STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   The proposed rule clearly defines and codifies the amount, duration, and scope of covered gender transition-related services available to Colorado Medicaid clients. Colorado Medicaid currently covers medically necessary counseling, hormone therapy, and surgery to eligible clients. The proposed rule does not add coverage of any new services.

2. An emergency rule-making is imperatively necessary

   [ ] to comply with state or federal law or federal regulation and/or
   [ ] for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

   92 CFR Part 92

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Colorado Medicaid clients and providers will both benefit from having the amount, duration, and scope of covered transgender-related services clearly defined and codified in the proposed rule.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

The proposed rule will have a positive impact on Colorado Medicaid clients' and providers' understanding of which services are covered, the eligibility criteria one must meet to provide or receive the covered services, as well as other requirements like documentation, potential limitations, etc.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The proposed rule does not increase the amount, duration, or scope of any covered service, nor does it add any new service to those currently covered by Colorado Medicaid.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

The probable cost of inaction is the continued confusion by Colorado Medicaid clients and providers as to the eligibility requirements and extent of coverage for transgender-related services. The benefit to the proposed rule is that it clearly defines, and makes enforceable, the Department's transgender related services coverage policy.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are not less costly or less intrusive methods for achieving the purpose of the proposed rule, which is clarifying and codifying the amount, duration, and scope of covered transgender related services.
6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule, which is clarifying and codifying the amount, duration, and scope of covered transgender related services.
8.735 TRANSGENDER SERVICES

8.735.1 Definitions

Cross Sex-Hormone Therapy means a course of hormone replacement therapy intended to induce or change secondary sex characteristics.

Gender Confirmation Surgery means a surgery to change primary or secondary sex characteristics to affirm a person's gender identity. Also known as gender affirmation surgery or sex reassignment surgery.

Gender Dysphoria means either: gender dysphoria, as defined in the Diagnostic Statistical Manual of Mental Disorders, 5th Edition (DSM-5), codes 302.85 or 302.6; or gender identity disorder, as defined in the International Classification of Disease, 10th Edition (ICD-10), codes F64.1-9, or Z87.890.

Gonadotropin-Releasing Hormone Therapy means a course of reversible pubertal or gonadal suppression therapy used to block the development of secondary sex characteristics in adolescents.

8.735.2 Client Eligibility

8.735.2.A. Clients with a clinical diagnosis of gender dysphoria are eligible for the transgender services benefit, subject to the service-specific criteria and restrictions detailed in section 8.735.5.

8.735.4 Provider Eligibility

8.735.4.A. Enrolled providers are eligible to provide transgender services if:

1. Licensed by the Colorado Department of Regulatory Agencies or the licensing agency of the state in which the provider practices;

2. Services are within the scope of the provider’s practice; and


8.735.5 Covered Services

8.735.5.A. The following requirements apply to all covered transgender services:

1. Client has a clinical diagnosis of gender dysphoria;

2. Requested service is medically necessary, as defined in section 8.076.1.8.;

3. Any contraindicated medical and behavioral health conditions have been addressed and are well-controlled;
4. Client has given informed consent for the service; and

5. Subject to the exceptions in C.R.S. §13-22-103, if client is under 18 years of age, client’s parent(s) or legal guardian has given informed consent for the service.

8.735.5.B. Requests for services for clients under 21 years of age are evaluated in accordance with the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program criteria detailed in section 8.280.

8.735.5.C. Behavioral health services are covered in accordance with section 8.212.

8.735.5.D. Hormone Therapy

1. Covered hormone therapy services are limited to the following:

a. Gonadotropin-Releasing Hormone (GnRH) Therapy

i) GnRH therapy is a covered service for a client who:

1) Meets the criteria at section 8.735.5.A.;

2) Meets the applicable pharmacy criteria at section 8.800; and

3) Has been referred to a licensed behavioral health provider and has a plan in place to receive behavioral health counseling concurrent with GnRH therapy.

b. Cross-Sex Hormone Therapy

i) Cross-sex hormone therapy is a covered service for a client who:

1) Meets the criteria at section 8.735.5.A.; and

2) Meets the applicable pharmacy criteria at section 8.800.

ii) Other cross-sex hormone therapy requirements

1) Prior to beginning cross-sex hormone therapy, a licensed behavioral health provider, with whom the client has an established and ongoing relationship, must determine that any behavioral health conditions or concerns have been addressed and are well-controlled.

2) For the first twelve (12) months of cross-sex hormone therapy:

a) Client must receive ongoing behavioral health counseling at a frequency determined to be
clinically appropriate by the behavioral health provider; and

b) Client must receive medical assessments at a frequency determined to be clinically appropriate by the prescribing provider.

8.735.5.E. Surgical Procedures

1. A surgical procedure listed in section 8.735.5.E.3.–5. is a covered service for a client who:
   a. Meets the criteria section 8.735.5.A.1.–4.;
   b. Is 18 years of age or older;
   c. Has lived in the preferred gender role for twelve (12) continuous months;
   d. Has completed twelve (12) continuous months of hormone therapy, unless medically contraindicated;
   e. Has been evaluated by a licensed medical provider within the past sixty (60) days; and
   f. Has been evaluated by a licensed behavioral health provider within the past sixty (60) days.

2. Rendering surgical providers must retain the following documentation for each client:
   a. A signed statement from a licensed behavioral health provider, with whom the client has an established and ongoing relationship, demonstrating that:
      i) Criteria in section 8.735.5.E.1.a.–d. and f. have been met; and
      ii) A post-operative care plan is in place.
   b. A signed statement from a licensed medical provider, with whom the client has an established and ongoing relationship, demonstrating that:
      i) Criteria in section 8.735.5.E.1.a.–e. have been met; and
      ii) A post-operative care plan is in place.

3. Covered genital surgeries are limited to the following:
   a. Ovariectomy/oophorectomy
b. Salpingo-oophorectomy

c. Hysterectomy

d. Vaginectomy

e. Vulvectomy

f. Metoidioplasty

g. Phalloplasty

h. Erectile prosthesis

i. Scrotoplasty

j. Testicular prostheses

k. Urethroplasty

l. Orchiectomy

m. Penectomy

n. Prostatectomy

o. Clitoroplasty

p. Vaginoplasty

q. Vulvoplasty

r. Labiaplasty

s. Permanent hair removal to treat surgical tissue donor sites

4. Covered breast/chest surgeries are limited to the following:

a. Mastectomy

b. Mammoplasty is covered when:

i. Client has completed twenty-four (24) continuous months of hormone therapy that has proven ineffective for breast development, unless medically contraindicated.

5. Pre- and post-operative services are covered when:
a. Related to a covered surgical procedure listed in section 8.735.5.E.; and
b. Medically necessary, as defined in section 8.076.1.8.

8.735.6 Prior Authorization

8.735.6.A. Prior authorization requests for hormone therapy services listed in section 8.735.5.D. must be submitted in accordance with the requirements in section 8.800.7.

8.735.6.B. All prior authorization requests must provide documentation demonstrating that the applicable requirements in section 8.735.5 have been met.

8.735.7 Non-Covered Services

8.735.7.A. The following services are not covered under the transgender services benefit:

1. Any items or services excluded from coverage under section 8.011.1.
2. Reversal of surgical procedures listed in section 8.735.5.E.