

# Health Services Advisory Council

## Minutes—November 10, 2016

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3:00 – 5:00 p.m.

DHS Andersen Building, St. Paul

### Members Present

Mary Braddock (by phone), Don Brunquell, Rachel Garaghty, Andrea Hillerud, Chris Johnson, Larry Lee, Jim Miner, and Jeff Schiff (non-voting)

### Members Absent

Howard Fink, Meghan Curry O’Connell, Tim Sielaff, Michael Thorn

### DHS Staff

Ryan Contin, Sara Drake, Ellie Garrett, Dave Hoang, Justine Nelson, Diogo Reis, Sarah Rinn

### Guests

Phil Duran (OutFront Minnesota)

## I. Welcome, introductions, minutes and updates

Jeff Schiff chaired the meeting in Tim Sielaff’s absence. He welcomed everyone, and introductions were made around the room. Ellie Garrett reported that the Commissioner appointed Meghan Curry O’Connell, MD, MPH, to fill the seat left vacant by Tamiko Morgan. Dr. O’Connell is a family medicine physician working for the Fond du Lac Band of Lake Superior Chippewa.

Garrett read the following correction to the October meeting minutes as requested by Eli Coleman, who spoke at that meeting:

A member asked whether therapy was always required, and Coleman clarified that while it can be beneficial to some individuals ~~always recommended~~, WPATH Standards of Care guidance does not ~~always~~ require psychotherapy prior to hormonal treatment or surgical procedures. ~~it~~. He gave the example of someone who has been ~~was~~ living stably in their gender role without counseling and who decided to seek GCS. When evaluated, therapy could be recommended as a condition of hormonal or surgical treatment. Overall, ~~For such a patient who continues to experience gender dysphoria, surgery could be appropriate even though the patient’s condition is stable. Counseling would be highly recommended, but the surgery shouldn’t be conditioned on it~~ psychotherapy if the mental health

professional has sufficient information to diagnose gender dysphoria and conduct an informed consent process.

On motion made and seconded, the minutes were approved unanimously as amended.

Schiff introduced Justine Nelson to talk about a project to identify Medicaid enrollees with the greatest health disparities. As part of that work, she is compiling a list of non-genetic health conditions that tend to be strongly related to the social determinants of health. She asked members to review the draft list and contact her with any suggestions by November 18. A member suggested including teen pregnancy on the list. Members discussed briefly. Schiff suggested identifying conditions that are treatable as this criterion is consistent with the goals of the project.

## **II. Gender conforming surgery for gender dysphoria**

Garrett summarized the draft recommendations dated November 10, 2016, drawing members' attention to the version with tracked changes, attached as Appendix A. In response to a question, she clarified DHS had already decided that to cover chest reconstruction for transgender men.

### **A. Public comment**

Garrett drew members' attention to Dr. Eli Coleman's emailed comments dated November 10.

Phil Duran from OutFront Minnesota offered comments in person. Duran had no additional disclosures to make other from those provided at previous HSAC meetings. He acknowledged that OutFront Minnesota is a plaintiff in a lawsuit against DHS on the topic of coverage for gender conforming surgery. The lawsuit makes claims under the Minnesota Constitution. He stated that the recommendations are overall in good shape, and he appreciated the work that had gone into them. He stated that DHS should not list specific procedures in section IV (exclusions) of the document, because the list will be out of date as the science changes and present legal issues for enrollees. If the list remains, then he suggested that it be prefaced with language like "unless otherwise recognized as the prevailing standard of practice," which would create some flexibility in the lists to recognize that standards evolve.

Duran cautioned that the language in section II(A)(3) regarding the length of time in which patients should live in a gender role congruent with gender identity should only apply to some surgical procedures and not all, consistent with WPATH guidance. Duran stated II(A)(6) regarding behavioral health therapy should also be changed to be consistent with WPATH guidance

No other public comments were offered.

### **B. Discussion**

Schiff proposed working through the recommendation document in sequence, starting with section II(A). Members discussed the age limitation. One member favored stating a presumption about age, recognizing that in specific circumstances the age limit could be lowered if in the patient's best interest. Another member asked

whether the age limit should be lowered for female-to-male (FtM) chest reconstruction. A member observed that the age of adulthood at 18 is a societal definition that is also reflected in providers' credentials to practice pediatrics or adult medicine. Age influences a patient's legal autonomy to make a health care decision. A member observed that while some physical characteristics of adulthood may be present by age 16, there is still a lot of neurological development between 16 and 18. She preferred an age 18 limitation to give the adolescent patient time to mature and develop. Another member stated that a bright line criterion leads to consistent and fair application of policy. Exceptions can be sought via the formal appeals process in which proof is required. All patients are informed of their right to appeal.

**A motion was made and second that age for chest surgery be 18, recognizing that there are appeal mechanisms for individual exceptions.** Discussion continued regarding the appeals process. **The motion carried with six in favor and one opposed.**

Schiff asked for consideration of section II(A)(3), length of time living in role congruent with identity. **A motion was made and seconded to accept the language of that section, as revised: "Length of time prior to surgery in which patients should live in a gender role that is congruent with their gender identity: 12 continuous months." The motion carried unanimously.**

Schiff asked for consideration of II(A)(4)(a) and (b) regarding behavioral health care. The term "behavioral health specialist" is defined in statute and might be too narrow for our purposes here. **Garrett mentioned Coleman's suggested language about "sufficient experience and training in diagnosing psychopathology and conducting psychosocial assessments." A motion was made and seconded to accept Coleman's language. The motion carried unanimously.**

With regard to section II(A)(4)(c), **a motion was made and seconded to accept the proposed tracked change: "A referral letter should include the clinician's attestation about expertise and training in transgender health, affirmation of gender dysphoria diagnosis, duration of treating relationship with patient, and attestation that GCS is in the patient's best interest." The motion carried unanimously.**

Garrett stated that section II(A)(5) regarding continuous months of hormone therapy was consistent with the Endocrine Society's clinical practice guideline. Since that section raises the question of coverage for breast augmentation, Schiff asked the members to skip ahead to that issue in section II(B). He asked members to decide whether to recommend covering breast augmentation to treat gender dysphoria in trans women. Discussion ensued. Members acknowledged the difficulty of defining "normal" breast development in response to hormone therapy. A member observed that the need for enhancement can be understood only in the context of treating a particular patient's dysphoria. **A motion was made and seconded to recommend coverage for MtF breast augmentation in cases of 24 months of failed hormone therapy and significant gender dysphoria related to the failure of hormone treatment. The motion carried unanimously.**

A member asked staff to add a bibliography of references to the final document.

With regard to section II(A)(6), Garrett reminded members of Coleman's comment that there is no evidence that 12 months of continuous behavioral therapy is always necessary. Members discussed what it means to have behavioral health therapy for a certain period, and whether it really means compliance with therapy as

recommended. **A motion was made to eliminate recommendation II(A)(6)(a) and instead require the treating clinician to attest that the patient is adherent to recommended medical and behavioral health treatment plans. The motion was seconded and carried unanimously.**

The remaining portion of section II(A)(6) pertains to stable remission of any comorbid health conditions. Discussion ensued. A member suggested adding day treatment to the list of care that would signal an unstable condition. **A motion was made and seconded approve the language of this section, with the addition of day treatment. The motion carried unanimously.**

Discussion turned to section II(C) regarding female to male (FtM) gender conforming surgeries. A member suggested that HSAC think about this issue in the same way as they considered MtF breast augmentation. It should be covered when needed as treatment for gender dysphoria. **A motion was made and seconded to recommend coverage of scrotoplasty, testicular expanders and testicular prostheses. The motion carried unanimously.**

The meeting was adjourned.

A copy of the final recommendations reflecting the members' discussions and votes during the November 10 meeting is attached as Appendix B.

# **Appendix A:**

## **Gender Conforming Surgery for People with Gender Dysphoria:**

### **DRAFT Recommendations from DHS Health Services Advisory Council**

- I. **Context:** Minnesota law prohibits coverage for gender confirming surgery within Minnesota Health Care Programs. A recent federal regulatory change disallows categorical exclusion of treatments for conditions such as gender dysphoria, effective January 1, 2017. This federal change prompted DHS to develop new coverage policy for surgical procedures intended to treat gender dysphoria. (DHS already covers non-surgical therapies (e.g., hormone therapies for adults and behavioral health therapies without age restrictions) for people with gender dysphoria.)
  
- II. **HSAC's recommendations:**
  - A. Medical necessity criteria (e.g., patient readiness considerations and appropriate referrals) for coverage of gender confirming surgery. Domains and parameters include:
    1. Particular spacing or sequencing of surgical therapies should be individualized for each patient.
    2. Age
      - a. 18 years of age or over for genital surgery
      - b. Consider mid-adolescence for chest surgery (DHS has no specific recommendation and requests HSAC's input on age for chest surgery)
    3. Length of time prior to surgery in which patients should live in a gender role that is congruent with their gender identity
      - a. 12 continuous months
    4. Referrals (number of referrals for which procedures and by whom)
      - a. For genital surgery: 2 independent clinicians with expertise in transgender health, at least one of whom is a behavioral health specialist or a medical provider with certification in an appropriate behavioral health field who have an established and ongoing relationship with the patient
      - b. For chest surgery: 1 clinician who is a behavioral health specialist or a medical provider with certification in an appropriate behavioral health field with expertise in transgender health and who has an established and ongoing relationship with the patient
      - c. A referral letter should include the clinician's attestation about expertise and training in transgender health, affirmation of gender dysphoria diagnosis, duration of treating relationship with patient, and attestation that GCS is in the patient's best interest.
    5. Hormone therapies recommended prior to surgery
      - a. 12 continuous months of hormone therapy for genital surgery unless contraindicated

- b. If breast augmentation is covered, 24 continuous months of hormone therapy (unless contraindicated) without response.
  - 6. Behavioral health therapy
    - a. Behavioral health therapy for gender dysphoria and related behavioral health conditions confirming the patient's gender stability in the identified gender status for 12 continuous months
    - b. Treatment to recovery or stable remission of any co-morbid behavioral health conditions that are not attributed to dysphoria (e.g., psychosis, trauma, substance use disorder) for 12 continuous months. Stable remission is defined as lack of hospitalization, urgent or emergent care for any co-morbid behavioral health conditions during the 12-month period before surgery.
- B. If HSAC recommends: Breast augmentation surgery coverage for male-to-female gender conforming surgery when unresponsive to hormone therapy. (Some insurers cover breast augmentation as part of surgical treatments for gender dysphoria; most categorize it as cosmetic and do not cover. DHS does not have a specific recommendation). If covered, must meet all relevant criteria in section II(A) above.
- C. If HSAC recommends: Scrotoplasty/testicular expanders/testicular prostheses for female-to-male gender conforming surgery. (Some insurers cover scrotoplasty/testicular expanders/testicular prostheses as part of surgical treatments for gender dysphoria; most categorize it as cosmetic and do not cover. DHS does not have a specific recommendation). If covered, must meet all relevant criteria in section II(A) above.

### III. **Cosmetic exclusions:** Background

- A. Public and private insurers routinely exclude coverage for cosmetic surgery, because it by definition is being performed for aesthetic not medical reasons—and thus isn't considered medically necessary. In contrast, plastic or reconstructive surgery is usually covered. The distinction between cosmetic and plastic surgery is well-recognized by specialists practicing in those fields.
  - 1. American Academy of Cosmetic Surgery definitions:
    - a. Cosmetic surgery is a unique discipline of medicine focused on enhancing appearance through surgical and medical techniques. Cosmetic surgery can be performed on all areas of the head, neck and body. Because treated areas function properly but lack aesthetic appeal, cosmetic surgery is elective.
    - b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
  - 2. American Board of Cosmetic Surgery
    - a. The procedures, techniques, and principles of cosmetic surgery are entirely focused on enhancing a patient's appearance. Improving aesthetic appeal, symmetry, and proportion are the key goals. Cosmetic surgery can be performed on all areas of the head, neck, and body. Because the treated areas function properly, cosmetic surgery is elective.

- b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
- 3. American Society of Plastic Surgeons
  - a. The plastic surgeon performs cosmetic surgery to reshape normal structures of the face or body in order to enhance the patient's appearance and self-esteem. Reconstructive surgery is performed to correct abnormalities of facial or body structures caused by congenital defects, developmental abnormalities, injuries, previous or concurrent surgeries, infection, tumors, or other disease. The purpose of reconstructive surgery is generally to improve function, but it may also be used to restore a normal appearance.
  - b. These distinctions have implications for insurance coverage. Nearly all insurance carriers cover reconstructive procedures for functional restoration but not those performed purely for cosmetic reasons. In general, the classification as cosmetic or reconstructive depends on the reason that the surgery is performed. For example, rhinoplasty to change the shape of the nose is considered cosmetic. However, rhinoplasty to restore the shape of the nose following traumatic deformity is reconstructive.

#### IV. DHS' Decisions already made consistent with federal regulatory changes and Medicaid policy

- A. **Covered procedures:** DHS will cover the following procedures as medically necessary for individuals meeting medical necessity criteria when the new policy takes effect:
  - 1. Female-to-male gender confirmation
    - a. Hysterectomy and salpingo-oophorectomy
    - b. Vaginectomy (including colpectomy, metoidioplasty, phalloplasty, urethroplasty, urethromeatoplasty)
    - c. Breast surgery (mastectomy; breast reduction; chest reconstruction)
    - d. Penile prosthesis (noninflatable/inflatable)
  - 2. Male-to-female gender confirmation:
    - a. Orchiectomy
    - b. Vaginoplasty (including colovaginoplasty, penectomy, labiaplasty, clitoroplasty, vulvoplasty, penile skin inversion, repair of introitus, construction of vagina with graft, coloproctostomy)

These decisions are consistent with the policies and practices of most other insurers that cover gender confirmation surgery,<sup>1</sup>

- B. **Excluded procedures:** DHS considers the following procedures as cosmetic and will exclude them from coverage (not an exhaustive list):
  - 1. Abdominoplasty
  - 2. Blepharoplasty
  - 3. Brow lift
  - 4. Calf implants
  - 5. Cheek/malar implants

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<sup>1</sup> Private and public coverage policies including those of Cigna, United, HealthPartners, PriorityHealth, Kaiser, Anthem, Molina Healthcare, Massachusetts Medicaid, New York Medicaid

6. Collagen injections
7. Electrolysis or laser hair removal unless other hair removal techniques on the site after surgery would be unsafe
8. Face/forehead lift
9. Facial bone reconstruction
10. Facial implants
11. Gluteal augmentation
12. Hair transplantation
13. Jaw reduction (jaw contouring)
14. Laryngoplasty
15. Lip reduction/enhancement
16. Lipofilling/collagen injections
17. Liposuction
18. Mastopexy
19. Neck tightening
20. Nose implants
21. Pectoral implants
22. Removal of redundant skin
23. Rhinoplasty
24. Skin resurfacing (dermabrasion, chemical peels)
25. Trachea shave/Thyroid cartilage reduction (chondroplasty)
26. Voice modification surgery
27. Voice therapy/voice lessons

These decisions by DHS are consistent with the policies and practices of other state Medicaid programs and most insurers that cover gender confirmation surgery listed above.



## Appendix B: Gender Confirming Surgery for People with Gender Dysphoria: Final Recommendations from DHS Health Services Advisory Council (reflecting changes made during November 10, 2016 meeting)

- I. **Context:** Minnesota law prohibits coverage for gender confirming surgery within Minnesota Health Care Programs. A recent federal regulatory change disallows categorical exclusion of treatments for conditions such as gender dysphoria, effective January 1, 2017. This federal change prompted DHS to develop new coverage policy for surgical procedures intended to treat gender dysphoria. (DHS already covers non-surgical therapies (e.g., hormone therapies for adults and behavioral health therapies without age restrictions) for people with gender dysphoria.)
  
- II. **HSAC's recommendations:**
  - A. Medical necessity criteria (e.g., patient readiness considerations and appropriate referrals) for coverage of gender confirming surgery (GCS)
    1. Particular spacing between or sequencing of surgical therapies should be individualized for each patient.
    2. Age: 18 years of age or older
    3. Length of time prior to surgery in which patients should live in a gender role that is congruent with their gender identity: at least 12 continuous months
    4. Referrals (number of referrals for which procedures and by whom)
      - a. For genital surgery: Two independent clinicians with expertise in transgender health, at least one of whom is a behavioral health specialist or a medical provider with sufficient experience and training in diagnosing psychopathology and conducting psychosocial assessments and who has an established and ongoing relationship with the patient
      - b. For chest surgery: One clinician with expertise in transgender health who is a behavioral health specialist or a medical provider with sufficient experience and training in diagnosing psychopathology and conducting psychosocial assessments and who has an established and ongoing relationship with the patient
      - c. A referral letter should include the clinician's attestation about each of the following;
        - i. Expertise and training in transgender health
        - ii. Duration of treating relationship with patient
        - iii. Affirmation of gender dysphoria diagnosis
        - iv. Patient's general identifying characteristics
        - v. Results of the patient's psychosocial assessment, including any other diagnoses
        - vi. Stability of any co-morbid psychiatric conditions (if applicable)
        - vii. Patient's adherence to recommended medical and behavioral health treatment plans

- viii. Informed consent has been obtained from the patient, and attestation that GCS is in the patient's best interest.
5. Hormone therapies recommended prior to surgery
  - a. 12 continuous months of hormone therapy for genital surgery unless contraindicated
  - b. For breast augmentation, 24 continuous months of hormone therapy (unless contraindicated) without response
6. Behavioral health therapy: Treatment to recovery or stable remission of any co-morbid behavioral health conditions that are not attributed to dysphoria (e.g., psychosis, trauma, substance use disorder) for 12 continuous months. Stable remission is defined as lack of hospitalization, day treatment or emergent care for any co-morbid behavioral health conditions during the 12-month period before surgery.
- B. In addition to the covered procedures described in section IV the following procedures should also be covered when medically necessary:
  1. Breast augmentation surgery for male-to-female GCS when the patient is unresponsive to at least 24 months of hormone therapy (unless contraindicated) and significant gender dysphoric symptoms remain after hormone treatment failure
  2. Scrotoplasty/testicular expanders/testicular prostheses for female-to-male GCS
  3. All relevant criteria in section II(A) above must also be met.

### III. **Cosmetic exclusions:** Background provided by DHS

- A. Public and private insurers routinely exclude coverage for cosmetic surgery, because it by definition is being performed for aesthetic not medical reasons and thus isn't considered medically necessary. In contrast, plastic or reconstructive surgery is usually covered. The distinction between cosmetic and plastic surgery is well-recognized by specialists practicing in those fields.
  1. American Academy of Cosmetic Surgery definitions:
    - a. Cosmetic surgery is a unique discipline of medicine focused on enhancing appearance through surgical and medical techniques. Cosmetic surgery can be performed on all areas of the head, neck and body. Because treated areas function properly but lack aesthetic appeal, cosmetic surgery is elective.
    - b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
  2. American Board of Cosmetic Surgery
    - a. The procedures, techniques and principles of cosmetic surgery are entirely focused on enhancing a patient's appearance. Improving aesthetic appeal, symmetry and proportion are the key goals. Cosmetic surgery can be performed on all areas of the head, neck and body. Because the treated areas function properly, cosmetic surgery is elective.
    - b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.

3. American Society of Plastic Surgeons
  - a. The plastic surgeon performs cosmetic surgery to reshape normal structures of the face or body in order to enhance the patient's appearance and self-esteem. Reconstructive surgery is performed to correct abnormalities of facial or body structures caused by congenital defects, developmental abnormalities, injuries, previous or concurrent surgeries, infection, tumors, or other disease. The purpose of reconstructive surgery is generally to improve function, but it may also be used to restore a normal appearance.
  - b. These distinctions have implications for insurance coverage. Nearly all insurance carriers cover reconstructive procedures for functional restoration but not those performed purely for cosmetic reasons. In general, the classification as cosmetic or reconstructive depends on the reason that the surgery is performed. For example, rhinoplasty to change the shape of the nose is considered cosmetic. However, rhinoplasty to restore the shape of the nose following traumatic deformity is reconstructive.

#### IV. DHS' decisions already made consistent with federal regulatory changes and Medicaid policy

A. **Covered procedures:** DHS will cover the following procedures for individuals meeting medical necessity criteria when the new policy takes effect:

1. Female-to-male GCS
  - a. Hysterectomy and salpingo-oophorectomy
  - b. Vaginectomy (including colpectomy, metoidioplasty, phalloplasty, urethroplasty, urethromeatoplasty)
  - c. Breast surgery (mastectomy; breast reduction; chest reconstruction)
  - d. Penile prosthesis (noninflatable/inflatable)
2. Male-to-female GCS:
  - a. Orchiectomy
  - b. Vaginoplasty (including colovaginoplasty, penectomy, labiaplasty, clitoroplasty, vulvoplasty, penile skin inversion, repair of introitus, construction of vagina with graft, coloproctostomy)

These decisions are consistent with the policies and practices of most other insurers that cover gender confirmation surgery.<sup>1</sup>

B. **Excluded procedures:** DHS considers the following procedures as cosmetic and will exclude them from coverage (not an exhaustive list):

1. Abdominoplasty
2. Blepharoplasty
3. Brow lift
4. Calf implants
5. Cheek/malar implants
6. Collagen injections
7. Electrolysis or laser hair removal unless other hair removal techniques on the site after surgery would be unsafe

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<sup>1</sup> Private and public coverage policies including those of Cigna, United, HealthPartners, PriorityHealth, Kaiser, Anthem, Molina Healthcare, Massachusetts Medicaid, New York Medicaid

8. Face/forehead lift
9. Facial bone reconstruction
10. Facial implants
11. Gluteal augmentation
12. Hair transplantation
13. Jaw reduction (jaw contouring)
14. Laryngoplasty
15. Lip reduction/enhancement
16. Lipofilling/collagen injections
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18. Mastopexy
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20. Nose implants
21. Pectoral implants
22. Removal of redundant skin
23. Rhinoplasty
24. Skin resurfacing (dermabrasion, chemical peels)
25. Trachea shave/Thyroid cartilage reduction (chondroplasty)
26. Voice modification surgery
27. Voice therapy/voice lessons

These decisions by DHS are consistent with the policies and practices of other state Medicaid programs and most insurers that cover gender confirmation surgery listed above.

## V. Bibliography

HSAC referred to the following resources during its deliberations leading to the recommendations contained in section II above.

- Aydin D, Buk LJ, Partoft S, et al. Transgender surgery in Denmark from 1994 to 2015: 20-year follow-up study. *J Sex Med.* 2016;13(4):720-5. doi: 10.1016/j.jsxm.2016.01.012
- Bockting W, Coleman E, Deutsch MB, et al. Adult development and quality of life of transgender and gender nonconforming people. *Curr Opin Endocrinol Diabetes Obes.* 2016;23(2):188-97. doi: 10.1097/MED.0000000000000232
- Colebunders B, De Cuypere G, Monstrey S. New criteria for sex reassignment surgery: WPATH standards of care, Version 7, Revisited. *Int J Transgender.* 2015;16(4):222-233. doi: 10.1080/15532739.2015.1081086
- Dhejne C, Lichtenstein P, Boman M, et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. *PLoS ONE.* 2011;6(2):e16885. doi:10.1371/journal.pone.0016885
- Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2009;94(9):3132-54. doi: 10.1210/jc.2009-0345

- Milrod, C, 2013. How young is too young: ethical concerns in genital surgery of the transgender MTF adolescent. *J Sex Med.* 2014 Feb;11(2):338-46. doi: 10.1111/jsm.12387
- Smith YL, Van Goozen SHM, Kuiper AJ, et al. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. *Psychol Med* 2004;35(1):89–99
- World Professional Association for Transgender Health (WPATH). *Standards of Care for the Health of Transsexual, Transgender and Gender Nonconforming People*, version 7. 2007. Accessed at [http://www.wpath.org/site\\_page.cfm?pk\\_association\\_webpage\\_menu=1351&pk\\_association\\_webpage=4655](http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=4655)



# Health Services Advisory Council

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Minutes — October 13, 2016  
3:00 – 5:00 p.m.  
DHS Andersen Building, St Paul

## Members Present

Mary Braddock (by phone), Don Brunnquell, Howard Fink, Andrea Hillerud, Chris Johnson, Larry Lee, Jim Miner, Jeff Schiff (non-voting), Michael Thorn

## Members Absent

Rachel Garaghty, Timothy Sielaff (chair)

## DHS Staff Present

Elizabeth Cooper, Sara Drake, Ellie Garrett, Dave Hoang, Cindy Marihart, Assistant Commissioner Nathan Moracco, Mary Beth Reinke, Diogo Reis, Sarah Rinn

## Others Present

Marc Arnold, (LivaNova) Diane Berg (University of Minnesota Medical School), Eli Coleman (University of Minnesota Medical School), Phil Duran (OutFront Minnesota), Eric Meininger (Gillette Children's Specialty HealthCare)

## I. Welcome, introductions, updates and minutes

Jeff Schiff welcomed everyone in attendance and chaired the meeting in Tim Sielaff's absence. Introductions were made around the room. Mary Braddock, a medical director from Medica, was welcomed as a new member. Larry Lee, who attended the previous meeting as a guest, was also welcomed as a new member. Lee is a medical director from UCare. Ellie Garrett also announced that Meghan O'Connell, a family physician with Fond du Lac Band of Lake Superior Chippewa had been appointed as a member.

Garrett reported one correction to the September minutes from Phil Doran who spoke at the September meeting:

- Phil Doran, legal director for OutFront Minnesota, offered comments. He disclosed that ~~he is representing transgender plaintiffs in a lawsuit against DHS at present.~~ OutFront Minnesota is currently a plaintiff in a lawsuit against DHS.

There were no other corrections. **On motion made and seconded, the members voted unanimously to approve the minutes as corrected.**

Schiff reported that DHS staff members were developing legislative proposals for the governor's consideration. More than one proposal concerns opioids.

## **II. Gender conforming surgery for gender dysphoria**

Schiff stated that the meeting's goals were to (1) continue discussion of gender conforming surgery for gender dysphoria and (2) introduce draft domains and parameters for medical necessity criteria for gender conforming surgery (GCS). Garrett recapped the September meeting and summarized the few prospective outcomes studies that were available in the GCS literature. A copy of her presentation is available upon request from [HSAC staff](#).

Schiff reiterated that the new federal rule is fundamentally about fairness and nondiscrimination. DHS will no longer categorically exclude medically necessary surgical procedures for gender dysphoria, but DHS also cannot cover cosmetic procedures for gender dysphoria that are excluded as cosmetic for other conditions.

A member stated that the lack of controlled studies and significant potential for selection bias limited the quality of the body of evidence supporting GCS. Garrett observed that the WPATH authors acknowledge in the guidelines that available studies suffer from small sample sizes and high risk of bias. There are many barriers to conducting research with patients whose gender identities have been culturally and even legally stigmatized throughout the world.

At DHS' invitation, Eli Coleman, Chair in Sexual Health at the University of Minnesota Medical School, presented on the World Professional Association for Transgender Health (WPATH) guidelines for GCS and to respond to questions that HSAC members had raised at its September meeting. He was accompanied by Diane Berg, also from the University's Sexual Health program, whose expertise included treating adolescents with gender dysphoria. A copy of his presentation is available upon request from [HSAC staff](#).

A member asked whether chest surgery could be reversed. Coleman stated that regrets are extraordinarily rare, so the issue is very unlikely to come up. For adolescents, he suggested that chest surgery could be done but reasons and therapeutic history must be well documented. He gave the example of a teenager who wished to have chest surgery before going to college.

A member also asked about breast augmentation for transgender women. Coleman stated that some transgender women do not respond to hormone therapy, and for some hormones are medically contraindicated. For such women, he stated that breast augmentation would be appropriate. He also clarified that for most people risks of hormones are not as significant as risks of invasive surgery, so he counsels his patients to try hormones unless there is a medical contraindication.

A member asked about facial surgeries, and Coleman stated that while it's not common, it can be critical for some patients. He recommends that facial feminization be considered if medically necessary. In response to a question about body dysmorphia, he stated that surgery is not a therapy for body dysmorphia; he works to distinguish gender dysmorphia from body dysmorphia in his clients. Part of a good assessment is recommending medically needed behavioral health therapy.

A member asked about pre-operative consultations, and Coleman stated that a minimum of two visits would be required. Berg clarified that there is usually a long waiting period between an introductory session and formal surgical consultation. Coleman stressed the importance of the evaluation process as

part of informed consent. He also clarified that both the mental health professional and the surgeon would conduct an informed consent process.

A member asked whether therapy was always required, and Coleman clarified that while it can be beneficial to some individuals, WPATH Standards of Care does not always require psychotherapy prior to hormonal treatment or surgical procedures. He gave the example of someone who has been living stably in their gender role without counseling and who decided to seek GCS. When evaluated, therapy could be recommended as a condition of hormonal or surgical treatment. Overall, the surgery shouldn't be conditioned on psychotherapy if the mental health professional has sufficient information to diagnose gender dysphoria and conduct an informed consent process.

Schiff introduced the draft domains and parameters for medical necessity, walking through the draft document attached as Exhibit A. Discussion ensued. A member questioned the use of the word "referral." He suggested requiring letters of recommendation or an attestation affirming a gender dysphoria diagnosis, informed choice of GCS, and that the patient meets other relevant criteria.

Members discussed recommendations II(A)(4) and (5) pertaining to pre-surgical recommended hormone and behavioral health therapies, respectively. One member questioned whether these therapeutic standards should be recommended or actually required (except when hormone therapy is contraindicated). Members also discussed the length of the behavioral health therapeutic relationship with a diagnosing and referring provider. They discussed the degree of stability and length of time patients should live in a gender role that is congruent with their gender identity. With regard to II(A)(5)(b), the behavioral health provider will need to have the expertise and be trusted to distinguish between co-morbid conditions such as depression that are or are not attributable to gender dysphoria in any particular patient.

## **Public Comment**

Eric Meininger, a physician with Gillette Children's Specialty Health Care and who consults to Family Tree Clinic, has worked with the transgender community for approximately 18 years. He had no conflicts of interest to disclose. He was alerted to HSAC's meeting by a colleague at Family Tree Clinic. He stated that he counsels patients about three different levels of medical intervention for gender dysphoria: fully reversible (hormone blockade); semi-reversible (cross-gender hormones); and non-reversible (surgery). Hormone therapy for children can begin once a child is able to understand consequences and the parent gives informed consent. Usually this is around age 16. Fertility is a key concern, and irreversible surgical interventions are usually inappropriate for children. He stated that an exception is chest reconstruction for transgender boys and men. Binding breasts can cause pulmonary and musculoskeletal problems, so referrals for chest reconstruction can occur before age 18. The surgical referral process, while time-consuming because of wait-times for the limited pool of surgeons with expertise, is fairly straightforward: The treating clinician identifies the needs, makes a referral, and the surgeon will meet separately with the patient to review surgical options. More consultation and time is required for genital surgery than for chest reconstruction.

Meininger asked that the phrase "period of time within which a patient should live in chosen gender prior to surgery," contained in II(A)(2) of Exhibit A be rewritten, because gender identity is not a matter of choice.

Meininger stressed that primary care physicians, including pediatricians, with expertise in diagnosing and treating gender dysphoria should be allowed to make surgical referrals. He stated that the pool of

behavioral health therapists with expertise in gender dysphoria is so small that requiring behavioral health referrals would be an undue burden and inhibit access to care.

Meininger stated that the notion of stable remission of co-morbid behavioral health conditions should be better defined. He suggested that stability be described in terms of length of time (six months) that a patient has not been hospitalized for the condition.

In response to a question from a member, Meininger stated that he had no other articles to recommend with regard to pediatric gender dysphoria patients.

Schiff closed the public comment section of the agenda after verifying that there were no others in the audience who wished to speak.

### **HSAC Members' Discussion**

Members discussed the definition of medical necessity in relation to surgical treatments for gender dysphoria and in particular the procedures described in II(B) and (C) (breast augmentation and scrotoplasty/testicular expanders/testicular prostheses, respectively). A member stated that if a patient required any of these procedures in order to treat gender dysphoric symptoms, then they should be provided. Not all patients will require or seek them, but for those who do, the procedures should be covered. Garrett stressed that no patient should be required to have any particular surgical intervention in order to access a different intervention; the nonbinary nature of gender identity dictates that GCS not be an all-or-nothing proposition, as it is or has been in some countries.

A member suggested that II(A)(6) regarding individualized spacing or sequencing of surgical therapies should be elevated in importance in the document.

Members discussed the difficulties in distinguishing gender dysphoric symptoms and symptoms of commonly co-occurring conditions such as anxiety or depression. A member stated that while distinctions are sometimes difficult, the DSM-5 criteria are relatively specific.

A member suggested specifying what a letter of support for surgery should contain, what sort of assessment the person should document. Another member volunteered to send as an example a copy of an attestation letter on another clinical topic to HSAC staff. He added that it is useful to require an attestation that in the clinician's judgment the requested intervention is in the patient's best interest. Schiff suggested that the clinician also attest to skill and experience with diagnosing and treating gender dysphoria.

Members discussed whether the 12-month recommendation for hormone therapy was based on expert opinion or scientific evidence. HSAC staff will look for source literature that supports WPATH's recommendation for the duration of hormone therapy.

A member also questioned why breast enhancement should be made available to transgender females when it is not made available to other women except after an injury or cancer-related mastectomy. Discussion ensued.

A member asked what qualifications referring clinicians should have, what qualifies them as experts. Discussion ensued.

Garrett asked members and guests to feel free to submit edits, questions and suggestions between HSAC's meetings.

The meeting adjourned at approximately 5:00.

## Exhibit A

### Gender Conforming Surgery for People with Gender Dysphoria: Scope and Domains for HSAC's Consideration

- I. **Context:** Minnesota law prohibits coverage for gender conforming surgery within Minnesota Health Care Programs. A recent federal regulatory change disallows categorical exclusion of treatments for conditions such as gender dysphoria, effective January 1. This federal change prompted DHS to develop new coverage policy for surgical procedures intended to treat gender dysphoria. (DHS already covers non-surgical therapies (e.g., hormone therapies for adults and behavioral health therapies without age restrictions) for people with gender dysphoria.)
  
- II. **HSAC's scope:** DHS recommended criteria for HSAC:
  - A. Medical necessity criteria (e.g., patient readiness considerations and appropriate referrals) for coverage of gender conforming surgery. DRAFT domains and parameters include:
    1. Age
      - a. 18 years of age or over for genital surgery
      - b. Consider mid-adolescence for chest surgery (DHS has no specific recommendation and requests HSAC's input on age for chest surgery)
    2. Period of time within which a patient should live in chosen gender prior to surgery
      - a. 12 continuous months
    3. Referrals (number of referrals for which procedures and by whom)
      - a. For genital surgery: 2 independent clinicians with expertise in transgender health, at least one of whom is a behavioral health specialist with an established and ongoing relationship with the patient
      - b. For chest surgery: 1 clinician who is a behavioral health specialist with expertise in transgender health and who has an established and ongoing relationship with the patient
    4. Hormone therapies recommended prior to surgery
      - a. 12 continuous months of hormone therapy for genital surgery unless contraindicated
      - b. If breast augmentation is covered, 24 continuous months of hormone therapy (unless contraindicated) without effective results
    5. Behavioral health therapy
      - a. Behavioral health therapy for gender dysphoria and related behavioral health conditions confirming the patient's gender stability in the identified gender status for 12 continuous months
      - b. Treatment to recovery or stable remission of any co-morbid behavioral health conditions that are not attributed to dysphoria (e.g., psychosis, trauma, substance use disorder) for 12 continuous months
    6. Particular spacing or sequencing of surgical therapies should be individualized for each patient.
  - B. If HSAC recommends: Breast augmentation surgery coverage for male-to-female gender conforming surgery when unresponsive to hormone therapy. (Some insurers cover breast

augmentation as part of surgical treatments for gender dysphoria; most categorize it as cosmetic and do not cover. DHS does not have a specific recommendation). If covered, must meet all relevant criteria in section II(A) above.

- C. If HSAC recommends: Scrotoplasty/testicular expanders/testicular prostheses for female-to-male gender conforming surgery. (Some insurers cover scrotoplasty/testicular expanders/testicular prostheses as part of surgical treatments for gender dysphoria; most categorize it as cosmetic and do not cover. DHS does not have a specific recommendation). If covered, must meet all relevant criteria in section II(A) above.

### III. **Cosmetic exclusions:** Background

- A. Public and private insurers routinely exclude coverage for cosmetic surgery, because it by definition is being performed for aesthetic not medical reasons—and thus isn't considered medically necessary. In contrast, plastic or reconstructive surgery is usually covered. The distinction between cosmetic and plastic surgery is well-recognized by specialists practicing in those fields.
  1. American Academy of Cosmetic Surgery definitions:
    - a. Cosmetic surgery is a unique discipline of medicine focused on enhancing appearance through surgical and medical techniques. Cosmetic surgery can be performed on all areas of the head, neck and body. Because treated areas function properly but lack aesthetic appeal, cosmetic surgery is elective.
    - b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
  2. American Board of Cosmetic Surgery
    - a. The procedures, techniques, and principles of cosmetic surgery are entirely focused on enhancing a patient's appearance. Improving aesthetic appeal, symmetry, and proportion are the key goals. Cosmetic surgery can be performed on all areas of the head, neck, and body. Because the treated areas function properly, cosmetic surgery is elective.
    - b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
  3. American Society of Plastic Surgeons
    - a. The plastic surgeon performs cosmetic surgery to reshape normal structures of the face or body in order to enhance the patient's appearance and self-esteem. Reconstructive surgery is performed to correct abnormalities of facial or body structures caused by congenital defects, developmental abnormalities, injuries, previous or concurrent surgeries, infection, tumors, or other disease. The purpose of reconstructive surgery is generally to improve function, but it may also be used to restore a normal appearance.
    - b. These distinctions have implications for insurance coverage. Nearly all insurance carriers cover reconstructive procedures for functional restoration but not those performed purely for cosmetic reasons. In general, the classification as cosmetic or reconstructive depends on the reason that the surgery is performed. For example, rhinoplasty to

change the shape of the nose is considered cosmetic. However, rhinoplasty to restore the shape of the nose following traumatic deformity is reconstructive.

#### IV. Decisions already made consistent with federal regulatory changes and Medicaid policy

A. **Covered procedures:** DHS intends to cover the following procedures as medically necessary for individuals meeting medical necessity criteria when the new policy takes effect:

1. Female-to-male gender confirmation
  - a. Hysterectomy and salpingo-oophorectomy
  - b. Vaginectomy (including colpectomy, metoidioplasty, phalloplasty, urethroplasty, urethromeatoplasty)
  - c. Breast surgery (mastectomy; breast reduction)
  - d. Penile prosthesis (noninflatable/inflatable)
2. Male-to-female gender confirmation:
  - a. Orchiectomy
  - b. Vaginoplasty (including colovaginoplasty, penectomy, labiaplasty, clitoroplasty, vulvoplasty, penile skin inversion, repair of introitus, construction of vagina with graft, coloproctostomy)

These decisions are consistent with the policies and practices of most other insurers that cover gender confirmation surgery,<sup>1</sup>

B. **Excluded procedures:** The following procedures will be considered cosmetic and excluded from coverage (not an exhaustive list):

1. Abdominoplasty
2. Blepharoplasty
3. Brow lift
4. Calf implants
5. Cheek/malar implants
6. Collagen injections
7. Electrolysis
8. Face/forehead lift
9. Facial bone reconstruction
10. Facial implants
11. Gluteal augmentation
12. Hair removal/hair transplantation
13. Jaw reduction (jaw contouring)
14. Laryngoplasty
15. Lip reduction/enhancement
16. Lipofilling/collagen injections
17. Liposuction
18. Mastopexy
19. Neck tightening

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<sup>1</sup> Private and public coverage policies including those of Cigna, United, HealthPartners, PriorityHealth, Kaiser, Anthem, Molina Healthcare, Massachusetts Medicaid, New York Medicaid

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20. Nose implants
21. Pectoral implants
22. Removal of redundant skin
23. Rhinoplasty
24. Skin resurfacing (dermabrasion, chemical peels)
25. Trachea shave/Thyroid cartilage reduction (chondroplasty)
26. Voice modification surgery
27. Voice therapy/voice lessons

These decisions are consistent with the policies and practices of other state Medicaid programs and most insurers that cover gender confirmation surgery listed above.



# Health Services Advisory Council

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Minutes — September 8, 2016  
3:00 – 4:30 p.m.  
DHS Andersen Building, St Paul

## **Members Present**

Timothy Sielaff (chair), Don Brunquell, Rachel Garaghty (by phone), Andrea Hillerud, Chris Johnson, Jim Miner, Jeff Schiff (non-voting)

## **Members Absent**

Howard Fink, Michael Thorn

## **DHS Staff Present**

Sara Drake, Ellie Garrett, Dave Hoang, Jordan Martinson, Assistant Commissioner Nathan Moracco, Justine Nelson, Diogo Reis, Selam Wako

## **Others Present**

Phil Duran (OutFront Minnesota), John Hennessey (Kepro; by phone), Larry Lee (UCare)

## **I. Welcome, introductions, updates and minutes**

Tim Sielaff called the meeting to order and asked members to review the minutes of the July meeting. **A motion was made and seconded to approve the minutes of the July meeting as written. The motion carried unanimously.**

Introductions were made around the room and by participants joining by phone. Jeff Schiff introduced Larry Lee, attending for the moment as a non-voting guest. Lee is awaiting formal appointment by the Commissioner of Health Services to HSAC (filling a seat dedicated to a health plan representative). Lee is the chief medical officer of UCare and brings a wealth of experience and expertise to the table.

Jeff Schiff provided updates from DHS. Most notably, HSAC is ten years old! We are also awaiting confirmation of other HSAC candidates whose schedules did not allow their participation today. Schiff reported on a national summit sponsored by the US Attorney General and focused on the opioid crisis. HSAC member Chris Johnson spoke at the summit. Commissioner of Human Services Piper and Dana Farley from the Minnesota Department of Health also served on a panel.

## II. Gender conforming surgery for gender dysphoria

### A. Introductory presentation

Ellie Garrett briefly presented on the context and scope of HSAC's discussions of gender dysphoria. A copy of her presentation is available upon request from [HSAC staff](#). In sum, she stated that the proposed work plan called for introduction of the topic today, continued discussions in October, and recommendations to be voted on in November. During the October meeting, Eli Coleman, PhD, Chair in Sexual Health, U of MN Medical School and lead author of the [WPATH guidance](#) will present and be available to answer questions.

For context, Garrett explained that Minnesota law prohibits coverage for gender conforming surgery within Minnesota Health Care Programs. A recent federal regulatory change disallows categorical exclusion of treatments for conditions such as gender dysphoria, effective January 1. This federal change prompted DHS to develop new coverage policy for surgical procedures intended to treat gender dysphoria. (DHS already covers non-surgical therapies (e.g., behavioral health and hormone therapies) for people with gender dysphoria.) Garrett distinguished terminology that refers to identity (e.g., transgender, gender non-conforming) from the clinical disorder known as gender dysphoria. As defined by the DSM-5, gender dysphoria refers to clinically significant discomfort or distress caused by a discrepancy between gender identity and sex assigned at birth.

Garrett reported that there is a paucity of good epidemiological research on transgender identification, prevalence and severity of gender dysphoria. There is also scant research on health disparities among transgender people and on the safety and effectiveness of surgical interventions. In a 2016 article, [Bockting, et al.](#) reported that gender dysphoria improves with gender-affirming treatment and that satisfaction with treatments is high, but that research has been limited to a binary model of gender. Increasing diversity in gender identify and expression along with corresponding treatments and outcomes have not been systematically studied. A [20-year retrospective study in Denmark](#) examined surgical treatment choices by people with gender dysphoria and reported a wide range of preferences, particularly among transgender men seeking female-to-male conforming surgery.

Schiff walked the members through a handout describing the scope of HSAC's discussions on surgical interventions for gender dysphoria (attached as Exhibit A).

The chair opened the floor for clarifying questions. The chair also suggested that though the WPATH document uses "standards of care" in its title, HSAC members instead refer to the document as guidance. The phrase "standards of care" has specific legal meaning that is not applicable to HSAC's discussion. A member asked for resources on surgical treatments for adolescents so that surgical treatments might be considered for adolescents on a case-by-case basis.

Members discussed briefly the limited data on surgical outcomes, and Garrett said that she would ask Dr. Coleman if there are more or better data available.

### B. Public comment

Garrett referred members to the Minnesota Medical Association's letter in support of coverage for gender conforming surgery. A copy of the letter is available upon request from [HSAC staff](#).

Phil Doran, legal director for OutFront Minnesota, offered comments. He disclosed that OutFront Minnesota is currently a plaintiff in a lawsuit against DHS. He declared that he had no conflicts of interest. He offered the following comments:

- The document dated September 2 should be corrected, because the legislature allowed coverage of surgery until 2005 for people who already had begun receiving treatment. He also stated that because medical necessity was part of the current lawsuit, January 1, 2017, shouldn't be the relevant effective date for new policy.
- He observed that though most people use the terminology of "trans man" and "trans woman" the same way in which Garrett used them in her slides (i.e., a trans man is a person born with female sex characteristics who identifies as a man; a trans woman is a person born with male sex characteristics who identifies as a woman), some people use the terms in exactly the opposite ways. Defining terminology at the outset is always useful.
- He observed that while CMS has not issued a national coverage decision, regional Medicare contractors may cover gender conforming surgery on a case by case basis.
- OutFront has no objections to the list of included services, but he suggested that the list state that it is not exhaustive because at some point it will become out of date. Similarly, he objected to a list of excluded services or suggested that the list at least be limited as of this date. As the science develops, new procedures will become medically necessary.
- He recommended covering breast augmentation as a useful treatment that helps move folks to wholeness.
- He recommended explicitly covering complications of surgeries, whether or not the original surgery was covered. For example, even if breast augmentation is not covered, DHS should still cover surgery to correct an implant that breaks or leaks.
- He stated that some surgery would be medically needed for teenagers, but most adolescents choose hormone therapy. Younger minors get hormone blockers; older teens get hormones of their identified gender. He stated for the record that DHS should cover hormone therapies for adolescents, but acknowledged the current legal constraints that preclude such coverage. (Federal law will not allow Medicaid to cover drug therapies that are either not FDA approved for the indication or not listed in any of the various pharmaceutical compendia that guide prescribing practice. Hormone therapies to treat adolescents with gender dysphoria are off-label and unlisted in any compendia. Covering such therapies would require passage of a new state law or else a relevant change at the federal level.)
- He stated that products marketed through MNsure are required to cover gender conforming surgery.
- In response to a question about treatment of minors, he stated that Diane Berg and Katie Spencer, both clinicians at the University of Minnesota, would have the relevant expertise.
- In response to another question about minor consent, he stated that OutFront recommends that parents and children work to agree on treatment decisions. Lack of parental agreement can impede healthy outcomes and access to treatment.
- A member asked whether DHS should require surgery to be performed at a center of excellence. Duran stated that requiring a center of excellence could be a barrier if no such center exists now. He suggested asking this question of Dr. Coleman.

Sielaff left the meeting early, and Schiff took over as chair. No other public comments were offered, and Schiff opened the floor up to discussion among HSAC members.

### C. Members' discussion

A member asked whether there are local providers with the expertise to perform the surgery and what would happen if the only surgical programs were out-of-state. Sara Drake from DHS responded that the out-of-state provider would have to agree to enroll as an MHCP provider and accept MHCP reimbursement rates, in which case DHS would agree to pay for medically necessary surgery out-of-state that was unavailable within Minnesota.

In response to a question, Garrett clarified that cosmetic vs. plastics/reconstructive distinctions usually hinge on the purpose for the surgery: If the surgery is to treat diseased tissue or an injury, then it would be considered reconstructive and medically necessary. If the procedure is solely for aesthetic purposes, then it would be considered cosmetic and not covered. In general, surgery on healthy tissue is not covered. A member clarified that sterilization procedures are covered, though they are on healthy tissue. Discussion ensued.

In response to a question, Drake stated that DHS covers breast augmentation now only after an injury or breast cancer.

Garrett asked what members would like to hear during Coleman's presentation and what other resources staff could provide between meetings. Members identified the following questions and needs:

1. Are there seminal reports or articles that Coleman recommends to HSAC members?
2. Expert opinion concerning:
  - Surgical outcomes, particularly effectiveness in reducing or eliminating gender dysphoria symptoms and common co-morbid conditions (such as anxiety, depression or substance use disorder) that may be rooted in gender dysphoria
  - Age limits or guidelines (particularly, how young is too young and for what procedures)?
3. When is the next version of WPATH guidance expected, and what can Coleman share about modifications that are likely from version 7?
4. What qualifications and expertise should health care professionals referring patients for surgery have? Can Coleman speak to criteria that would help describe adequate adjunctive behavioral health therapy and evaluation for someone who is considering surgery? How many evaluations should be required for what procedures and patients (i.e. should some surgeries be performed only after more than one gender dysphoria evaluation)?
5. When treating a patient with gender dysphoria and co-morbid behavioral or mental health conditions, how does a clinician determine patient readiness in terms of the co-morbid conditions? For example, how does one differentiate between a patient whose depressive symptoms need to be stabilized or reduced before surgery from a patient for whom surgery is required in order to stabilize or reduce depressive symptoms rooted in gender dysphoria? What co-morbid conditions or severity of symptoms would point to delaying surgery?
6. What should the criteria be for time living in the gender of preference? What are appropriate criteria for hormone therapy prior to surgery? What would be the reasons for which hormone therapy would not be indicated?
7. Are there "gender conforming" surgeries for individuals who identify as non-conforming or non-binary? Are there recommendations in this regard?
8. What qualifications and expertise should surgeons have? Should DHS consider a center-of-excellence approach, and if so, what criteria would usefully describe a center of excellence?

The meeting adjourned at approximately 4:30.

## Exhibit A

# Gender Conforming Surgery for People with Gender Dysphoria: Scoping HSAC's Conversation

- I. **Context:** For nearly two decades, Minnesota law has prohibited coverage for gender conforming surgery within Minnesota Health Care Programs. A recent federal regulatory change will no longer allow states categorically to exclude gender confirmation surgery effective January 1. This federal change prompted DHS to develop new coverage policy for surgical procedures intended to treat gender dysphoria. DHS already covers non-surgical therapies (e.g., behavioral health and hormone therapies) for people with gender dysphoria.
- II. **HSAC's scope:** DHS requests HSAC to recommend
  - A. Medical necessity criteria (e.g., patient readiness considerations and appropriate referrals) for coverage of gender conforming surgery
  - B. Whether breast augmentation surgery should be covered for male-to-female gender conforming surgery (Some insurers cover breast augmentation as part of surgical treatments for gender dysphoria; most categorize it as cosmetic and do not cover. Because there is no clear industry standard, HSAC is asked to weigh in.)
- III. **Cosmetic exclusions:** Background
  - A. Public and private insurers routinely exclude coverage for cosmetic surgery, because it by definition is being performed for aesthetic not medical reasons—and thus isn't considered medically necessary. In contrast, plastic or reconstructive surgery is usually covered. The distinction between cosmetic and plastic surgery is well-recognized by specialists practicing in those fields.
    1. American Academy of Cosmetic Surgery definitions:
      - a. Cosmetic surgery is a unique discipline of medicine focused on enhancing appearance through surgical and medical techniques. Cosmetic surgery can be performed on all areas of the head, neck and body. Because treated areas function properly but lack aesthetic appeal, cosmetic surgery is elective.
      - b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
    2. American Board of Cosmetic Surgery
      - a. The procedures, techniques, and principles of cosmetic surgery are entirely focused on enhancing a patient's appearance. Improving aesthetic appeal, symmetry, and proportion are the key goals. Cosmetic surgery can be performed on all areas of the head, neck, and body. Because the treated areas function properly, cosmetic surgery is elective.

- b. Plastic surgery is defined as a surgical specialty dedicated to reconstruction of facial and body defects due to birth disorders, trauma, burns, and disease. Plastic surgery is intended to correct dysfunctional areas of the body and is reconstructive in nature.
- 3. American Society of Plastic Surgeons
  - a. The plastic surgeon performs cosmetic surgery to reshape normal structures of the face or body in order to enhance the patient's appearance and self-esteem. Reconstructive surgery is performed to correct abnormalities of facial or body structures caused by congenital defects, developmental abnormalities, injuries, previous or concurrent surgeries, infection, tumors, or other disease. The purpose of reconstructive surgery is generally to improve function, but it may also be used to restore a normal appearance.
  - b. These distinctions have implications for insurance coverage. Nearly all insurance carriers cover reconstructive procedures for functional restoration but not those performed purely for cosmetic reasons. In general, the classification as cosmetic or reconstructive depends on the reason that the surgery is performed. For example, rhinoplasty to change the shape of the nose is considered cosmetic. However, rhinoplasty to restore the shape of the nose following traumatic deformity is reconstructive.

#### IV. Decisions already made consistent with federal regulatory changes and Medicaid policy

- A. **Covered procedures:** DHS intends to cover the following procedures as medically necessary for individuals meeting medical necessity criteria when the new policy takes effect:
  - 1. Female-to-male gender confirmation
    - a. Hysterectomy and salpingo-oophorectomy
    - b. Vaginectomy (including colpectomy, metoidioplasty, phalloplasty, urethroplasty, urethromeatoplasty)
    - c. Breast surgery (mastectomy; breast reduction)
  - 2. Male-to-female gender confirmation:
    - a. Orchiectomy
    - b. Vaginoplasty (including colovaginoplasty, penectomy, labiaplasty, clitoroplasty, vulvoplasty, penile skin inversion, repair of introitus, construction of vagina with graft, coloproctostomy)

These decisions are consistent with the policies and practices of most other insurers that cover gender confirmation surgery,<sup>1</sup>

- B. **Excluded procedures:** The following procedures will be considered cosmetic and excluded from coverage (not an exhaustive list):
  - 1. Abdominoplasty
  - 2. Blepharoplasty
  - 3. Brow lift
  - 4. Calf implants
  - 5. Cheek/malar implants
  - 6. Collagen injections

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<sup>1</sup> Private and public coverage policies including those of Cigna, United, HealthPartners, PriorityHealth, Kaiser, Anthem, Molina Healthcare, Massachusetts Medicaid, New York Medicaid

7. Electrolysis
8. Face/forehead lift
9. Facial bone reconstruction
10. Facial implants
11. Gluteal augmentation
12. Hair removal/hair transplantation
13. Jaw reduction (jaw contouring)
14. Laryngoplasty
15. Lip reduction/enhancement
16. Lipofilling/collagen injections
17. Liposuction
18. Mastopexy
19. Neck tightening
20. Nose implants
21. Pectoral implants
22. Removal of redundant skin
23. Rhinoplasty
24. Skin resurfacing (dermabrasion, chemical peels)
25. Trachea shave/Thyroid cartilage reduction (chondroplasty)
26. Voice modification surgery
27. Voice therapy/voice lessons

These decisions are consistent with the policies and practices of other state Medicaid programs and most insurers that cover gender confirmation surgery listed earlier.



# Health Services Advisory Council

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Minutes — July 14, 2016  
3:00 – 5:00 p.m.  
DHS Andersen Building, St Paul

## Members Present

Timothy Sielaff (chair), Don Brunquell, Rachel Garaghty (by phone), Andrea Hillerud, Chris Johnson, Jim Miner, Jeff Schiff (non-voting), Cedric Skillon, Michael Thorn

## Members Absent

Amelia Burgess, Howard Fink, Patrick Irvine

## DHS Staff Present

Sara Drake, Karen Dopson, Ellie Garrett, Dave Hoang, Tara Holt, Charlie Mishek, Fritz Ohnsorg, Sara Rogers

## Others Present

Elizabeth Ariano (Indivior), Juliana Milhofer (Minnesota Medical Association, by phone), Todd Kailas (Alkermes, Inc.), Sandra Westerman (Alkermes, Inc.), Will Mullen (Indivior), Christine Zimmer (Winthrop & Weinstine)

## I. Welcome, introductions, updates and minutes

Tim Sielaff called the meeting to order and asked members to review the minutes of the May meeting. Ellie Garrett read the following correction to the minutes, which were offered by Sandra Westerman:

- Sandra Westerman from Alkermes, Inc. spoke next. Alkermes manufactures Vivitrol, which is a branded, extended release, injectable form of naltrexone—one of the medications used in MAR. She disclosed her employment as her sole financial conflict of interest. She circulated materials about Vivitrol and suggested the committee reference [SAMHSA's new pocket guide on medication-assisted treatment of opioid use disorder](#). She suggested that the DHS staff handout (Appendix B) be revised to use generic drug names throughout. She stated that extended-release injectable naltrexone (Vivitrol) is a non-narcotic, non-addictive medicine that prevents relapse to opiates particularly useful during detoxification and that unlike buprenorphine, prescribers of naltrexone do not need special training or DEA certification. Because this treatment requires a patient to be opiate-free for 7-10 days before use, she She suggested that HSAC's recommendations include more content on detoxification services on the front end of a treatment regimen instead of only in a tapering of methadone or suboxone at the end of a regimen. She circulated materials about Vivitrol that are available upon request from [HSAC staff](#).

No other corrections were offered. **A motion was made and seconded to approve the minutes of the May meeting as corrected. The motion carried unanimously.**

Introductions were made around the room and by participants joining by phone.

Schiff provided brief DHS updates: This summer marks the tenth anniversary of HSAC, and we'll celebrate HSAC and honor its current and former members at the next meeting. The Opioid Prescribing Work Group (OPWG) is now working on protocols for treating post-acute pain. The short legislative session is winding down. DHS, in collaboration with the Minnesota Department of Health and other partners, has applied for federal grants from both CDC and SAMHSA that relate to preventing and treating opioid use disorder (OUD).

## **II. HSAC member vacancies**

Ellie Garrett reported that six slots for physicians were open for renewal or new appointments. Cedric Skillon is resigning early because he is moving to Oregon. Tamiko Morgan resigned earlier in the summer because she has received a fellowship on the east coast. Amelia Burgess completed a three-year term and has decided against seeking a second term, because she is changing jobs this autumn. Patrick Irvine also completed a three-year term and has decided against seeking a second term, because his duties as a medical director with South Country are waning as he nears retirement from that position. Chris Johnson and Jim Miner's first terms have expired, and they have graciously agreed to seek reappointment.

More specifically, the vacancies are as follows:

- Three-year terms expiring August 31, 2019:
  - Three licensed physicians actively engaged in the practice of medicine in Minnesota, at least one of whom is a physician specialist;
  - One licensed physician who represents a health plan currently under contract to serve medical assistance recipients;
- One-year terms expiring August 30, 2017. (Normally, new appointees serve three-year terms, but these vacancies arise due to members' resignations following job changes. The new appointees may choose to re-apply for full 3-year terms in mid-2017.):
  - A licensed physician actively engaged in the practice of medicine in Minnesota and whose practice includes being actively engaged in the treatment of persons with mental illness;
  - One licensed physician who represents a health plan currently under contract to serve medical assistance recipients.

Page 5 of the July notice of vacancies on the [Secretary of State's website](#) contains more information about the vacancies.

## **III. Health care infrastructure needed to improve access and quality of medication-assisted recovery (MAR) services for opioid use disorder (OUD)**

Schiff drew members' attention to the revisions made to the draft HSAC recommendations after HSAC's May meeting (see changes noted in Appendix A). After summarizing the revisions, he asked for

clarifying questions. The questions and brief discussion centered on the interval for expecting or prompting tapering, and on how best clinicians can support tapering. A member suggested that the language about “self-directed” tapering should be changed to “patient-centered and encouraged by the prescribing clinician,” and other members agreed. Members also agreed that readiness to taper should be assessed at least annually. Members also discussed the importance of information sharing within the treating team, and that patient consent to information sharing should be sought at the outset of treatment.

### **Public comment**

The chair opened the floor to public comments. Sandra Westerman from Alkermes Inc. spoke first. She reported that her conflicts of interest disclosure provided at the May meeting remained accurate. She requested that HSAC use the same terminology when referring to medication options as the SAMHSA pocket guide, specifically, “extended-release injectable naltrexone.”

William Mullen from Indivior spoke next. Mullen disclosed that he is a salaried employee of Indivior and had no other conflicts of interest. He stated that new federal regulations have raised the cap on patients and expanded the supervisory roles for physicians prescribing buprenorphine.

### **Continuation of members’ discussion**

No other public comments were offered, and the chair opened the floor up for member discussion.

Members disagreed with Ms. Westerman’s recommendation to adopt SAMHSA’s terminology. The reference to extended-release, injectable naltrexone was overly specific, since other delivery mechanisms are available.

Schiff summarized the edits discussed so far:

- **Patients should be assessed for readiness to taper at regular intervals and at least annually. The decision to taper should be voluntary, patient-centered and encouraged by the prescribing clinician.**
- **While patients cannot be required to consent to information sharing, providers must do all that they can to facilitate and encourage information sharing at the outset of treatment among members of the medical and behavioral health treatment team.**

**A motion was made and seconded to adopt these changes to the draft recommendations. The motion carried unanimously.** A copy of the final recommendations reflecting these changes is attached as Appendix B.

## **IV. Next topic for HSAC’s discussion**

Schiff reported that HSAC would next be asked to consider medical necessity criteria for surgical treatments for gender dysphoria.

The meeting was adjourned at approximately 4:40 p.m.

## Appendix A

DRAFT: ~~05-04-2016~~ 07-13-2016 (incorporating HSAC's comments from May 4 meeting)

### Recommendations for HSAC's Consideration

#### Initiative for Medication Assisted Recovery Outside of Rule 31 Outpatient Treatment Programs to Treat Opioid Use Disorder

##### Background

Opiate Use Disorder (OUD) has reached unprecedented levels nationally. While Minnesota's OUD rates are not as high as most other states, Minnesota's disparities among some populations—particularly among American Indian people—are among the nation's worst. The impact on individuals, families, communities and health and social service systems is devastating. New approaches are needed for people seeking effective treatment and durable recovery.

Nationally, some of the most promising treatment initiatives support behavioral health interventions in coordination with medical management. This initiative will be designed to support increased access to high quality, well-coordinated care. Its focus is on medical management provided outside of Rule 31 Opiate Treatment Programs (OTPs). It is intended to complement these existing approaches with primary care based services that are fully integrated with supporting addiction medicine specialists, behavioral health interventions and recovery supports.

Medication Assisted Recovery (MAR) offers stabilization of OUD through buprenorphine, methadone, or naltrexone integrated with behavioral health interventions and recovery supports. For many patients, it provides a means of abstaining from illicit substance use, helping them to attain and consolidate functional gains and eventually taper from medication support.

A number of states have been able to successfully promote MAR, but in doing so have found it necessary to reassess strategies and policies related to OUD treatment and regulation. The following is a brief outline of an approach recommended for HSAC's consideration and revision. After consideration by HSAC, these recommendations will be part of the opioid strategic recommendations for Minnesota DHS.

The goals for the initiative are to (1) support access to high quality, well-coordinated medical clinic based MAR that results in improved health for Minnesota's public health care program recipients who suffer from OUD and (2) minimize diversion of drugs prescribed for MAR.

##### Assessment and Referral

- Patients diagnosed with OUD should be assessed carefully at intake, and patients should be triaged to an appropriate level of care.
  - Patients with severe OUD should be detoxified and stabilized prior to initiating MAR.
  - Buprenorphine or naltrexone, together with intensive outpatient behavioral therapy, should be made available to patients with mild to moderate OUD.
  - Severity of illness should guide treatment choices around site and medications. Patients with severe OUD should be considered for inpatient therapy and may be considered for buprenorphine or methadone as appropriate with outpatient follow-up.

DRAFT: ~~05-04-2016~~ 07-13-2016 (incorporating HSAC's comments from May 4 meeting)

- MDirectly observed therapy, administered via an OTP based on severity of OUD, may be preferred based on comorbidities and social risk factors
- Geographic access may be factored into triage decisions.

### Induction and Stabilization

- Induction onto a medication should be performed by or in consultation with clinicians with demonstrated training and experience. Clinicians who are not yet experienced with managing medication induction of OUD patients should have access—either in person or via telemedicine—to consultation with an experienced specialist. (Patients requiring methadone must be referred to an OTP, in conformance with federal regulations.)
- Pharmacologically stabilized patients should be encouraged to commence behavioral health therapy as soon as possible.

### Behavioral Health Integration

- Patients receiving MAR need high quality, well-coordinated, evidence based, culturally integrated behavioral health care. Follow up by the MAR provider should be part of the continuing coordination plan to assure that behavioral health services are initiated and maintained.

### Ongoing Medical Management

- Ongoing management of MAR requires coordination of supports and services, such as behavioral and physical health care, life skills training, employment, self-help and family involvement.
- Access to consultation with an experienced specialist should be available to manage relapse, dosing and other issues. Telemedicine may support this consultation service between the specialist and the primary care provider/patient.
- Case management to assure integration of resources should be provided in a culturally appropriate context
- DPrescribing guidance including adherence to evidence based dosing levels, oversight of other prescribed agents (benzodiazepines) and review of the prescription drug monitoring program.
- Random and ongoing drug screening must be enforced, but progressively balanced by rewarding patient successes with increased privileges such as take home doses. Protocols should be created and maintained to assure consistency across providers and over time.
- Consequences for diversion and concomitant substance use must be clearly articulated and consistently enforced. Protocols should be created and maintained to assure consistency across providers and over time.

### Review of Progress

- Ongoing and periodic review of progress should be based on objective criteria.

DRAFT: ~~05-04-2016~~ 07-13-2016 (incorporating HSAC's comments from May 4 meeting)

- Standardized reporting should be required at all levels of care.
- [Recovery Maintenance](#)
- OUD is a chronic condition requiring maintenance, including behavioral health supports, over time. MAR can play a role in maintaining recovery, though patients should be given the opportunity to taper and wean as they are ready. Recovery maintenance should be community-based, high quality, well-coordinated, evidence based, and culturally integrated.

### [Planned Withdrawal from Medication](#)

- Patients who prematurely or too abruptly attempt medication discontinuation have a high risk of relapse. Patients should be assessed for readiness to taper at regular intervals. Tapering should be voluntary and self-directed and should be managed by clinicians with demonstrated training and experience. Clinicians managing tapering should have access to telemedicine consultation with an experienced specialist.

Ongoing medical and behavioral support is especially important during the first 3 – 6 months after withdrawal. [MAR in Special Circumstances](#)

- MAR is the preferred treatment for women who are identified as having OUD in pregnancy. Culturally appropriate care must be coordinated with obstetrical care and child welfare services to create an integrated, culturally appropriate approach for safe pregnancy, delivery and post-partum care.
- Special consideration should be given to treating individuals who have a history of OUD and are being released from settings in which opioids have not been available to them, such as jail or prison. Consideration should be given to continuous health care benefit access, behavioral health supports, and provision of naltrexone at change in status.

### [System Coordination](#)

- Planning, collaborative effort and targeted capacity building are needed to support provider recruitment, training and certification of qualified prescribers within systems of primary care.
- Provider back up needs should be considered and addressed within health care systems.
- Standardized means of obtaining consent for information sharing between the prescribing provider and behavioral health treatment provider should be developed and implemented. While patients cannot be required to consent to information sharing, providers must do all that they can to facilitate and encourage information sharing among members of the medical and behavioral health treatment team.
- System quality improvement should assess dosing, diversion risk, adherence to medical and behavioral health treatment protocols, coordination of social support services and other issues.V

## Appendix B

08-22-2016 (final version, incorporating changes from HSAC's July 14 meeting))

# Recommended Initiative for Medication Assisted Recovery Outside of Rule 31 Opioid Treatment Programs to Treat Opioid Use Disorder

## Background

Opioid Use Disorder (OUD) has reached unprecedented levels nationally. While Minnesota's OUD rates are not as high as most other states, Minnesota's disparities among some populations—particularly among American Indian people—are among the nation's worst. The impact on individuals, families, communities and health and social service systems is devastating. New approaches are needed for people seeking effective treatment and durable recovery.

Nationally, some of the most promising treatment initiatives support behavioral health interventions in coordination with medical management. This initiative will be designed to support increased access to high quality, well-coordinated care. Its focus is on medical management provided outside of Rule 31 Opioid Treatment Programs (OTPs). It is intended to complement these existing approaches with primary care based services that are fully integrated with supporting addiction medicine specialists, behavioral health interventions and recovery supports.

Medication Assisted Recovery (MAR) offers stabilization of OUD through buprenorphine, methadone, or naltrexone integrated with behavioral health interventions and recovery supports. For many patients, it provides a means of abstaining from illicit substance use, helping them to attain and consolidate functional gains and eventually taper from medication support.

A number of states have been able to successfully promote MAR, but in doing so have found it necessary to reassess strategies and policies related to OUD treatment and regulation. The following is a brief outline of an approach recommended for HSAC's consideration and revision. After consideration by HSAC, these recommendations will be part of the opioid strategic recommendations for Minnesota DHS.

The goals for the initiative are to (1) support access to high quality, well-coordinated medical clinic based MAR that results in improved health for Minnesota's public health care program recipients who suffer from OUD and (2) minimize diversion of drugs prescribed for MAR.

## Assessment and Referral

- Patients diagnosed with OUD should be assessed carefully at intake, and patients should be triaged to an appropriate level of care.
  - Patients with severe OUD should be detoxified and stabilized prior to initiating MAR.
  - Buprenorphine or naltrexone, together with intensive outpatient behavioral therapy, should be made available to patients with mild to moderate OUD.
  - Severity of illness should guide treatment choices around site and medications. Patients with severe OUD should be considered for inpatient therapy and may be considered for buprenorphine or methadone as appropriate with outpatient follow-up.
  - Directly observed therapy, administered via an OTP based on severity of OUD, may be preferred based on comorbidities and social risk factors

- Geographic access may be factored into triage decisions.

### Induction and Stabilization

- Induction onto a medication should be performed by or in consultation with clinicians with demonstrated training and experience. Clinicians who are not yet experienced with managing medication induction of OUD patients should have access—either in person or via telemedicine—to consultation with an experienced specialist. (Patients requiring methadone must be referred to an OTP, in conformance with federal regulations.)
- Pharmacologically stabilized patients should be encouraged to commence behavioral health therapy as soon as possible.

### Behavioral Health Integration

- Patients receiving MAR need high quality, well-coordinated, evidence based, culturally integrated behavioral health care. Follow up by the MAR provider should be part of the continuing coordination plan to assure that behavioral health services are initiated and maintained.

### Ongoing Medical Management

- Ongoing management of MAR requires coordination of supports and services, such as behavioral and physical health care, life skills training, employment, self-help and family involvement.
- Access to consultation with an experienced specialist should be available to manage relapse, dosing and other issues. Telemedicine may support this consultation service between the specialist and the primary care provider/patient.
- Case management to assure integration of resources should be provided in a culturally appropriate context
- Prescribing guidance including adherence to evidence based dosing levels, oversight of other prescribed agents (benzodiazepines) and review of the prescription drug monitoring program.
- Random and ongoing drug screening must be enforced, but progressively balanced by rewarding patient successes with increased privileges such as take home doses. Protocols should be created and maintained to assure consistency across providers and over time.
- Consequences for diversion and concomitant substance use must be clearly articulated and consistently enforced. Protocols should be created and maintained to assure consistency across providers and over time.

### Review of Progress

- Ongoing and periodic review of progress should be based on objective criteria.
- Standardized reporting should be required at all levels of care.

## Recovery Maintenance

OUD is a chronic condition requiring maintenance, including behavioral health supports, over time. MAR can play a role in maintaining recovery, though patients should be given the opportunity to taper and wean as they are ready. Recovery maintenance should be community-based, high quality, well-coordinated, evidence based, and culturally integrated.

## Planned Withdrawal from Medication

- Patients who prematurely or too abruptly attempt medication discontinuation have a high risk of relapse. Patients should be assessed for readiness to taper at regular intervals and at least annually. The decision to taper should be voluntary, patient-centered and encouraged by the prescribing clinician. Tapering should be managed by clinicians with demonstrated training and experience. Clinicians managing tapering should have access to telemedicine consultation with an experienced specialist.
- Ongoing medical and behavioral support is especially important during the first 3 – 6 months after withdrawal.

## MAR in Special Circumstances

- MAR is the preferred treatment for women who are identified as having OUD in pregnancy. Culturally appropriate care must be coordinated with obstetrical care and child welfare services to create an integrated, culturally appropriate approach for safe pregnancy, delivery and post-partum care.
- Special consideration should be given to treating individuals who have a history of OUD and are being released from settings in which opioids have not been available to them, such as jail or prison. Consideration should be given to continuous health care benefit access, behavioral health supports, and provision of naltrexone at change in status.

## System Coordination

- Planning, collaborative effort and targeted capacity building are needed to support provider recruitment, training and certification of qualified prescribers within systems of primary care.
- Provider back-up needs should be considered and addressed within health care systems.
- Standardized means of obtaining consent for information sharing between the prescribing provider and behavioral health treatment provider should be developed and implemented. While patients cannot be required to consent to information sharing, providers must do all that they can to facilitate and encourage information sharing at the outset of treatment among members of the medical and behavioral health treatment team.
- System quality improvement should assess dosing, diversion risk, adherence to medical and behavioral health treatment protocols, coordination of social support services and other issues.



# Health Services Advisory Council

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Minutes — May 12, 2016

3:00 – 5:00 p.m.

DHS Andersen Building, St Paul

## Members Present

Timothy Sielaff (chair; by phone), Don Brunquell, Amelia Burgess, Rachel Garaghty (by phone), Andrea Hillerud, Patrick Irvine, Jim Miner (by phone), Tamiko Morgan, Jeff Schiff (non-voting), Cedric Skillon, Michael Thorn

## Members Absent

Howard Fink, Chris Johnson

## DHS Staff Present

Sara Drake, Geneva Finn, Ellie Garrett, Dave Hoang, Tara Holt, Charlie Mishek

## Others Present

Elizabeth Ariano (Indivior), Tom Hanson (Winthrop & Weinstine), Dave Hartford (CentraCare), Juliana Milhofer (Minnesota Medical Association) Jenny Rowland (Allergan), Sandra Westerman (Alkermes, Inc.)

## I. Welcome, introductions, updates and minutes

Because Tim Sielaff was participating by telephone, Jeff Schiff chaired the meeting. Schiff welcomed attendees, and introductions were made around the room. Rachel Garaghty and Michael Thorn were welcomed as new HSAC members. Garaghty is a consumer representative and comes highly recommended by HSAC's outgoing consumer member, Lance Hegland. Thorn is an advanced practice nurse at Mayo Clinic and holds one of the two seats the Legislature assigned to non-physician health care professionals. Tamiko Morgan announced that she was resigning from HSAC in order to pursue a Robert Wood Johnson fellowship on the east coast. Schiff and all thanked Morgan for her service on HSAC.

Ellie Garrett offered one correction to page 3 of the minutes of the March 10 meeting as follows:

- “Charlie Mishek, a program manager with DHS’ alcohol and drug abuse division, stated that there is no requirement that ~~licensed OTPs~~ Rule 31 clinics accept patients who are using medication-assisted therapies.”

No other corrections were offered. **A motion was made and seconded to approve the minutes of the March meeting as corrected. The motion carried unanimously.**

Schiff provided brief DHS updates: The Opioid Prescribing Work Group (OPWG) will be meeting next Thursday to finish its draft recommendations on prescribing for acute pain and will begin discussing sentinel measures for acute pain prescribing and protocols for post-acute pain. The short legislative session is winding down. DHS, in collaboration with the Minnesota Department of Health and other partners, has applied for federal grants from both CDC and SAMHSA that relate to preventing and treating opioid use disorder (OUD).

## **II. Case management redesign set-up project**

Schiff introduced Sue Koch, director of strategic initiatives for DHS' Community Supports Administration, to describe a new case management redesign set-up project. A copy of her handout describing the project is attached to these minutes as Appendix A. For several years the Legislature has asked for improvements in case management, and in response DHS has tackled parts of the problem. This current effort is designed to be more comprehensive and get to some of the basics, including rates. The project has a long set-up phase, in which staff have been reviewing all case management policies over the last two decades, interviewing stakeholders, and describing the complexities of the current multitude of approaches. The project is beginning with case management outside of medical care coordination. A member commented that at some point medical care coordination needs to become part of the conversation, because of the complexities in coordinating medical and social services. There is significant overlap between the two. Another member suggested that health plans should also provide input, because many are employing innovative approaches to triggering case management and measuring outcomes and throughput. In response to a question from the audience, Koch clarified that initiatives like Health Home, with embedded coordination, are relevant to this project. Schiff thanked Koch for her presentation and invited her to return as the project progresses.

## **III. Health care infrastructure needed to improve access and quality of medication-assisted recovery (MAR) services for opioid use disorder (OUD)**

Schiff drew members' attention to a handout, which is attached as Appendix B. The handout builds on the initial conversations about MAR begun at the March HSAC meeting and comprises staff's recommendations about MAR for the Council's consideration and revision. HSAC's recommendations regarding MAR will be relevant to DHS in several ways: (1) to inform policy making; (2) to improve applications for federal grants; and (3) to support a request for resources, in the event that the Governor decides to make MAR part of his legislative package.

### **Public comment**

After walking members through the handout, brief discussion ensued and Schiff opened the floor to public comments.

Dave Hartford from CentraCare spoke first, and he had no financial conflicts of interest to disclose. He stated that the line between pain and addiction is blurry. Assessing opioid use disorder in a patient who has been prescribed opioids to treat pain can be difficult and requires particular skill. From a preventive perspective, it would be good to enlist surgeons and other physicians who initiate opioid prescriptions to improve their prescribing practices. (Schiff interjected that the Opioid Prescribing Work Group is working in this domain.) Hartford also stated that Rule 31 providers aren't generally well trained to take patients who are on MAR.

Sandra Westerman from Alkermes, Inc. spoke next. Alkermes manufactures Vivitrol, which is a branded, extended release, injectable form of naltrexone—one of the medications used in MAR. She disclosed her employment as her sole financial conflict of interest. She circulated materials about Vivitrol and suggested the committee reference [SAMHSA's new pocket guide on medication-assisted treatment of opioid use disorder](#). She suggested that the DHS staff handout (Appendix B) be revised to use generic drug names throughout. She stated that extended-release, injectable naltrexone (Vivitrol) is a non-narcotic, non-addictive medicine that prevents relapse to opiates and that unlike buprenorphine, prescribers of naltrexone do not need special training or DEA certification. Because this treatment requires a patient to be opiate-free for seven to ten days before use, she suggested that HSAC's recommendations include detoxification services on the front end of a treatment regimen instead of only in a tapering of methodone or suboxone at the end of a regimen. She circulated materials about Vivitrol that are available upon request from [HSAC staff](#).

### **HSAC members' discussion**

Several themes emerged during members' discussion of the MAR recommendations:

- The importance of behavioral health therapy and of coordinating medical and behavioral health therapies should be stated more strongly. Psycho-social supports are essential to sustained recovery.
- Chronic pain and OUD often co-exist, so it's important to assess and treat both.
- Prevention of OUD should remain a priority, and HSAC members look forward to hearing about the work of the Opioid Prescribing Work Group as it progresses on its statutory charge to develop recommendations for prescribing protocols and measurement.
- Case management will be important to well-coordinated MAR.
- There is tension between the need to offer opportunities to taper MAR while curtailing MAR too early in a patient's recovery. Access to specialized medical support is important. Tapering should be voluntary and self-directed. Approaches that partner with the patient and are not perceived as punitive are best. A skilled provider can nudge a patient toward a successful taper.
- The needs of specific populations should be addressed, such as pregnant women, seniors and adolescents.
- Managed care organizations and behavioral health homes might be better positioned to support well integrated MAR than traditional fee-for-service, though opportunities exist within fee-for-service to smooth access to MAR.
- Lack of access to behavioral health providers, and especially providers who are experienced with treating patients receiving MAR is a statewide concern. The problem is particularly acute in greater Minnesota. Not all Rule 31 programs will admit patients on MAR. For workforce development, paired training opportunities between primary care and behavioral health providers would be helpful.

Staff will synthesize HSAC's comments and bring a refined handout for discussion in July.

The meeting was adjourned at approximately 5:00.

# Case Management Redesign Project: Set-up Phase

Draft as of 5/5/16 by Sue Koch

As directed by the Minnesota Legislature, DHS will partner with counties, tribes, and other stakeholders to redesign case management to achieve the following:

1. Increase opportunities for choice of case management service provider
2. Define the service of case management to include the identification of roles and activities of a case manager to avoid duplication of services
3. Provide guidance on caseload size to reduce variation across the state
4. Develop a statewide system to standardize case management provider standards, which may include establishing a licensure or certification process
5. Develop reporting measures to determine outcomes for case management services to increase continuous quality improvement
6. Establish rates for the service of case management that are transparent and consistent for all medical assistance-paid case management
7. Develop information for case management recipients to make an informed choice of case management service provider
8. Provide waiver case management recipients with an itemized list of case management services provided on a monthly basis

Based on feedback from 25 interviews with participants in past planning efforts, DHS is beginning with a 6-month set-up phase to develop an internal consensus within DHS about a vision for case management and to review and formulate the input that has already been received from stakeholders about case management redesign. The set-up phase is designed as follows:

1. A small, multi-stakeholder work team is preparing the following analyses (April-June, 2016).<sup>1</sup> It is important to stress that the work team will not develop new solutions to case management problems, but will just formulate past input and existing data to clarify the issues and set the table for more efficient planning beginning in the fall of 2016. The team will:
  - a. Create a summary of the major conclusions of past legislative reports on case management that identifies issues around which there is fair agreement and issues that require more data, analysis, and/or collaboration to resolve.
  - b. Based on past reports and analysis of the current policy environment (including health care reform, Olmstead planning, and integrated service delivery projects), draft a vision or visions of the role and practice of case management in the next 20 years in

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<sup>1</sup> The small team is envisioned to comprise a project leader, DHS staff representatives from Mental Health, Disability Services, and Child Welfare (1 rep each), a metro, suburban, and non-metro county representative, a tribal representative, a health plan representative, a case manager representative, two consumer/family representatives, and a DHS researcher. The team would also be informed by a set of subject matter experts in financial operations, federal relations, legislative affairs, communications, and licensing.

Minnesota. This draft would be a starting place for collaborative development of a joint vision by stakeholders.

- c. Summarize data on the basic utilization and spending on case management in Minnesota.
  - d. Explain the funding models and rate-setting processes for the various types of case management in Minnesota.
  - e. Create a policy map of the major DHS and lead agency initiatives that are affecting—or are likely to affect—case management. Includes a list of pressing case management issues that are being held back while we try to do overall case management planning (e.g., new forms of TCM like SUD TCM, video-supported TCM, response to CMS’s letters about our current system, etc.).
  - f. Summarize other states’ approaches to case management.
  - g. Summarize stakeholders’ position papers on case management.
2. Circulation of the set-up phase documents and stakeholder position papers to a wide variety of stakeholders for comment and questions (June 2016).
  3. Based on reactions to the above documents, the set-up phase team would propose a Case Management Redesign Project, including project goals, scope, activities, and timeline. This proposal would serve as an invitation to a 1-day stakeholder workshop to discuss the proposal (July 2016).
  4. A one-day workshop would be held to review the project context, summarize the background documents and stakeholder positions, and present the Case Management Redesign Project proposal (September 20, 2016).
  5. The set-up team would make changes to the proposal based on reactions, and then support the establishment of a Case Management Redesign Steering Committee and an ongoing project team. This would mark the end of the set-up phase (October 2016).

The priorities and timelines for the expected outcomes of the case management redesign project will be determined in collaboration with partners and stakeholders as the planning gets underway in October, 2016. There are many overlapping and competing perspectives on what changes should be made, so it is impossible to lay out a timeline for likely outcomes this early in the project.

~~For more information or to schedule a meeting, please contact Project Leader Susan Koch at [Susan.E.Koch@state.mn.us](mailto:Susan.E.Koch@state.mn.us) or (651) 431-2325.~~

<p>Note from HSAC staff: Following the May HSAC meeting, the case management project was reassigned. At this writing, the project leader is Amanda Calmbacher at <a href="mailto:amanda.calmbacher@state.mn.us">amanda.calmbacher@state.mn.us</a> or 651-431-2627.</p>
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## Appendix B

DRAFT: 05-04-2016

### Recommendations for HSAC's Consideration

#### Initiative for Medication Assisted Recovery Outside of Rule 31 Outpatient Treatment Programs to Treat Opioid Use Disorder

##### Background

Opiate Use Disorder (OUD) has reached unprecedented levels nationally. While Minnesota's OUD rates are not as high as most other states, Minnesota's disparities among some populations—particularly among American Indian people—are among the nation's worst. The impact on individuals, families, communities and health and social service systems is devastating. New approaches are needed for people seeking effective treatment and durable recovery.

Nationally, some of the most promising treatment initiatives support medical management in coordination with behavioral health interventions. This initiative will be designed to support increased access to high quality, well-coordinated care. Its focus is on medical management provided outside of Rule 31 Opiate Treatment Programs (OTPs). It is intended to complement these existing approaches with primary care based alternatives.

Medication Assisted Recovery (MAR) offers stabilization of OUD through suboxone, similar medications or opioid antagonists integrated with behavioral health interventions and recovery-based supports. For many patients, it provides a means of abstaining from illicit substance use, helping them to attain and consolidate functional gains, and eventually tapering from medication support.

A number of states have been able to successfully promote MAR, but in doing so have found it necessary to reassess strategies and policies related to OUD treatment and regulation. The following is a brief outline of an approach recommended for HSAC's consideration and revision. After consideration by HSAC, these recommendations will be part of the opioid strategic recommendations for Minnesota DHS.

##### Assessment and Referral

- Patients diagnosed with OUD should be assessed carefully at intake (via comprehensive substance use disorder or comprehensive medical evaluation), and patients should be triaged to an appropriate level of care.
  - Suboxone or naltrexone, together with intensive outpatient behavioral therapy, should be made available to patients with mild to moderate OUD.
  - Patients with severe OUD should be considered for inpatient therapy, and may be considered for suboxone or methadone as appropriate.
  - Methadone may be the preferred agent, administered via an OTP based on severity of OUD, comorbidities, social risk factors and availability of other alternatives in the geographic area.

## Induction and Stabilization

- Induction onto a medication should be performed by clinicians with demonstrated training and experience. Clinicians who are not yet experienced with managing medication induction of OUD patients should have access to consultation with an experienced specialist. Telemedicine may support this consultation service between the specialist and the primary care provider/patient. (Patients requiring methadone must be referred to an OTP, in conformance with federal regulations.)
- Pharmacologically stabilized patients should be encouraged to commence behavioral health therapy as soon as possible.

## Behavioral Health Integration

- Patients receiving MAR need access to high quality, well-coordinated, evidence based, and culturally integrated behavioral health care. Referral follow up by the MAR provider should be part of the coordination plan to assure that behavioral health component is initiated and maintained.
- After-care should be should be community-based, high quality, well-coordinated, evidence based, and culturally integrated.

## Ongoing Management

- Ongoing management of MAR requires coordination of supports and services, such as mental and physical health care, life skills training, employment, and self-help.
- Access to consultation with an experienced specialist should be available to manage relapse, dosing, and other issues. Telemedicine may support this consultation service between the specialist and the primary care provider/patient.
- Case management to assure integration of resources should be provided in a culturally appropriate context
- Dosing oversight including adherence to evidence based dosing levels, oversight of other prescribed agents (benzodiazepines), and review of the prescription drug monitoring program.
- Random and ongoing drug screening must be enforced, but progressively balanced with rewards for success. . Protocols should be created and maintained to assure consistency across providers and over time.
- Consequences for diversion and concomitant substance use must be clearly articulated and consistently enforced. Protocols should be created and maintained to assure consistency across providers and over time.

## Review of Progress

- Ongoing and periodic review of progress should be based on objective criteria.
- Standardized reporting should be required at all levels of care.

## Planned Withdrawal from Medication

- Patients who prematurely or too abruptly attempt withdrawal have a high risk of relapse. Patients should be assessed for readiness to taper. Tapering should be voluntary and self-directed and should be managed by clinicians with demonstrated training and experience. Clinicians managing tapering should have access to telemedicine consultation with an experienced specialist.
- Ongoing medical support is especially important during the first 3-6 months after withdrawal.

## System Coordination

- Planning, collaborative effort, and targeted capacity building are needed to support provider recruitment, training, and certification of qualified prescribers within systems of primary care.
- Provider back up needs should be considered and addressed within health care systems.
- Standardized means of obtaining consent for information sharing between the prescribing provider and behavioral health treatment provider should be developed and implemented.
- System quality improvement should assess dosing, diversion risk, adherence to treatment protocol and other issues.



# Health Services Advisory Council

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Minutes — March 10, 2016  
3:00 – 5:00 p.m.  
DHS Andersen Building, St Paul

## Members Present

Timothy Sielaff (chair; by phone), Don Brunquell, Amelia Burgess, Andrea Hillerud, Chris Johnson, Jim Miner, Jeff Schiff (non-voting), Cedric Skillon

## Members Absent

Howard Fink, Patrick Irvine, Tamiko Morgan

## DHS Staff Present

Geneva Finn, Ellie Garrett, Dave Hoang, Tara Holt, Cindy Marihart, Charlie Mishek, Fritz Ohnsorg, Sarah Rinn, Brian Zirbes

## Others Present

Marc Arnold (LivaNova), Mary Nienow (Hennepin County Medical Center), Juliana Milhofer (Minnesota Medical Association), William Mullen (Indiver)

## I. Welcome, introductions, updates and minutes

Tim Sielaff joined the meeting by phone, so Jeff Schiff chaired on his behalf. Schiff welcomed attendees, and introductions were made around the room. **A motion was made and seconded to approve the minutes of the February meeting without correction. The motion carried unanimously.**

Schiff provided brief DHS updates: The legislative session has begun, and there is some interest in the legislature around medication-assisted recovery from opioid use disorder and opioid diversion. The Opioid Prescribing Work Force has met monthly since November and is wrapping up its recommendations on prescribing protocols for acute pain. Ellie Garrett reported that DHS has recently updated its fee-for-service provider manual to expand coverage for acupuncture services consistent with HSAC's recommendations.

## II. Health care infrastructure needed to improve access and quality of medication-assisted recovery (MAR) services for opioid use disorder

Schiff introduced the topic for HSAC's deliberations, explaining the potential of primary care to support MAR in an integrated way with behavioral health providers. The term "MAR" connotes an integrated, holistic approach to treating patients with medication-assisted treatments (MAT). DHS is asking HSAC

to consider what support primary care providers need in order to position them for success in treating their patients with MAR.

Garrett and Fritz Ohnsorg presented an overview. A copy of their presentation is available upon request from [HSAC staff](#). Garrett summarized the problem as one of insufficient access to high-quality, integrated, culturally responsive health care for MAR. The access and quality problems are likely inextricably linked: if providers were better supported to provide high-quality care for patients suffering opioid use disorder, they would likely be more willing to provide the medical management that patients need. DHS is requesting input at a fairly high level of generality, so the topic is not likely to require more than three HSAC meetings. Ohnsorg described three successful buprenorphine programs, each of which have features that Minnesota might consider embracing: The Baltimore Buprenorphine Initiative; Michigan's Treatment Guidelines for Opioid Use Disorders; and the Vermont Hub and Spoke Model. Policy features for discussion include:

- A system for assessment and referral
- Recommendations for induction and stabilization of patients
- Integration with behavioral health therapies
- Standards for ongoing patient management
- Standards for reviewing patients' progress
- Policies concerning drug screening
- Recommendations for planned withdrawal

A member asked about cultural responsiveness, and Garrett clarified that the goal is to support treatment approaches that meet people where they live and build upon strengths in their communities. A member commented that intensive inpatient or outpatient behavioral health support is often required at the beginning of recovery, in the neighborhood of four to six weeks of daily treatment. A connection to behavioral health support will be essential.

A member asked about the empirical evidence supporting buprenorphine versus methadone assisted treatment. Ohnsorg stated that there is little long-term evidence, because of the difficulty with tracking people for long periods of time. There is good evidence that both medications are important as part of well-designed systems to support recovery. Garrett drew the group's attention to the SAMHSA guidance, which contains some good discussions about buprenorphine, methadone and abstinence-based programs.

In response to a question regarding financial incentives, Sara Drake (DHS' deputy director for purchasing and service delivery and also manager of DHS' pharmacy unit) explained that methadone is reimbursed as part of the daily rate provided to Opioid Treatment Programs (OTPs), which covers both medication and therapy. The cost of buprenorphine will depend on the dose and delivery mode. List price before federal rebates is in the \$400 - \$800 range per month for the medication alone. Schiff added that another cost related to methadone includes subsidized transportation to OTPs, which can be substantial in greater Minnesota. He also stated that during pregnancy, buprenorphine has been shown to decrease severity of symptoms and length of recovery for infants born with neonatal abstinence syndrome (NAS).

Members briefly discussed the pharmacology of suboxone and the patient profiles that might respond better to suboxone compared to methadone and vice versa. They also discussed some of the complexities associated with diagnosing patients and initiating treatment.

Members discussed the geographic disparities in distribution of treatment resources (including behavioral health specialists) around the state. Schiff stressed that DHS' goal is to link medical management provided outside of OTPs (e.g., through primary care) with a behavioral health support system. More recovery and drug treatment options need to be available around the state and for longer periods of time. Primary care-centered care offers potential for improving the coordination of patient care.

**Schiff opened the floor for public comments.**

With regard to one of the slides in the presentation, a staff member from DHS suggested that a “crutch” metaphor not be used when discussing medication assisted recovery options for opioid use disorder. Medications for other diseases are not seen as a crutch, nor should medications for opioid use disorder.

Mary Nienow from Hennepin County Medical Center offered a public comment and had no conflicts of interest to disclose. She stated that policy makers as well as treatment providers were too often resistant to MAR. HCMC provides training in MAR for its addiction treatment fellowship, but in so doing has met resistance from some policy makers.

**There were no other public comments.**

Members briefly discussed the criminalization of substance use disorders, and the salutary impact of drug courts and of “ban the box” initiatives designed to help people in recovery obtain meaningful employment.

Members asked about the degree to which the behavioral health treatment community has embraced medication assisted recovery. Charlie Mishek, a program manager with DHS' alcohol and drug abuse division, stated that there is no requirement that Rule 31 clinics accept patients who are using medication-assisted therapies. Some programs are resistant, but Hazelden Betty Ford Foundation's relatively recent embrace of MAR reflects important change within the treatment community.

In response to a question about demographics, Ohnsorg stated that most patients with OUD are initially exposed to opioids as teenagers. OUD patients represent a very broad demographic. American Indians are suffering disproportionately compared to other Minnesotans. Most people who have OUD started with exposure to prescription opioids. Broad demographic. Nationwide is a rural, white problem, but all are involved.

Several members agreed that primary care practitioners too often feel alone in addressing their patients' OUD on their own. Many would welcome some support, because OUD patients are often complicated patients who require much time, coordination and care. More specifically, a member identified several issues: (1) ready access to mental health care, either onsite or through a referral to a partnering organization; (2) intensive case management, recognizing that many patients are struggling and will need significant assistance to continue their care; and (3) staffing to manage routine, random and observed urinalysis tests and the confirmatory tests that are often needed.

A member suggested that DHS conduct some focus groups over the phone with providers in greater Minnesota, because HSAC members are almost entirely based in the Twin Cities and do not have experiences with the operational challenges outside of the metro area. Another member observed that telemedicine support could help improve access to specialists. It will also be useful to have measures and protocols to support good medical management.

There was some discussion about “rule 31 providers”—the alcohol and drug addiction counsellors and facilities that are licensed and certified under Minnesota’s rule 31 to provide substance use disorder services. Individual rule 31 providers cannot accept third party reimbursement; they must work under a rule 31 facility provider. In response to a question, Mishek stated that some rule 31 providers will work with patients who are on MAR; others do not.

Schiff thanked members for the discussion. Staff will synthesize the points raised today and present a rough draft of a proposal for HSAC’s consideration and revision.

The meeting was adjourned at approximately 4:45.



# Health Services Advisory Council

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Minutes — February 11, 2016  
3:00 – 5:00 p.m.  
DHS Andersen Building, St Paul

## Members Present

Timothy Sielaff (chair), Don Brunquell, Amelia Burgess (by phone), Andrea Hillerud, Patrick Irvine, Chris Johnson, Jim Miner (by phone), Tamiko Morgan (by phone), Jeff Schiff (non-voting), Cedric Skillon

## Members Absent

Howard Fink

## DHS Staff Present

Ellie Garrett, Dave Hoang, Cindy Marihart, Sarah Rinn

## Others Present

Mike Jablonski (Assurex Health), Alison Martinez (Oklahoma Health Care Authority; by phone), Jim Pollard (Assurex Health), Molly Sajady (University of Minnesota), Charleton Smith (Assurex Health), Kristine Willey (Assurex Health)

## I. Welcome, introductions, updates and minutes

Timothy Sielaff welcomed everyone, and introductions were made around the room. Alison Martinez joined by phone. Martinez is a geneticist with the Oklahoma Health Care Authority, and DHS staff asked that she participate in order to respond to members' questions today.

Ellie Garrett stated that the meeting minutes needed to be corrected to reflect the date, time and location of the January meeting (January 14, 3:00 – 5:00 p.m., DHS Andersen Building). **On motion made and seconded, the members voted unanimously to approve the January meeting minutes as corrected.**

Jeff Schiff provided brief updates from DHS: The Institute of Medicine's *Vital Signs* report is catalyzing national discussions about improving quality measurement, discussions of which DHS is a part. HSAC member Chris Johnson has been named chair of DHS' Opioid Prescribing Work Group. A request for information will be issued soon regarding the next iteration of integrated health partnerships. The behavioral health homes program is scheduled to launch in July. A request for proposals has been issued in connection with a legislatively mandated report on using social risk factors as a consideration in health care payment models.

## II. HSAC membership update

DHS has interviewed candidates for the two HSAC vacancies, and invitations have been extended to two superb candidates, conditioned upon the Commissioner's approval.

## III. Pharmacogenetic testing and GeneSight Psychotropic

### A. Presentation – Ellie Garrett

Ellie Garrett summarized the evidence pertaining to GeneSight that she'd presented at the last HSAC meeting:

- There are no published studies of the GeneSight algorithm in use today. Both genes and drug lists have expanded since studies were conducted.
- All studies were authored or co-authored and funded by the manufacturer or patent-holder.
- All studies have high risk of bias.
- The manufacturer's claims about effectiveness hinge on two, small open-label studies and one small, partially blinded randomized controlled trial with statistically insignificant results and a meta-analysis of same, all of which call for more study.
- Published cost-effectiveness/resource utilization analyses rely either on the above effectiveness studies, or are otherwise limited (a retrospective analysis of one psychiatrist's practice in one case; reliance on pharmacy data alone without adding in the cost of the intervention in another).
- There are more studies underway.

Garrett also updated members on Medicare's decision-making process regarding lab tests such as GeneSight. Pursuant to [CMS' Medicare Managed Care Manual, Chapter 4, Section 90.4.1](#), a favorable decision of a single Medicare regional contractor will bind all other regional contractors and have national impact when, as is the case with GeneSight, there is only one provider for the proprietary lab service. DHS staff recommends that HSAC members adopt and apply the National Human Genome Research Institute's three questions to evaluate a genetic test pertaining to analytical and clinical validity and clinical utility and add a fourth consideration pertaining to algorithmic validity:

- Is the test accurate and reliable? (Analytical validity)
- Is the test result medically meaningful? (Clinical validity)
- Does the test improve healthcare? (Clinical utility)
- Has the algorithm's utility and scientific basis been clearly established? (Algorithmic validity)

### B. Clarifying questions

No questions were asked at this time.

### C. Public comment

Garrett drew members' attention to the written comments and disclosures that were in their folders and distributed electronically in advance of the meeting. In response to a question from Jim Pollard, Garrett stated that comments submitted after the meeting would likely be too late to influence HSAC, since HSAC was scheduled to make its recommendations during the meeting. Schiff added that comments would be welcome at any time for the Commissioner's consideration.

Mike Jablonski, a neuroscientist with Assurex Health, the manufacturer of GeneSight, offered these comments:

- FDA drug labels increasingly contain dosage limits or suggestions based on genotype, and 29 of the drugs in GeneSight’s panel have such language on their labels. FDA is now looking at the combined effects of various genes, as well as enzymes.
- The analytical validity of GeneSight’s labs is confirmed by an extensive laboratory testing and inspection process.
- Consistent outcomes from all studies of GeneSight in comparison to treatment-as-usual groups establish clinical validity. Patients in treatment-as-usual groups who are taking red-binned drugs consistently show worse outcomes than those taking green or yellow-binned medications.
- With regard to clinical utility, improved patient outcomes make the GeneSight test quite useful.
- With regard to the suggested algorithmic validity consideration, it is important to differentiate between a single gene analysis and a panel of genes. Assurex’ algorithm considers the effect of multiple enzymes, the phenotypes based on them and then how the drugs are metabolized.
- With regard to the studies’ risk of bias, all of the articles were accepted and published in peer-reviewed journals, with designs based on real-world trials.
- Future studies are progressing the technology and evidence behind it. To date, though, GeneSight has already been studied sufficiently to demonstrate beneficial outcomes for patients with major depression.

The chair opened the floor up to questions from members. A member asked about the estimated lifetime savings, and Jablonski clarified that the savings were from reduction in total health care visits, which would be reduced if a patient were taking a green or yellow-binned drug compared to a red one. Garrett added that the article in question described results of an economic model that relied on the effectiveness assumptions from three small pilot studies (two open-label studies and one partially blinded RCT with statistically insignificant results).

A member asked how new genes are selected for addition to the panel. Jablonski stated that Assurex has strict criteria to add genes to the GeneSight panel. The criteria are based on literature, including large scale meta-analyses and reproducible genetic effects.

In response to a question from a member, Jablonski stated that Assurex’ studies have not confirmed with blood tests that medication levels indicate that drugs are being metabolized as predicted by GeneSight’s results.

In response to another question, Jablonski clarified that the test provides information about gene/drug interactions, not interactions between two or more drugs.

Jablonski also clarified that the manufacturer recommends using the test for treatment response-resistant patients, because half of treatment-naïve patients already respond well to therapy and do not need the additional test. He stated that in treatment resistant groups, the test works better than current trial-and-error approaches.

## **D. Discussion and recommendations:**

### **1. Coverage criteria for pharmacogenetic testing generally**

Members discussed the proposed criterion regarding algorithmic validity at length, with some members commenting that it is unnecessary because clinical utility criterion is sufficient. Others suggested that it’s a useful criterion for tests reflecting a proprietary algorithm. **A member moved to recommend the**

**first three criteria (analytical validity, clinical validity and clinical utility) and add the fourth criterion (algorithmic validity) as a subset of clinical utility. The motion was seconded. Brief discussion ensued. The motion carried, with one vote opposed.**

## **2. Coverage of GeneSight Psychotropic**

Applying the coverage criteria to GeneSight Psychotropic, a member suggested the following to frame the discussion:

- Assurex' laboratory is certified by the applicable accreditation body, so the analytical validity criterion is satisfied.
- Clinical validity is satisfied, recognizing that the literature shows that people with differing gene phenotypes have different responses to medications.
- The clinical utility criterion (health care improvement) is not satisfied, given the dearth of evidence supporting GeneSight's effectiveness and cost-effectiveness. The studies conducted thus far are insufficient to support a conclusion that health care is improved by use of GeneSight.

Discussion ensued. Some members questioned whether GeneSight satisfied the clinical validity criterion. In response to a question, Martinez suggested that the clinical validity criterion was satisfied, given that there is a relationship between a genotype and some biochemical marker. But it does not give one enough information to be useful clinically—one needs to know not just whether a mutation is present, but whether there is enough information to be measurable in a body. **A motion was made and seconded that the first and second criteria were satisfied with regard to GeneSight. The motion carried with two votes opposed.**

Brief discussion ensued with regard to the clinical utility criterion. Consensus emerged that the published studies are insufficient to establish the test's clinical utility. **A motion was made and seconded that coverage of GeneSight not be recommended because the test did not meet the clinical utility criterion. The motion carried unanimously.**

Schiff thanked members for their recommendation and stated that staff will be sharing the recommendation internally to inform DHS policy making for the fee-for-service program. In response to a question, he clarified that contracted managed care plans are free to establish more expansive policy if they wish.

## **IV. Other business/next steps**

There was no other business. The meeting was adjourned.



# Health Services Advisory Council

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Minutes — January 14, 2016  
3:00 – 5:00 p.m.  
DHS Andersen Building, St Paul

## Members Present

Timothy Sielaff (chair), Don Brunquell, Amelia Burgess, Howard Fink, Andrea Hillerud, Patrick Irvine, Chris Johnson, Tamiko Morgan, Jeff Schiff (non-voting), Cedric Skillon

## Members Absent

Jim Miner

## DHS Staff Present

Ellie Garrett, Dave Hoang, Robert Lloyd, Cindy Marihart, Sarah Rinn

## Others Present

Melissa Geyer (Assurex Health), Tamara Graziano (psychiatric nurse) Jim Pollard (Assurex Health), Amber Soukkala (University of Minnesota), Joel Winner (Assurex Health), Kristine Willey (Assurex Health)

## I. Welcome, introductions, updates and minutes

Timothy Sielaff welcomed everyone, and introductions were made around the room. **On motion made and seconded, the members voted unanimously to approve the November meeting minutes with no corrections.**

Jeff Schiff provided brief updates from DHS: Governor Dayton appointed Emily Johnson Piper as the new Commissioner of Human Services. The Opioid Prescribing Work Group (OPWG) is meeting monthly, having convened for the first time in November. Chris Johnson represents HSAC on the OPWG. The legislative session will be short this year, since it's a bonding and not a budget year. Work has begun to plan for the 2017 session.

## II. HSAC membership update

Ellie Garrett introduced Chris Johnson, who was attending his first HSAC meeting in person. (He participated by phone in November.) HSAC has two vacancies, strong candidates for which have been identified.

### III. Principles for prioritizing existing quality measures

Robert Lloyd summarized ongoing work at DHS to reduce the burden of quality measurement and prioritize measures that better reflect health outcomes and health status. A copy of his presentation is available upon request from [HSAC staff](#). The proposal builds on the [Institute of Medicine's \*Vital Signs\*](#) report as a basis for rethinking quality measurement. Schiff observed that the challenge is to bridge health care and population or public health. Members discussed the *Vital Signs* report's domains and elements. A member asked for context about quality measures. Perspectives about a measure's utility will vary depending on whether it's being used for quality improvement or accountability, for example. Another member observed that some of the higher level measures, like injury and violence are too broad; a more finely tuned approach would discern between different causes and interventions. Another member observed that measurement is costly, and if measurement results are not well used, then those dollars that could otherwise be directed to patient care are wasted.

A member discussed measurement of value (expressed as cost and quality combined) and of equity. Another asked about resources to act on problems identified through measurement and of connecting measurement to outcomes. Discussion concluded, and the chair opened the floor up to public comments. There were no comments offered regarding this topic.

### IV. Pharmacogenetic testing and GeneSight Psychotropic

Garrett summarized the federal regulatory environment for pharmacogenetic testing and the published studies pertaining to GeneSight Psychotropic. According to the National Human Genome Research Institute (NHGRI), which is part of the National Institutes of Health, these tests are largely unregulated at the federal level. NHGRI suggests evaluating a genetic test's usefulness based on three criteria:

- Is the test accurate and reliable? (Analytical validity)
- Is the test result medically meaningful? (Clinical validity)
- Does the test improve healthcare? (Clinical utility)

The GeneSight product analyzes various genes and then groups drugs for the patient's individual genetic profile into three categories according to a proprietary algorithm:

- Green: use as directed
- Yellow: use with caution
- Red: use with increased caution and with more frequent monitoring

Garrett reported that the scientific evidence supporting GeneSight Psychotropic's usefulness for the treatment of depression or major depression is scant and flawed:

- The GeneSight product being marketed today is not the one that was studied. Both the number of genes and drugs have expanded since the studies were performed.
- All studies were authored or co-authored and funded by the manufacturer or patent-holder and have high risk of bias due both to study design and to unmanaged conflicts of interest.
- The manufacturer's claims about effectiveness hinge on two, small open-label studies and one small, partially blinded randomized controlled trial (an RCT with statistically insignificant results) and a meta-analysis of same. The published articles call for more study.

- The manufacturer’s claims about cost-effectiveness rely either on the small effectiveness studies mentioned above or two studies that are otherwise limited: (1) in one case, a retrospective analysis of one psychiatrist’s practice; and (2) an examination of pharmacy costs alone that ignores the cost of the intervention or of other health care utilization.

A copy of Garrett’s presentation is available upon request from [HSAC staff](#). Members asked several questions concerning the GeneSight studies’ methodology and results. In response to questions, Garrett or Assurex representatives clarified several points, including;

- The randomized controlled trial reported in Winner 2013 was not blinded to the treating physician/prescriber. It was blinded to the patient and investigator.
- The red/yellow/green categories do not purport to predict which drugs work for what patients, but are designed to suggest whether (and if so, the degree to which) more caution or monitoring would be appropriate.
- Joel Winner, an Assurex Health representative and a psychiatrist, explained that drugs prescribed for depression are metabolized by multiple enzymes. The GeneSight approach takes into account the complex response of multiple genes. Winner disclosed that he is Assurex Health’s medical director and as such owns stock in the company.
- Winner explained how control patients were matched for propensity in the drug cost study. Savings were reported for one year of drug costs. The cost of the intervention (GeneSight test) was not reflected. A member commented that one cannot extrapolate based on the study that cost savings would continue into later years.
- Another member questioned whether the studies (or underlying studies) established whether the genotypes in question really predicted phenotypic action.

In response to a question, Schiff clarified that DHS is being requested to cover GeneSight, and there are more such tests on the horizon. Discussion ensued.

The chair opened the floor up for public comments, and Winner drew the council’s attention to several PowerPoint slides. A copy of Winner’s full PowerPoint presentation, which he did not have time to present in whole, is available from [HSAC staff](#). Among other things, he stated that the Food and Drug Administration (FDA) includes pharmacogenomic language in the package inserts for 29 of the 38 medications on the GeneSight Psychotropic test. Questions from members continued during his presentation. He clarified that GeneSight is intended to be used along with medical history, not to supplant patient history and other relevant treatment information. He also clarified that it is for treatment resistant depression, and has not yet been studied in treatment naïve patients. In response to a question, he stated that the Assurex lab provides two-day turnaround for test results.

A member pointed out that achieving a 3-point difference on a 60-point depression scale is not meaningful. Winner drew the council’s attention to his slide showing the current standard of care, with a quote from the American Psychiatric Association, “The effectiveness of antidepressant medications is generally comparable between classes and within classes of medications.” The slide also showed the shrinking return in terms of lowered treatment responses and increased side effects for patients undergoing numerous drug trials.

Tammy Graziano, a psychiatric nurse practitioner from Advanced Practice Solutions and working with Ramsey County Jails, Meridian and NorthPoint, offered public comment. She stated that she has used GeneSight for a year, and her patients have had favorable outcomes. Patients have a voice with this tool, and can see how their genetic profile informs her prescribing practice. At first she used it only with

patients who were not complying with their drug therapy. Now she uses it for every initial diagnostic evaluation, and explains with each patient how their genetic profile guides her prescribing.

Jim Pollard from Assurex clarified that Assurex is currently providing the test at no cost for Medicaid and other low-income patients lacking coverage for the test, but will have to begin billing for the test in the future. Assurex has also obtained a favorable Medicare local coverage decision, the only neurological pharmacogenetic test to have such standing. Pollard stated that he appreciated HSAC's transparency and welcomed input from Minnesota's Medicaid program about what kind of data it needs to support coverage.

A member asked for information about the study designs of the trials currently in progress. Another member asked about the diversity of the populations being studied. Garrett agreed to circulate information about the research protocols.

The chair asked members to remember that its discussions of GeneSight are as a case study, offering an opportunity to derive principles on which new pharmacogenetic tests can be considered.

The meeting was adjourned.