April 12, 2018

Health and Human Services Commission
P.O. Box 13247
Austin, Texas 78711-3247

Sent via email to SYPNW@hhsc.state.tx.us

RE: Comments on proposed revised draft of "So You're Pregnant, Now What?"

To Whom It May Concern:

On behalf of the Texas District of the American Congress of Obstetricians and Gynecologists (ACOG) and the Texas Association of Obstetricians and Gynecologists (TAOG), representing nearly 4,000 ob/gyns, we write with suggestions for the revised "So You're Pregnant, Now What?" pamphlet posted on March 16, 2018. Our organizations have significant concerns with some of the material and how it is presented. We are thankful for the opportunity to offer input on this revision.

Section 33.011 of the Texas Family Code states that the Texas Department of Health and Human Services (DSHS) is to produce and distribute informational materials that explain the rights of a minor under Texas' judicial bypass law as well as provide information relating to alternatives to abortion, and the possible risks associated with abortion. The presentation of this information does not even begin until page 10 of a 17-page document. The proposed revised SYPNW pamphlet has deviated from that statutorily established purpose, and now mirrors the already existing "A Woman's Right to Know" pamphlet required for informed consent for an abortion procedure. In the past, ACOG and TAOG have also weighed in on the inaccuracies of the WRTK pamphlet.

When physicians, including ob/gyns, provide counseling and information to our patients, we endeavor to be "non-directive" in our counseling that is based on scientific evidence. The purpose of the counseling is to provide education so that a patient can understand her condition and the risks, benefits, and alternatives of care. The SYPNW material does not fulfill these aims. The information in the brochure is biased and the risks presented are primarily the risks of abortion. The section that outlines the risks to a woman's life from carrying a pregnancy (the alternative) is much more limited. Any medical procedure comes with risks, yet this is the one procedure where the state mandates the development and dissemination of a scripted document.

Specific concerns with the wording in the SYPNW packet include:

- Throughout materials: The use of "baby" instead of the clinical standard term "fetus" is not scientific and sends an ideological message, as does the use of "mother" instead of "woman." The proper term for the second to eighth week is "embryo." The embryo becomes a fetus at 10 weeks. The term "fetus"

is the correct term to use until birth. The use of the term “womb” is not scientific. The medically relevant term is “uterus”.

- On page 8: when discussing the full range of risks to consider regarding pregnancy, SYPNW should include the death rate for continuing a pregnancy as well as for having an abortion. The risks of abortion are far less than the risks of carrying a pregnancy to term and delivering. This should be conveyed to women considering the risks, benefits, and alternatives. The fatality rate from induced abortions is 0.6/100,000 compared to 12-28 maternal deaths per 100,000 live births. [WHO; Pazol]

- On page 15: The information on mental health risks is poorly presented and not based on scientific evidence. "Some women, after their abortion, have reported feelings of grief, anxiety, lowered self-esteem, regret, sexual dysfunction, avoidance of emotional attachment, flashbacks, and substance abuse. These emotions may appear immediately after an abortion, or gradually over a longer period of time." These are also emotional responses that can occur in women after a miscarriage, and even after a healthy delivery. This information should be removed. We recommend using the language and finding of the American Psychological Association Committee Opinion regarding this issue. [APA.]

- On page 16: References to adverse pregnancy outcomes and future infertility risks are not based on the latest medical data. Many studies have found little to no negative effect of induced abortion on future pregnancy outcomes and this information should be included in the brochure to reflect our most accurate medical evidence. [Raatikainen, Parazzini, Virk, Kara]

- On page 16: The statement pointing to decreased protection from developing breast cancer after an induced abortion is not consistent with current and relevant science. Pregnancy does not reduce the risk of breast cancer. Both the National Cancer Institute and the American College of Obstetricians and Gynecologists (ACOG) conclude in position statements that induced abortions have not been shown to increase a women’s chance of developing breast cancer. If the statement in the materials were accurate, the same could be said of those women who have had miscarriages. [ACOG; NCI]

- On page 12-16: The physical risks of the medical procedures are portrayed in an exaggerated manner. The risks of abortion are actually less than the risks of carrying a pregnancy to term and delivering.

- On page 16: Information is presented that private counseling organizations (crisis pregnancy centers) may provide support and counsel. It is important to note that these organizations will not counsel a woman on her full range of options. It is also important to convey that while some of these centers may offer ultrasounds, they are not health care providers. Ultrasounds performed at these centers may not fulfill the sonogram requirement for obtaining an abortion, and a woman may choose not to view the images and not hear the heart auscultation when she is a minor obtaining a judicial bypass.

- On page 14: The information on dilation and evacuation is unnecessarily graphic in its description. We suggest the following description: “The contents of the uterus are removed by a suction device that is inserted into the uterus. It also may be called vacuum curettage.” The sentence discussing the use of removing pieces with surgical instruments is overly graphic and not accurate. The length of the procedure is also exaggerated. The dilation and evacuation procedure normally takes 15-30 minutes, not an hour.

- On page 12-13, the process for a medical abortion should be updated to reflect updated FDA guidelines approved as of March 2016. The current proposed version has inaccuracies throughout that need to be amended. Going to the doctor's office or clinic to take the second pill is no longer law because of the update, and should be removed. The guide should cite the medication guide with the approval date of 3/2016. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088643.pdf
    - Bullet #1-4: The numbers used in the pamphlet overemphasize possible complications. Most recent data shows 2-7 out of 100 women may need a surgical procedure because the pregnancy did not pass or to stop bleeding. In a study of 200,000 medication abortion procedures, a significant adverse event only occurred in .16% of cases, with emergency department treatment in .10% and hospital admission in .06%. [Cleland].
    - Bullet #5: states that there is a risk of hemorrhaging, but this is not cited. Risk of hemorrhage is never mentioned in the FDA Medication Guide for Mifeprex. The risk of hemorrhage is extremely rare.
    - Bullet #7: the description is unnecessarily graphic; we recommend replacing it with "…require a surgical procedure of some kind to stop heavy bleeding."
    - Bullet #9: description is unnecessarily graphic; we recommend replacing it with "If your pregnancy has ended, but has not yet completely passed from your uterus, your provider will talk with you about other choices you have, including waiting, taking another dose of misoprostol, or having a surgical procedure to empty your uterus."
    - Bullet #10: presents an increased risk of future infertility—this statement is not cited and is not reflected in risks found by the FDA. As previously stated, many studies have found little to no negative effect of induced abortion on future pregnancy outcomes and this information should be included in the brochure to reflect our most accurate medical evidence. [Raatikainen, Parazzini, Virk, Kara].
    - Overstates the risk of possible infection and leaves out important information that there is no information that the use of Mifeprex and misoprostol caused deaths. We recommend replacing this with, "Although cramping and bleeding are expected, rarely, serious and potentially life-threatening bleeding, infections, or other problems may occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Serious infection has resulted in death in a very small number of cases, however, there is no information that use of Mifeprex and misoprostol caused these deaths. *Source: FDA Medication Guide for Mifeprex, reference ID* 3909592*:* *http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088643.pdf*

- Page 13: the description of the process for a medical abortion is inaccurate and reflects outdated FDA guidelines. We recommend this section be updated with this recommended language:

    "Mifeprex will be given to you by a healthcare provider in a clinic, medical office, or hospital. You and your healthcare provider will plan the most appropriate location for you to take the misoprostol (taken 24-48 hours after the Mifeprex), because it may cause bleeding, cramps, nausea, diarrhea, and other symptoms that usually begin within 2 to 24 hours after taking it. Most women will pass the pregnancy within 2 to 24 hours after taking the misoprostol tablets. Bleeding or spotting can be expected for an average of 9 to 16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. The most common side effects of Mifeprex treatment include: nausea, weakness, fever/chills, vomiting, headache, diarrhea and dizziness. Your provider will tell you how to manage any pain or other side effects."

- Page 13: the description of a first trimester abortion using a suction curettage procedure uses the term "baby" instead of the medically appropriate term of "fetus." Risks are presented in an exaggerated manner and are overemphasized. As previously stated, many studies have found little to no negative effect of induced abortion on future pregnancy outcomes and this information should be included in the brochure to reflect our most accurate medical evidence. [Raatikainen, Parazzini, Virk, Kara]

- Page 14: the risks presented for a second trimester abortion using a dilation and evacuation procedure are done so in an exaggerated manner. Death is extremely rare, yet is the first listed risk. Cervical laceration and perforation of the uterus are also extremely rare. According to the Texas Department of State Health Services (DSHS) data from 2015, out of 52,963 abortions performed-- 0 deaths occurred, 2 women experienced cervical laceration, 2 experienced uterine perforation, and 10 experienced hemorrhage. 2008 is the last time a death was reported due to complications from an abortion in Texas. In comparison, DSHS reported 382 maternal deaths from 2012-2015. 20 deaths were attributed to hemorrhage and 32 attributed to infection/sepsis. Risks for a D&E are similar to those that come along with delivery, and actually occur at a lesser rate. The risks for this procedure are disproportionately exaggerated when the risks of carrying a pregnancy to term and delivering are equivalent, and data shows to be more common. Fewer than 0.5% of women obtaining abortions experience a complication, and the risk of death associated with abortion is about one-tenth that associated with childbirth.

- Page 8: the risks of pregnancy and childbirth are downplayed and not presented in their entirety. Abortion is one of the safest surgical procedures for women in the United States. The risk of death associated with childbirth is 10 times greater than that associated with an abortion procedure.

- Page 9: the subtitle should read "Postpartum Depression Symptoms," instead of "Postpartum Symptoms." Postpartum is the time period (usually the first 12 months) occurring after childbirth, with reference to the mother. Postpartum depression is a specific disorder that shows onset during the postpartum period.

- Page 17: for the SYPNW booklet to be credible, its sources for clinical and mental health information must be peer-reviewed and appear in a publication recognized by the U.S. National Library of Medicine's Medline index. Reports and research of public medical and scientific organizations, such as the Centers for Disease Control and Prevention and the National Institutes of Health, also are reliable as they follow appropriate study and research methods and processes subject to peer review and comment.

Thank you for the opportunity to provide our input. ACOG and TAOG stand firm that information we are compelled to provide to our patients on behalf of the State of Texas must be scientifically based and medically accurate.

ACOG and TAOG are happy to be a resource to HHSC and DSHS as it goes through this review and comment period. Please do not hesitate to contact us.

Sincerely,

C. Tony Dunn, MD, FACOG
Chair, Texas District American Congress of Obstetricians and Gynecologists

G. Sealy Massingill, MD, FACOG
President, Texas Association of Obstetricians and Gynecologists

National Cancer Institute, "Abortion, Miscarriage, and Breast Cancer Risk Fact Sheet"
http://www.cancer.gov/cancertopics/factsheet/Risk/abortion-miscarriage

American College of Obstetricians and Gynecologists Committee Opinion No. 434, "Induced Abortion and Breast Cancer Risk" (2009).
http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Gynecologic%20Practice/co434.pdf?dmc=1&ts=20120304T0707314206

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Virk J, Zhang J, Olsen J. Medical Abortion and the Risk of Subsequent Adverse Pregnancy Outcomes. N Engl J Med 2007; 357:648-653Aug. 16, 2007.

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