Medicolegal Update in Late 2024: Guidelines, Regulations and Their Impact

Gender Care in the Heartland 2024

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Objectives

- Review the details of the regulations for care of gender expansive patients under the age of 19 in Nebraska
- Review the impact of legislation targeting medical professionals in the area of reproductive health on the healthcare workforce
- Review published data on how laws restricting or prohibiting gender care impact the access to care and the mental health of gender expansive people
- Review selected points and statements from the testimony and passage of NE LB574 as a testament to the cruelty and ignorance that suffused this process

Disclosures

- Leslie Dvorak: I own Pride Health Clinic. I am also a Human Rights Campaign and Trevor Project donor.
- Trainer, Organon

 Alex Dworak: I have no relevant financial disclosures that provide me any benefits. I am a Human Rights Campaign and Trevor Project donor, and a member of the Board of Nebraska AIDS Project.

WPATH SOC 8

Health Care Providers and Mental Health Providers:

- -Address any mental health symptoms that may interfere with a person's ability to give informed consent.
- -Offer care and support for mental health symptoms that may interfere with the person's ability to participate in their perioperative care.
- -If any Mental Health or Substance Abuse exists, assess the impact it may have on the surgical outcome.
- -Help the individual with smoking cessation prior to surgery.
- -Assess the need for psychosocial as well as practical support in the perioperative period.
- -Maintain existing HRT if patient is hospitalized on an inpatient unit for psychiatric or medical reason, unless contraindicated.
- -Ensure staff use correct name and pronouns as well as ensuring they have bathrooms and sleeping arrangements that align with their gender identity.
- -Encourage and support patient in developing and maintaining social support systems.
- -Not making psychotherapy mandatory prior to gender affirming treatment, while acknowledging it may be helpful for some.
- -No conversion therapy.

WPATH SOC 8 - Adults

- -Health care providers assessing patients for gender affirming care should work with providers from different disciplines in trans health and refer as needed.
- -IF a letter is REQUIRED for gender affirming care or surgical treatment only 1 letter from a HEALTH CARE professional who has competencies in the assessment of trans gender persons.

Criteria for hormones:

Gender incongruence

Meets diagnostic criteria for GI where DX is necessary to access care

Pt is able to give informed consent

Other possible causes ruled out

Mental and Physical conditions that could negatively impact the outcome has been assessed, risks and benefits discussed

Patients understands possible impact on reproduction and options have been given

Surgical..

Same as for hormones except

Understands impact surgery has on reproduction.

Stable on Gender affirming hormone treatment (6 mos or longer) if hormones will impact desired surgical outcome, unless if HRT not desired or is medically contraindicated it doesn't

Adult Gender Affirming Care in NE

Patient is over 19 years of age

Able to give informed consent

Understands reproductive impact and are given fertility preservation options

Not contraindications to Hormones

Surgery: Often driven by insurance

Non-reproductive surgery: 1 letter from a Mental Health Provider

Reproductive surgery 2 letters from Mental Health Providers

The regulations

https://dhhs.ne.gov/Pages/CMO-Communications.aspx

https://rules.nebraska.gov/rules?agencyld=37&titleId=110

The Regulations: Definitions

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 (emphasis added--this excludes all other uses of these same medications)*.

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;

- 003. PUBERTY BLOCKING DRUGS. Prior to prescribing...
- (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;

- 003. PUBERTY BLOCKING DRUGS. Prior to prescribing...
- (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.

O05. 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

006.01 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-identityfocused contact hours (45-60 mins) 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.

Side Note: About sexual side effects

- THE EFFECT OF PUBERTY SUPPRESSION ON SEXUAL FUNCTIONING IN TRANSWOMEN AFTER GENDER AFFIRMATIVE SURGERY
- van der Meulen Isabelle, PhD/MD student, van der Miesen Anna, PhD/MD, Hannema Sabine, PhD/MD, de Vries Annelou, PhD/MD Amsterdam UMC, The Center of Expertise on Gender Dysphoria, Amsterdam, Netherlands
- Conclusions: Both transwomen treated with early and late puberty suppression are equally able to experience an orgasm after vaginoplasty. Likewise, it is not necessary to experience desire, arousal or orgasms presurgery to be able to experience these postsurgery. The majority of transwomen sometimes experience some difficulties in their sex life, but this is not dependent on the puberty stage they started blockers in.
- https://academic.oup.com/jsm/article/20/Supplement 4/qdad062.090/72 20244 Published: 06 July 2023

- 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.

- 010. 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.
- "Services are not as widely available in rural areas, which can impact access to quality care. You don't have specialists around every corner or 15 pharmacies you can choose from," said Carritt. "There may be one primary care physician who serves an entire county."
- Ongoing shortages in the health care workforce exist across rural Nebraska. Fourteen of the state's 93
 counties do not have a primary care physician. Shortages affect every health care profession, and clinics and
 hospitals confirm challenges in hiring staff to provide care to the residents of this state. These shortages
 limit the health care that rural Nebraskans can access, and they impact the ability of communities to attract
 new residents and businesses.

- 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 (CECH) 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 crosssex 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).



A Tribute

We lost Dr. Meghan Sheehan in September to a tragic and unexpected aneurysm. She donated her organs, continuing to make life better for others. She was instrumental in personally talking with legislators and made the difference in 2023 not being severely worse for reproductive health and the trans community than it already was. A committed psychiatrist with a special focus on reproductive health, I ask you to lift up her story and be inspired by her memory. If you choose, a donation to a charity supporting women's or trans rights would be a fitting tribute to her work and legacy.



Thank you!

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https://apod.nasa .gov/apod/ap230 515.html

