NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES

Jim Pillen, Governor

October 1, 2023

Governor Jim Pillen
PO Box 94848
Lincoln, NE 68509-4848

RE: Title 181 NAC 8

Dear Governor Pillen:

Pursuant to Nebraska Revised Statute (Neb. Rev. Stat.) § 84-901.04, the Chief Medical Officer is requesting the adoption of emergency regulations to implement the requirements pertaining to the treatment of gender nonconformity or gender dysphoria for individuals under the age of 19 as required by the Let Them Grow Act, Neb. Rev. Stat. §§ 71-7301 to 71-7307. Without these regulations, a healthcare practitioner cannot provide gender altering procedures to individuals under the age of 19 for the treatment of gender nonconformity or gender dysphoria. The inability for healthcare practitioners to provide gender altering procedures for the treatment of gender nonconformity or gender dysphoria to individuals under the age of 19 is sufficient justification for emergency regulations as outlined in Neb. Rev. Stat. § 84-907.04(1)(a) relating to health, safety, or welfare of Nebraska residents. Implementing emergency regulations will allow otherwise eligible individuals under the age of 19 to receive these procedures or begin the process to become eligible for the treatment of gender nonconformity or gender dysphoria.

Due to the time-limited authority of emergency regulations, the Chief Medical Officer will also be initiating the formal rulemaking process for these regulations.

Sincerely,

Timothy A Tesmer

Dr. Timothy Tesmer
Chief Medical Officer
Division of Public Health
Department of Health and Human Services

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Approved by the Governor

Date 10/1/23

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 181	Prepared by: Ryan Daly
Chapter: 8	Date prepared: 9/25/2023
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.

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.

EFFECTIVE

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

181 NAC 8

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 8 NONSURGICAL PHARMACEUTICAL GENDER ALTERING TREATMENTS

001. SCOPE AND AUTHORITY. These regulations govern 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:

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(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 be clinically neutral and not in a gender affirming or conversion context; 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) 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;

(C) Injectable prescribed medications must be administered in the prescribing practitioner's office by staff who are properly credentialed to administer drugs by injection;

(D) 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

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

009. 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.

010. USE OF CROSS-SEX HORMONES. Prior to prescribing, dispensing, or administering cross-sex hormones for the treatment of gender nonconformity or gender dysphoria, 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.

011. 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.

012. 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) 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; and
(C) Injectable prescribed medications must be administered in the prescriber's office by staff who are properly credentialed to administer drugs by injection;
(D) 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
(E) The prescribing practitioner must document the ongoing contact hours of therapeutic treatment as required by this chapter.

013. 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.

014. 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.

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

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PROPOSED REGULATION QUESTIONNAIRE

Title 181 NAC 8

1) Is the regulation essential to the health, safety, or welfare of Nebraskans? Yes. These minimum standards are necessary to ensure the health, safety, and welfare of Nebraskans using nonsurgical pharmaceutical gender altering treatments under the Let Them Grow Act. They provide minimum protection standards to ensure patient safety for individuals younger than 19 years of age.

2) Do the costs of the regulation outweigh the benefits? Provide specific data and reasoning. No. These minimum standards are necessary to ensure the health, safety, and welfare of Nebraskans younger than 19 years of age receiving nonsurgical pharmaceutical gender altering treatments. Without these standards, there is no opportunity for Nebraskans younger than 19 years of age to receive nonsurgical gender altering care for the treatment of gender nonconformity or gender dysphoria.

3) Does a process exist to measure the effectiveness of the regulation? If so, explain. Regulations are reviewed regularly by the Department and Chief Medical Officer to ensure they continue to protect the health, safety, and welfare of Nebraskans served by licensed prescribing practitioners. The public has a grievance and complaint process for credentialed healthcare practitioners.

4) Has a less restrictive alternative been considered? Yes. These regulations are required by Neb. Rev. Stat. § 71-7305. They establish minimum standards for care, treatment, and services provided by health care practitioners to individuals under the age of 19 and their parents seeking nonsurgical pharmaceutical gender altering treatment. The regulations were drafted to minimize restrictions while ensuring public safety and meeting statutory requirements.

5) Was the regulation solely promulgated due a state statutory requirement? If so, provide citations. Yes. The regulations are required by the Let Them Grow Act, Neb. Rev. Stat. §§ 71-7301 to 71-7307. However, even if the statute were changed to be permissive, the Chief Medical Officer and the Department would still need regulations to require and enforce provisions relating to initial and ongoing therapeutic contact hours, medical record documentation, required waiting period, and prescription, administration, delivery, sale, or use of puberty blocking or cross-sex hormones.

6) Was the regulation promulgated as the result of a federal mandate? No.

PROPOSED REGULATION
POLICY PRE-REVIEW CHECKLIST

Agency: DHHS – Division of Public Health
Title, Chapter of Regulation: Title 181, Chapter 8
Subject: Nonsurgical Pharmaceutical Gender Altering Treatments
Prepared by: Lindsy Braddock
Telephone: 402-471-9193

A. Policy Changes and Impacts

1. What does the regulation do and whom does it impact? Provide a brief description of the proposed rule or regulation and its impacts on state agencies, political subdivisions, and regulated persons or entities.

   181 NAC 8 provides minimum standards necessary to ensure the health, safety, and welfare of Nebraskans younger than 19 years of age for nonsurgical pharmaceutical gender altering procedures under the Let Them Grow Act (Neb. Rev. Stat. § 71-7301 – 71-7307). The regulations provide standards to ensure patient safety for those who have not reached the age of 19 and provide specific requirements for prescribing practitioners.

   181 NAC 8 includes provisions relating to: patient medical record documentation requirements, minimum therapeutic contact hours required before the administration, minimum ongoing therapeutic contact hours required, delivery, sale, or use of puberty blocking drugs, cross-sex hormones, or both, discussion of the side effects of prescribed medications, informed consent requirements, the minimum waiting period between the time of obtaining informed consent and administering, prescribing, or delivering prescribed medications.

   Practitioners providing care relating to nonsurgical gender altering procedures will be impacted. The regulations provide for specific continuing education requirements and additional documentation requirements to administer nonsurgical pharmaceutical gender altering procedures for Nebraskans under the age of 19. Individuals under the age of 19 will have additional minimum requirements prior to receiving nonsurgical gender altering procedures.

   No other state agency or political subdivisions are impacted by these regulations.

2. Describe changes being proposed to current policy and briefly provide rationale.

181 NAC 8 are new regulations in their entirety and required under Neb. Rev. Stat. § 71-7305. The regulations define terms; provide requirements for the prescribing, dispensing, or administering of puberty blocking drugs and use of cross-sex hormones; establish initial and ongoing therapeutic contact hour requirements, therapist attestation requirements, informed consent requirements, waiting period requirements, and details requirements related to the administration, prescription, delivery, sale, or use of puberty blocking drugs or cross-sex hormones.

B. <u>Why is the rule necessary? Explain and provide an identification of authorizing statute(s) or legislative bill(s).</u>

The regulations are required under Neb. Rev. Stat. § 71-7305 to provide minimum standards necessary to ensure the health, safety, and welfare of Nebraskans under the age of 19 using nonsurgical pharmaceutical gender altering procedures. The regulations provide standards to ensure patient safety for those who have not reached the age 19 and provide specific requirements for prescribing practitioners.

1. Update of regulation (repeal of obsolete statutes, reflect current policy, editing or technical language changes, etc.)

   A new chapter of regulations is required under Neb. Rev. Stat. § 71-7305.

2. Annual changes – cost of living, hunting season schedules, etc.

   None.

3. Law was changed – federal ___ or state _X_ [Cite authorizing statute(s) or legislative bill(s)]

   LB 574 (2023); Neb. Rev. Stat. §71-7305.

4. Extension of established policy or program, new initiatives, or changes in policy (within statutory authority) Yes.

5. Constituent initiated No.

6. Financial needs – increases/decreases in fees No.

7. Litigation requires changes in rules No.

8. Addresses legal or constitutional concerns of Attorney General's office No.

9. Implements federal or court mandate No.

10. Other (explain)

C. <u>What happens if these rules are not adopted?</u>

If regulations are not promulgated DHHS is out of compliance with Neb. Rev. Stat. § 71-7305. Without the adoption of the rules, Nebraskans under the age of 19 would be unable to receive nonsurgical pharmaceutical gender altering care for the treatment of gender nonconformity or gender dysphoria.

D. <u>Policy Checklist</u>

1. Is this an update or editorial change reflecting essentially no change in policy? This new chapter of regulations is required by Neb. Rev. Stat. § 71-7305.

2. Does the policy in the proposed regulation reflect legislative intent?

   Yes.

3. Is the policy proposed in the regulation a state mandate on local government? N/A. Is it funded? N/A.

4. Is the policy proposed in the regulation a federal mandate on local government? N/A. Is it funded? N/A.

E. <u>Fiscal Impact. In addition to completing the required Fiscal Impact Statement (a copy must be attached to this document), the agency must address the following:</u>

1. Will the proposed regulation reduce, increase, or have no change in resources – funds, personnel, or FTE? No change in fees or resources.

2. Have initial contacts been made with citizens or organizations that may be impacted by the proposed regulation?

   No.

3. Does the proposed regulation impact another agency? Explain the impact.

   No, the regulations do not impact another agency.

4. Will the proposed regulation reduce, increase, or have no change on reporting requirements of businesses?

No change in reporting requirements to the Department. As required by Neb. Rev. Stat. § 71-7305, the regulations establish patient medical record documentation requirements.

5. What is the agency's best estimate of the additional or reduced spending? If there is none, please note. If receipt of federal funds is contingent upon approval of the proposed regulation, then indicate the amount and nature of the federal funds affected and enclose laws or correspondence from federal officials substantiating the information.

   No change in spending.

6. Include a description of the impact that the proposed regulation will have on the number of state employees and how the agency intends to address proposed increases or decreases in FTE.

   No impact.

F. Unique problems or issues and recommendations.

There are no unique problems or issues and recommendations.

G. Who is expected to be affected, or to oppose or support the proposed regulation? Explain what initial informal contacts have been made with organizations or citizens who may be affected by the regulation prior to the public hearing.

Healthcare practitioners providing nonsurgical gender altering procedures to minors and individuals under 19 years of age seeking gender altering procedures are impacted by these regulations. Many individuals, associations, and agencies have voiced opposition.

The Chief Medical Officer, Nebraska Department of Health and Human Services will solicit public comment on the proposed regulations at the public hearing.

H. Are these proposed rules a likely candidate for negotiated rulemaking? Explain. Has the process been completed? If so, explain how the issues were addressed.

No.

DHHS Division Director's Verification of Review

I have reviewed these proposals and verify that, at this stage of the regulation's development, these questions have been accurately addressed.

Timothy A. Tesmer, M.D.
Chief Medical Officer
Division of Public Health
Department of Health and Human Services

OCT 1, 2023
Date