(B) Unless the individual taking receipt of the dispensed medications is personally and positively known to the pharmacist and or dispensing practitioner, the individual shall display a valid driver's or operator's license, a state identification card, or military identification card, an alien registration card, or a passport as proof of identification; and

(C) Prescription drugs that are otherwise lawful to be sent by home delivery, must be delivered to the address of patient's parent or legal guardian, or the patient's address if the patient is an emancipated minor.

009.01 EXEMPTIONS. The additional requirements of this subsection shall not apply if the pharmacist documents that the patient began receiving the prescribed medication prior to October 1, 2023, that the medication is not being prescribed for the treatment of gender nonconformity or gender dysphoria, or that the patient has reached the age of 19. A pharmacist is not required to determine that the prescribing practitioner has complied with the additional requirements of this chapter prior to dispensing prescribed medications, as defined in this chapter, to a patient under the age of 19.

009.02 PHARMACIST AUTHORITY. This chapter does not otherwise limit or expand the scope of practice of a pharmacist. Prescriptions must continue to meet all other state and federal statutes, rules, and regulations.

0010. PUBERTY BLOCKING DRUGS WAITING PERIOD. A minimum waiting period of seven calendar days is required between the time the prescribing practitioner obtains informed patient consent and the time the puberty-blocking drugs are prescribed, administered, or delivered to a patient who has not reached the age of majority.

011. USE OF CROSS-SEX HORMONES. Prior to prescribing, dispensing, or administering cross-sex hormones for the treatment of gender nonconformity or gender dysphoria to a patient who has not reached the age of majority, the prescribing practitioners must meet the following:

(A) Obtain three hours of Category 1 Continuing Competency Education for prescribing drugs for the purpose of treating gender nonconformity or gender dysphoria within the most recent biennial renewal period;

(B) Determine or document:

(i) Puberty blocking treatment, if occurring, has been successful at reducing patient distress and discomfort;

(ii) That gender nonconformity or gender dysphoria is driving the patient's distress and not other mental or physical health conditions, that there is no reasonable expectation of natural resolution of gender nonconformity, and that there has been a long-lasting and intense pattern of gender nonconformity or gender dysphoria which began or worsened at the start of puberty;

(iii) There is an expectation of increased distress if puberty blocking treatment is terminated or cross-sex hormone treatment is not initiated;

(iv) Cross-sex hormones would be effective and are not likely to negatively impact, or exacerbate other mental or physical health conditions;

(v) The patient has received at least 40 contact hours of therapeutic treatment as required by this chapter;

(vi) The patient has at least six consecutive months of living primarily as the preferred gender and has continued living primarily as the preferred gender;

(vii) For individuals not suffering from gender dysphoria or for whom a clinical diagnosis of gender dysphoria is not available, documentation that without cross-sex hormone treatment the patient will experience harm; and

(viii) The appropriate supports are in place for the patient including appropriate social, and familial support prior to initiating cross-sex hormone treatment;

(C) Discuss the following with the patient and parent or legal guardian or the patient, if the patient is an emancipated minor:

(i) The recommended dosage and route of treatment for the cross-sex hormones; and

(ii) The minimum waiting period of seven calendar days as required by this chapter;

(D) Obtain signed informed consent and patient assent as required by this chapter; and

(E) Document all the foregoing in the patient's medical record.

012. PATIENT INFORMED CONSENT FOR CROSS-SEX HORMONE TREATMENT. A patient consent form must be obtained by the prescribing practitioner and include the following, in addition to information otherwise required in a consent form:

(A) Discussion of appropriateness of care has taken place;

(B) All the known side effects of cross-sex hormone, the risks associated with taking them and the risks associated with discontinuing the treatment including, but not limited to, long-term effects on cardiovascular and cerebrovascular systems, metabolic disorders, increased risk of cancer, bone density, brain development, impact on fertility, sexual side effects including, but not limited to, loss of sexual gratification, and effects upon physical growth and development;

(C) List of alternatives to treatment including, but not limited to, social, behavioral, and physical alternatives, and that these alternatives have been discussed with the patient and parent or legal guardian or the patient, if the patient is an emancipated minor;

(D) Signed consent of a parent or legal guardian or the signed consent of the patient, if the patient is an emancipated minor;
(E) When the patient is an unemancipated minor, patient assent to treatment; and
(F) Whether the medication is being prescribed for off-label use or otherwise not approved by the Food and Drug Administration.

013. CROSS-SEX HORMONE PRESCRIPTIONS. The following restrictions apply for a patient who has not reached the age of majority in addition to all other applicable laws relating to the administration, prescribing, delivery, sale, or use of cross-sex hormones:
(A) Prescriptions must identify the drugs being prescribed are for the treatment of gender nonconformity or gender dysphoria;
(B) Prescriptions must identify the patient's parent or legal guardian or if the patient is an emancipated minor;
(C) Prescribed medications picked up from a pharmacy are required to be picked up by the patient's parent, legal guardian, or the patient if the patient is an emancipated minor;
(D) Injectable prescribed medications must be administered either in the prescribing practitioner's office or in the office of the patient's primary care provider, by staff who are properly credentialed to administer drugs by injection;
(E) The prescribing practitioner must document no adverse effects on the patient's mental health during the course of treatment and that continued treatment is still medically appropriate as required by the chapter; and
(F) The prescribing practitioner must document the ongoing contact hours of therapeutic treatment as required by this chapter.

014. PHARMACIST REQUIREMENTS. A pharmacist dispensing cross-sex hormones, as defined in the Let Them Grow Act, to a patient under the age of 19 shall comply with the following restrictions:
(A) Prescribed medications picked up from a pharmacy are required to be picked up by the patient's parent, legal guardian, or the patient if the patient is an emancipated minor;
(B) Unless the individual taking receipt of the dispensed medications is personally and positively known to the pharmacist and or dispensing practitioner, the individual shall display a valid driver's or operator's license, a state identification card, or military identification card, an alien registration card, or a passport as proof of identification; and
(C) Prescription drugs that are otherwise lawful to be sent by home delivery, must be delivered to the address of patient's parent or legal guardian, or the patient's address if the patient is an emancipated minor.

014.01 EXEMPTIONS. The additional requirements of this subsection shall not apply if the pharmacist documents that the patient began receiving the prescribed medication prior to October 1, 2023, that the medication is not being prescribed for the treatment of gender nonconformity or gender dysphoria, or that the patient has reached the age of 19. A pharmacist is not required to determine that the prescribing practitioner has complied with the additional requirements of this chapter prior to dispensing prescribed medications, as defined in this chapter, to a patient under the age of 19.

014.02 PHARMACIST AUTHORITY. This chapter does not otherwise limit or expand the scope of practice of a pharmacist. Prescriptions must continue to meet all other state and

federal statutes, rules, and regulations.

015. CROSS-SEX HORMONES WAITING PERIOD. A minimum waiting period of seven calendar days is required between the time the prescribing practitioner obtains informed patient consent and the time the cross-sex hormones are prescribed, administered, or delivered to a patient who has not reached the age of majority.

016. EXEMPTIONS. This chapter does not apply to the use of approved treatments for precocious puberty, or for treatments exempted in the Let Them Grow Act. A patient who has not reached the age of majority who began using puberty blocking drugs prior to October 1, 2023, but did not begin using cross-sex hormones prior to October 1, 2023, must comply with the requirements of this chapter prior to receiving cross-sex hormones.

017. COMPLIANCE. A prescriber who complies with this chapter satisfies the requirements of Neb. Rev. Stat. § 71-7304(4).