TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Texas Medical Disclosure Panel (TMDP)
DRAFT: Meeting Minutes
Thursday, February 8, 2024
2:00 p.m.

Physical Location: Department of State Health Services
Robert D. Moreton Building, Room M-100
1100 49th Street
Austin, TX 78756
TEAMS Virtual Meeting

Agenda Item 1: Welcome
The Texas Medical Disclosure Panel (TMDP) meeting was called to order at 2:01 p.m. by Panel Vice-Chairman Robert Spurck. Vice-Chair, Mr. Spurck, welcomed all attendees and announced public comment would be taken before and during the discussion of agenda item #6 as well as again on agenda item #12. Mr. Spurck, Vice-Chair, turned the meeting over to Ms. Cates-Brown.

Ms. Kayla Cates-Brown, facilitator with HHSC Advisory Committee Coordination Office (ACCO) reviewed the logistical announcements and conducted member roll call. Ms. Cates-Brown informed Mr. Spurck, Vice-Chair, that a quorum was present.

Table 1: Texas Medical Disclosure Panel member attendance at the Friday, September 8, 2023 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Appel, Dr. Noah (Chair)	X		Nwanze, Dr. Chukwusomnazu	X	
Egbuniwe, Ms. Nneka	X		Pederson, Dr. William (Chris)	X	
Esquivel, Dr. Sandra	X		Perry, Dr. Jeremie	X	
Holcomb, Dr. John	X		Spurck, Mr. Robert	X	
Hughes, Mr. Wilbert	X				
			Other Staff:		
			Harrison, Mack (HHS Legal)	X	

Yes: Indicates attended the meeting No: Indicates did not attend the meeting

Agenda Item 2: Consideration of minutes from December 6, 2023, meeting.
Mr. Spurck, Vice-Chair, called for members to review the draft minutes from the December 6, 2023, meeting and requested for any changes or edits. Hearing no comments, Mr. Spurck, Vice-Chair, requested a motion to approve the minutes as presented.

MOTION: Dr. Appel moved for approval of the December 6, 2023, minutes as presented in the meeting. Dr. Perry seconded the motion. The motion was approved unanimously with 9 yays (Appel, Egbuniwe, Esquivel, Holcomb, Hughes, Nwanze, Pederson, Perry, Spurck) with no nays and no abstentions.

Agenda Item 3: Update on 25 TAC Chapter 601 revision project rules organization and format revisions (Repeal and Replace)

Ms. Kelli Weldon, panel liaison, said in order to make List A, Procedures Requiring Full Disclosure of Specific Risks and Hazards, List B, Procedures Requiring No Disclosure of Specific Risks and Hazards, and disclosure and consent forms more accessible and user-friendly, the TMDP repealed and replaced portions of the Texas Administrative Code. These changes went into effect December 26, 2023. You can read more about the changes in the Texas Register. To ensure that providers have up-to-date versions of each form, providers should visit the TMDP webpage, rather than using a search engine or bookmarked page.

Agenda Item 4: Review of 25 TAC §601.2(i) Breast Surgery (Non-cosmetic) and §601.2(p) Urinary treatments and procedures – List A

Mr. Spurck, Vice-Chair, introduced Dr. Holcomb and Dr. Esquivel, who led the review of 25 TAC §601.2 (i). 25 TAC §601.2(p) Urinary Treatments and Procedures and Breast Surgery (Non-cosmetic).

Highlights of review and member discussion:

Breast system:

- Dr. Appel said the panel has mostly completed its review of the breast surgery lists but we are keeping it on the agenda until we publish.
- Dr. Pederson said he was looking over the breast system treatments and procedures list, and recommends the panel include anaplastic large cell lymphoma as a risk to be listed for breast reconstruction with implant and breast augmentation.
    - He advised adding something along the lines of "Development of cancer around the implant" and asked for the panel's feedback on wording. Dr. Perry suggested the wording "cancer originating in the implant capsule" to plastic surgery #1 augmentation/mammoplasty as well as #6 breast reconstruction with other flaps and/or implants. Dr. Appel suggested specifying it is lymphoma. Dr. Pederson said "development of lymphoma or cancer in the implant capsule" and Ms. Egbuniwe suggested clarifying it is "lymphoma that requires additional treatment."
    - The panel agreed on this wording: "Development of lymphoma (cancer) originating in the capsule of the implant requiring further treatment."
- Urinary system: Dr. Appel asked whether there was any update from Drs. Holcomb and Esquivel on the wording of the GU systems as discussed in the last meeting.
    - Dr. Esquivel said she did not have updates or changes. Dr. Appel said for the next meeting the panel should share a document that shows actual wording revisions [in Track Changes] and send it out to everybody and hopefully make approvals on that at the next meeting.

Agenda Item 5: Review of endocrine and digestive system treatments and procedures

Mr. Spurck, Vice-Chair, introduced himself, Dr. Appel, Dr. Pederson, Dr. Perry and Mr. Hughes to lead the review.

Highlights of review and member discussion:

- Mr. Hughes asked if the panel could get an email to everyone on the committee between now and the next meeting [with the revisions highlighted in Track Changes].
- Dr. Appel said we needed to update the GI system because there are endoscopic procedures that need to be listed.

- With the endocrine system it was about looking at the thyroid surgeries and endocrine list A and list B.
    - Dr. Appel provided an overview of proposed revisions, detailed below:
        - List A had thyroidectomy, parathyroidectomy, adrenalectomy, and pancreatectomy with references to the appropriate section.
        - For thyroidectomy we had the standing risks including acute airway obstruction requiring temporary tracheostomy, injury to nerves resulting in impairment of speech, injury to paraythyroid glands resulting in requirement of medication. It used to be a longer listing and we decided to simplify it. And then D was lifelong requirement of thyroid medication.
        - The next one if we add under there and we lump these together as minimally invasive techniques for thyroidectomy, there are several but the main ones would be transaxillary and transoral with specific additional risks we would list for them under their own headings.
        - For the axillary/transaxillary approach (through the armpit), risks would include injuries to the nerves in the shoulder or neck/injury that can affect the muscles and sensation that can affect the extremity, there is a potential for tract seeding of thyroid tissue whether it is benign or cancerous tissue and there are methods for minimizing that risk but it can still happen.
        - One that came up several times was development of post operative seroma and in the standard neck incision for thyroidectomy seroma is relatively uncommon, but with the transaxillary approach it is more common and can require drainage and additional procedures. And then finally vessel injuries at the top of the chest and neck, and injuries to those are among risks that are particular to this approach.
        - And then for the transoral approach—also called vestibular approach—the risks more specific to that would be carbon dioxide embolism, mental nerve injury which would cause pins and needles sensation in the lower lip and/or chin, skin perforation, burns, and surgical space infection.
        - Dr. Appel said those would be his additions and there are others such as minimally invasive video-assisted parathyroidectomy—and those would be the same risks as endoscopic procedures and there's also anterior chest approach. For parathyroidectomy the panel had added one more risk as item D, under #2, persistent high calcium level requiring additional treatment or surgery
        - We made sure to list in here as a number 6 but to indicate that for pituitary surgery, see the neurosurgery section since that could fall under either. Dr. Perry concurred with those changes.
- For GI, Dr. Appel provided an overview of changes outlined in the last meeting and asked some clarifying questions of the panel:
    - Dr. Appel noted previously the panel had listed a relatively finite number of procedures. He asked whether the panel would consider cleft palate surgery "respiratory" as with tonsillectomy or adenoidectomy. Dr. Pederson said it is respiratory and not GI because it's primarily fixed for speech reasons and so

liquid doesn't come out of your nose when you're drinking. Dr. Appel said specific risks to list for that would be development of a palatal fistula causing hypernasal speech, articulation disorders, nasal regurgitation of food and drink. He asked if there are other specific risks that should be listed. Dr. Pederson said it's primarily the fistula where they don't heal properly and he would add there is not uncommonly a need for further surgery to correct speech difficulties.

- Dr. Appel mentioned other procedures to be listed including the implantation of magnets around the G.E. junction that can be adjusted to decrease acid reflux. Risks include vomiting, difficulty swallowing, concern for long term erosion which has also been seen with lap bands.
- Dr. Perry noted he did not see exploratory laparotomy for bowel obstruction or perforated viscus. Dr. Appel asked the panel if that should go on List A or List B. Dr. Perry said a diagnostic laparotomy could be added and as a risk we could list the need for other procedures involving the G.I. system; Dr. Appel advised the panel to consider placement of a laparotomy on the lists for discussion at the next meeting.
- Mr. Hughes asked about whether gastric sleeve should be listed and Dr. Appel said it should be listed under bariatric surgery but the panel needs to break them out into subsections because they do not have the same risk. Dr. Pederson agreed and noted Gastric bypass, also called "Roux-en-Y" has metabolic complications and those should be separate. Dr. Esquivel said as far as development of gallstones I would remove Roux-en-Y because you see that with all types of bariatric surgery and that's all inclusive. Dr. Appel asked if it should be clarified as "stones for any of the bariatric surgeries," anything where you are losing weight rapidly, potentially. Dr. Esquivel agreed.
- Dr. Perry asked whether gastrectomy is listed; Dr. Appel said it can be added.
- Dr. Esquivel asked if bleeding should be listed as a specific risk and Dr. Appel advised if any in particular specific risk that is higher than the standard risk of bleeding then the panel would list it there as hemorrhage/bleeding.
- Dr. Appel asked how specific the panel should be with endoscopy procedures list? Dr. Perry suggested a general category (since there will be more procedures down the road that won't be listed) e.g. "upper gastroendoscopy" which would cover most things. Dr Perry said the panel should go back and look at some of the risks and hazards more closely.
- Dr. Appel said he would come back with more information and wording on the GI systems at the next meeting.
- **List B.** At the conclusion of this agenda item, Dr. Perry asked for clarification regarding how the panel is identifying items for List B; he said previously for the GI system we were having List B as requiring no disclosure of specific risks and hazards and he reread through the statute and that's not actually what List B is; he said his understanding of List B is that it should be things we as a panel do not feel require disclosure in a written format at all. Dr. Appel advised he does not think that is accurate, and advised the panel should discuss further during agenda item 7.

Agenda Item 6: Discuss informed consent for gender-affirming surgery and medical treatments and procedures
Mr. Spurck, Vice-Chair, introduced Dr. Holcomb.

Highlights of review and member discussion:

- **Informed consent for surgical risks:**
  - Dr. Holcomb reviewed some published information but was not able to find information about informed consent, and noted the kinds of surgery discussed are things that the panel already have informed consent guidance for, for example flap procedures.
  - The panel discussed where on List A and List B these types of procedures should go; Dr. Perry said the vast majority of these are ones the panel has an established place for already and asked if the panel should consider genital surgery in these cases as distinct from procedures where surgeons are taking something that was non-functioning because of cancer etc and making it functioning. Dr. Pederson said he could look into the topic and come back with a summary for the panel to discuss at a future meeting.
  - Mr. Hughes also asked whether there is data on failure rates for these surgery and said, as a non physician member of the panel that if that is the case the panel could inform the public of that as a risk.
- **Informed consent for non-surgical risks.**
  - Dr. Holcomb said these types of procedures involve hormone therapy, which comes with risks including pulmonary embolism. He said he saw in some news articles that people came back later and say they were not informed of these types of risks. Dr. Holcomb questioned whether the pulmonary embolism risk is higher with hormonal therapies than it is for oral contraceptives. He said every doctor that hands out birth control pills talks about the risks, and it is his understanding that is not happening with high-dosage hormonal therapy. He suggested this may be a special area where we have a place for off-label use of medications that carries with it side effects; that we need to take a closer look into.
  - Dr. Pederson noted that most major surgeries result in patients having psychological concerns, but the panel's focus is on identifying and listing potential surgical complications and risks.
  - Dr. Appel said the TMDP does not weigh in on medicines, which is why TMDP does not have informed consent disclosure forms specifically for chemotherapies etc., even though they do have risks. The panel is focused on risks of surgical procedures, with a few limited exceptions. At Dr. Holcomb's request, Dr. Appel advised at the next meeting the panel can take another look at this topic and specifically discuss whether or not off-label medication usage is something the panel needs to look at further.

Agenda Item 7: Discussed updates to Frequently Asked Questions page on the TMDP website Mr. Spurck, Vice-Chair, handed the meeting over to Dr. Jeremie Perry.

Highlights of review and member discussion:

- Dr. Perry – It would be helpful to enumerate all of the FAQs. Ms. Egbuniwe noted that they were numbered previously but we discussed whether we could have an update date associated with each question, and those were not supported by the HHSC format or requirements for the website. If that is not supported then perhaps in the text itself the FAQ can include the date of the most recent change.
- Currently there is an item in the FAQ that asks who is administrating the panel that needs to be updated (it is outdated and says DSHS but it should say HHSC).
- Dr. Appel – on #1 my comment on the response is it says it doesn't explicitly prohibit them to do it … but it's not in the spirit of the form—it's the specific individual. On #3 just because a procedure is not on List A or List B doesn't mean it doesn't require consent—it is just about disclosure of specific risks. Dr. Perry said it also goes back to our discussion of List A vs List B. As an example, an IV does not require specific written consent/disclosure. We do get verbal consent from the patient. There is a spectrum of procedures that don't require specific consent but we need to look at it a little more closely. Drs. Perry and Appel asked Mack Harrison to review of the verbiage concerning List B and requirements to make disclosures whether or not it appears on List A or List B.
- Dr. Perry said he would get the complete list of the draft revised FAQ to Kelli to share it with all panel members between now and the next meeting.

Agenda item 8: Public Comment

Vice-Chair, Mr. Spurck, turned the meeting over to Ms. Cates-Brown. Ms. Cates-Brown announced that three person registered to provide oral public comment in the virtual platform. There were no requests on-site to provide public comment.

<u>Oral registered public comment in the virtual platform:</u>

<u>On-site public comment:</u>

- Dr. Patrick Lappert – Provided testimony. Summary: I am a retired plastic and reconstructive surgeon who served in the U.S. military doing reconstructive surgery including genitourinary reconstruction, breast reconstruction, head and neck. All of these surgeries/operations under "gender affirming surgery" are familiar to me. I am not here to offer advice to the board about known surgical complications. What I'm here to present to the board is the level of scientific evidence upon which rests the service line which goes by the name of gender affirming care. This month in The White Journal, the journal of plastic and reconstructive surgery, there is an article by Kilmer that says there is as yet no good quality evidence in support of the goals of those surgeries to remedy the psychological disturbances the patient experiences and disharmony in their heart. All benefits related to psychological improvement including substance abuse, hospitalization for psychological crises and self harming behaviors and suicide there is no level-three evidence or better that informs that as a benefit to people undergoing the surgery. Because everything contained in these operations is based in level 4 and level 5 evidence that is insufficient to guide clinical decision-making. There is no scientific data of level three evidence or better in support of those operations, so these should be understood by the patients and their families as "experimental surgery." All of the literature is based in quality of life survey data, patient satisfaction surveys, and that level of data is sufficient to assess results in cosmetic surgery. The difference here is you're talking about surgeries with known harms to the patient and the benefit is not yet demonstrated; this was found by the National Health Services in Great Britain in terms of its application to children.
- Dr. Kathleen Goonan – Provided testimony. Summary: I am an internal medicine physician trained in Boston at Massachusetts General Hospital and in addition to practicing primary care

medicine I served as senior vice president for health affairs at Blue Cross Blue Shield of Massachusetts where I oversaw evidence-based medical policy. I now serve as a volunteer patient advocate for "adult detransitioners"—people who have undergone various procedures under discussion today—and help them identify specialists who will assist them after the complications they experienced and psychological distress they are experiencing regarding barriers to full informed consent about the procedures and their risks and many of them are now suing. The population has radically changed over the last 15-20 years and so the adults I'm now dealing with are very different from whom whatever evidence we have, evidence was generated. it's not just the UK, it's Sweden, Finland and France and the state of Florida medical boards have put a pause on and are attempting to put "guardrails" on because of the amount of risk that's misunderstood by patient populations. Upwards of 1/3 of patients seeking treatment have autism or untreated trauma. And I think there is a window of opportunity to allow for informed consent for patients considering these medical procedures.

- Dr. Richard Bosshardt – provided testimony. Summary: I am a plastic surgeon for 35 years still in practice in Florida and was asked by Do No Harm to provide a surgical perspective on this whole issue of informed consent and gender reassignment surgery. For the panelists and people listening in, people don't understand cosmetic surgery is taking a normal organ or feature and to make it better than normal. Reconstructive surgery is intended to take a normal feature that in some way has been disfigured affected by an accident or trauma etc. and make it normal again. Gender reassignment surgery is outside of these and are unique; these are not standard procedures because we are taking normal anatomy and destroying it to make a facsimile of normal anatomy. We don't have the ability of having for anything other than the minimum of adverse affects. Plastic surgeons are well aware of the danger of operating on people with body dysmorphia where we are treating a mental condition with a surgical procedure. A systematic review and meta analysis showed that complication rate was 70% overall for some of these gender-altering procedures and we would never accept that complication rate in any cosmetic procedure. So I think we have to approach informed consent in a manner different from how we would approach reconstructive or cosmetic surgery. This is a unique area that has to be looked at very differently.
  Note: Mr. Hughes asked if Dr. Bosshardt could expand on the 70% complication rate. Response/Summary of comments from Dr. Bosshardt: I came across a systematic review and meta analysis in the Journal of Sexual Medicine Review of 1,731 patients in genital reconstruction, and they came up with a overall complication rate of 76.5%, they had nearly 35% fistula complications, and strictures in 25%. So if we are talking about any operation in surgery and talking about complication rates this high, we have to ask if we have really reached the level in surgery of offering these as routine or standard procedures.

Dr. Appel thanked all public commenters for providing their comments. Dr. Appel said the panel appreciates opinions held with what the panel does, and helping to make the lists. It is important to note there are different issues here: 1) whether the surgery should be getting performed, and, 2) if the surgery is going to be performed, making sure people are informed of what the risks are. The TMDP's role is to make sure people are properly informed of what the risks are.

Agenda Item 13: Announcement of next meeting and agenda items

Highlights of announcements and agenda items:

- Announcement of next meeting – Wednesday, April 4 2024 at 1 p.m. Dr. Appel asked the panel whether anyone would prefer a May date over April and there was no response; he said let's leave it as is.
- Dr. Perry said he would love to see more people here at the meetings and asked, is the panel required to have 4 meetings, or could we narrow it to 3 to increase the

chances of people being able to come to Austin? Mr. Harrison noted the statute says they meet at the call of the chair and said he would also check the bylaws to see if there is additional guidance there.

- Deadline for submitting TMDP members' personal financial statements with the Texas Ethics Commission is April 30.
- Per discussion, agenda items for next meeting will also include:
    - Continue discussion on review of treatments and procedures (genitourinary, breast, digestive, endocrine)
    - Continue discussion on gender-affirming treatments and procedures
    - Continue discussion on updating FAQs on TMDP webpage.

Agenda Item 14: Adjourn

Vice-chair, Mr. Spurck, thanked the members for their participation and adjourned the meeting at 3:53 p.m. CST.

The following is the link to the archived video of the February 8, 2024, Texas Medical Disclosure Panel meeting that can be viewed approximately two years from date of meeting. (To view and listen to the entirety of the meeting click on the link).

Texas Medical Disclosure Panel