Texas Hospital Association
1108 Lavaca Street, Suite 700
Austin, Texas 78701
512/465-1000
www.tha.org

October 19, 2018

via electronic submission to:
pamela.adams@hhsc.state.tx.us

Pamela Adams, Interim Manager
Facility Licensing Group
Texas Health and Human Services Commission

Re: Proposed Amendments to Informed Consent Rules (25 Tex. Admin. Code §§ 601.4, 601.8)

Dear Ms. Adams:

On behalf of its more than 465 hospital and hospital system members, the Texas Hospital Association appreciates the opportunity to provide comments on the proposed changes to the Texas disclosure and consent form for medical and surgical procedures and the disclosure and consent form for a hysterectomy as published in the September 19, 2018 *Texas Register*.

Disclosure and Consent Form for Medical and Surgical Procedures (§601.4)

THA appreciates the effort of the Texas Medical Disclosure Panel to make the form more reader-friendly and more understandable, and believes the proposed form generally accomplishes this worthy goal. THA provides the following comments which it believes will further improve the form:

(1) Revise the opening paragraph as follows: TO THE PATIENT: You have the right to be informed about 1) your condition, 2) the ~~recommended~~ medical, surgical, or diagnostic treatment/procedure ~~you are about to undergo~~that is described in this form, and 3) the related risks…")

Rationale: Obtaining informed consent for a patient is a process. Documenting the process and obtaining the patient's signature is part of and concludes that process, but the existing language suggests that the patient has already made the decision to have the procedure at the time the consent form is being reviewed and the informed consent process is being undertaken. We believe the revision is more emblematic of an informed consent *process*.

(2) Under "Description of Medical, Surgical, or Diagnostic Treatment/Procedures", delete the reference to "discipline".

Rationale: The reference to the "discipline" of the performing practitioner is a new addition to the form and we believe it is vague and has the potential to create confusion and inconsistencies in completing the form.

(3) Under "Potential for Additional Necessary Treatments/Procedures", immediately above "Please initial "yes" or "no"", insert "During your treatment/procedure, you may need blood and blood products." Then, under the section related to blood products that follows, revise as follows: "I consent to the use of blood and blood products~~, including _____~~ as necessary for my health during the treatment/procedure. I understand that the following risks and hazards may occur in connection with the use of blood and blood products:".

Rationale: For the first change, we believe some introductory language provides helpful context. For the second change, *i.e.*, the deletion of "including _____" we believe it is unnecessary to list or to even attempt to list the types of blood products that might be used, *e.g.*, whole blood, packed red blood cells, FFP, platelets, etc., and doing so could limit the scope of the consent to only those items expressly identified. In practice, practitioners will likely list all types of blood and blood products to avoid any ambiguity in what has been authorized by the patient, which seems unnecessary and is not particularly meaningful within the informed consent process. Practitioners may also inadvertently (or intentionally) not list anything in the blank, creating ambiguity in the form as to what blood or blood product components are authorized. For the last change, we believe the language adds clarity around the purpose of the language that follows related to risks (and is consistent with the hysterectomy consent form).

(4) Revise "Risks Related to this Treatment/Procedure" as follows: "I understand that all treatments/procedures involve the potential for some risk, ranging from minor to severe. These risks include infection, blood clots in veins, ~~and~~ lungs, and other organs, hemorrhage, allergic reactions, poor wound healing, and death…",

Rationale: We believe this is more comprehensive and accurate since blood clots can occur in other organs besides the lungs.

(5) Further under "Risks Related to this Treatment/Procedure", revise as follows: "Additional risks (~~line through if none~~list other risks):" or alternatively delete that subsection entirely.

Rationale: We question whether this section is necessary at all, since additional risks could be listed in the sections above, but if the subsection remains part of the form, then we believe the directive to "line through if none" will be inconsistently followed, leaving an ambiguity in the form if nothing at all appears in the blank and putting the validity of the form into question.

(6) Under "Granting of Consent for this Treatment/Procedure", delete "Granting of".

Rationale: This wording is unnecessary and understood by the remaining language and the signature.

(7) Further under "Granting of Consent for this Treatment/Procedure", revise as follows: "I understand that this treatment/procedure does not guarantee a result or a cure to my condition.

Rationale: The current consent form includes "result or cure". Not all treatments/procedures are curative, particularly elective or cosmetic procedures. The current form contains the word "result" and that should be preserved in the new form.

(8) Further under "Granting of Consent for this Treatment/Procedure", revise as follows: "3) ~~Steps that~~What will occur during my treatment/procedure".

Rationale: The use of the term "steps" suggests an overly detailed explanation of the each and every action that will occur during the procedure is required, which we believe should not be the standard for informed consent, and further is unnecessary and possibly even confusing to the patient.

(9) Under "PATIENT/OTHER LEGALLY AUTHORIZED REPRESENTATIVE (signature required):", we recommend adding a line for "Relationship to Patient (if other than the patient)".

Rationale: This will provide clarity around the status and standing of the person signing the form to provide consent.

(10) Under "WITNESS:", it appears the signature line has been omitted.

Disclosure and Consent Form for a Hysterectomy (§601.8)

(1) Consistent with the above comment, revise the language related to blood clots in the second paragraph on page 2 as follows: "blood clots in veins, ~~and~~ lungs, and other organs…"

Rationale: We believe this is more comprehensive and accurate since blood clots can occur in other organs besides the lungs.

(2) Consistent with the above comment, under "PATIENT/OTHER LEGALLY AUTHORIZED REPRESENTATIVE (signature required):", we recommend adding a line for "Relationship to Patient (if other than the patient)". Additionally, there should be a space for "Print name" as in the Medical/Surgical Consent Form.

Rationale: This will provide clarity around the status and standing of the person signing the form to provide consent.

Again, the Texas Hospital Association appreciates the opportunity to provide this information to the Panel. Please feel free to contact me by telephone at 512/465-1577 or email at swohleb@tha.org with any questions.

Sincerely,

Stephen G. Wohleb
Senior Vice President and General Counsel
Texas Hospital Association