John Hellerstedt, MD
Executive Commissioner,
Texas Department of State Health Services
Austin, Texas

RE: Maternal Rules Language Related to HB-1164, 87th legislative session

Dear Dr. Hellerstedt,

Thank you for your leadership over our state services. Your dedication over the years for the patients in Texas is laudable and much appreciated. We appreciate the opportunity to present our recommendations regarding HB1164.

Over the last few months, the Perinatal Advisory Council through our Placenta Accreta Spectrum Disorder Subcommittee has worked diligently on evaluating available state data provided by DSHS and receiving stakeholder input on the importance of including this disorder spectrum in the maternal rules of hospital designation. Our deliberations have culminated in the attached recommendations, which have good intentions in promoting and assuring high standards of care for placenta accreta spectrum disorders (PASD). During our process, we heard from numerous stakeholders during the Perinatal Advisory Council meetings and PASD Subcommittee meetings, and our recommended changes to the maternal rules of designation (attached) will allow for implementation with improvement in care and considering potential unintended consequences.

Limitations exist in the world of placenta accreta spectrum disorders (PASD). No national standard from professional organizations exists for diagnosing PASD antepartum, though consensus involves various history gathering and possible imaging antepartum. The field is evolving with new innovations and understanding on the horizon. Texas has taken a leadership role in attempting to define designation criteria in this complex spectrum of disorders, and the information already gathered by DSHS has impressed our council. We believe that changes in the maternal rules in the ways outlined will avoid unintended consequences brought up by our Council as well as stakeholders.

Respectfully,

Emily Briggs, MD, MPH, FAAFP
Chair, Perinatal Advisory Council

PASD Subcommittee Letter to Perinatal Advisory Council

DATE: **October 6, 2021**

TO: **Perinatal Advisory Council**

FROM: **Placenta Accreta Spectrum Disorder Subcommittee**

RE: **Considerations for Maternal Rules Language Related to HB-1164**

The Placenta Accreta Spectrum Disorder Subcommittee met following the recent Perinatal Advisory Council Meeting on September 22, 2021 and wanted to bring forth several consideration as the PAC finalized the maternal rules recommendations related to HB-1164.

SCREENING FOR PLACENTA ACCRETA SPECTRUM DISORDERS (PASD):

HB-1164 contains the following language

"(d) The patient safety practices developed under Subsection (b) must, at a minimum, require a hospital assigned a maternal level of care designation under Section 241.182 to:
(1) screen patients for placenta accreta spectrum disorder, if appropriate;

To address this element of HB-1164, the subcommittee proposed the following language:

"(13) The facility shall have written guidelines or protocols for various conditions that place the pregnant or postpartum patient at risk for morbidity and/or mortality, including promoting prevention, early identification, early diagnosis, therapy, stabilization, and transfer. The guidelines or protocols must address a minimum of:

(__) Placenta accreta spectrum disorders, including team education, risk factor assessment, screening, evaluation, diagnosis, referral, treatment, and multidisciplinary management of both anticipated and/or unanticipated placenta accreta spectrum disorder cases;"

The subcommittee was intentionally flexible related to risk factor assessment, screening, and evaluation to allow facilities to identify strategies that would work best for their facility and setting. Aside from a prior cesarean delivery and concurrent presence of placenta previa which have clear association with risk for PASD, there are varied factors reported related to be related to PASD. Screening could range from history screening related to prior cesarean delivery and prior ultrasound with placenta previa vs expanded history-based screening vs ultrasound-based screening vs variations of the above.

PASD Subcommittee Letter to Perinatal Advisory Council

EDUCATION - PLACENTA ACCRETA SPECTRUM DISORDERS

HB-1164 contains the following language

"(d) The patient safety practices developed under Subsection (b) must, at a minimum, require a hospital assigned a maternal level of care designation under Section 241.182 to:

(5) develop a written hospital preparedness and management plan for patients with placenta accreta spectrum disorder who are undiagnosed until delivery, including educating hospital and medical staff who may be involved in the treatment and management of placenta accreta spectrum disorder."

The subcommittee proposed the following maternal rule language for all maternal levels related to education related to PASD:

(#___) Placenta accreta spectrum disorders: The facility shall have a written hospital preparedness and management plan for patients with placenta accreta spectrum disorder who are undiagnosed until delivery, including educating hospital and medical staff who may be involved in the treatment and management of placenta accreta spectrum disorder.

The subcommittee raised consideration for increasing specificity related to what the education of hospital and medical staff. The subcommittee asks the PAC to consider whether adding additional specificity about the focus of education is needed. If additional specificity is desirable, the subcommittee recommends the following amendment

"…including educating hospital and medical staff who may be involved in the treatment and management of placenta accreta spectrum disorders about risk factors, diagnosis, and management"

This language modification was approved at the PAC meeting on 10/6/2021 and incorporated into the proposed maternal rule change.

PLACENTA ACCRETA SPECTRUM DISORDER TEAM – ANESTHESIA REQUIREMENT:

The subcommittee proposed the following maternal rule language related to the Placenta Accreta Spectrum Disorder Team for Level IV Centers in response to HB-1164.

(#__) Placenta Accreta Spectrum Disorder Team. The facility shall have a Placenta Accreta Spectrum Disorder (PASD) Team whose members have expertise to assume responsibility for the diagnosis and management of pregnant or postpartum patients with suspected or unanticipated placenta accreta spectrum disorder, including;

(A) the multidisciplinary team must be comprised of a minimum of an obstetric anesthesiologist, obstetrician/gynecologist or maternal-fetal medicine physician, surgeon or

surgeons with expertise in pelvic, urologic and gastroenterological surgery, interventional radiologist, blood bank/transfusion medicine service specialist, and neonatologist, and experienced nursing and operating room personnel;

The subcommittee recognizes that all maternal facilities, even Level IV facilities may not have an "obstetric anesthesiologist" available. Based on feedback from stakeholder input, the subcommittee recommends using the verbiage for the anesthesiologist for Level IV facilities "an anesthesiologist with training and/or experience in obstetric anesthesia" rather than "obstetric anesthesiologist"

This language modification was approved at the PAC meeting on 10/6/2021 and incorporated into the proposed maternal rule change.

PLACENTA ACCRETA SPECTRUM DISORDER TEAM – INTERVENTIONAL RADIOLOGY REQUIREMENT:

The subcommittee proposed the following maternal rule language related to the Placenta Accreta Spectrum Disorder Team for Level IV Centers in response to HB-1164.

(#__) Placenta Accreta Spectrum Disorder Team. The facility shall have a Placenta Accreta Spectrum Disorder (PASD) Team whose members have expertise to assume responsibility for the diagnosis and management of pregnant or postpartum patients with suspected or unanticipated placenta accreta spectrum disorder, including;

(A) the multidisciplinary team must be comprised of a minimum of an obstetric anesthesiologist, obstetrician/gynecologist or maternal-fetal medicine physician, surgeon or surgeons with expertise in pelvic, urologic and gastroenterological surgery, interventional radiologist, blood bank/transfusion medicine service specialist, and neonatologist, and experienced nursing and operating room personnel;

The subcommittee recognizes that all maternal facilities, even Level IV facilities may not have an "interventional radiologist" available. Based on feedback from stakeholder input, the subcommittee recommends using the verbiage for the interventional radiologist for Level IV facilities "a radiologist with critical interventional radiology skills" rather than "interventional radiologist"

This language modification was approved at the PAC meeting on 10/6/2021 and incorporated into the proposed maternal rule change.

PLACENTA ACCRETA SPECTRUM DISORDER TEAM COMPOSITION/URGENT REQUEST REQUIREMENT:

The subcommittee proposed the following maternal rule language related to the Placenta Accreta Spectrum Disorder Team for Level IV Centers in response to HB-1164.

(#__) Placenta Accreta Spectrum Disorder Team. The facility shall have a Placenta Accreta Spectrum Disorder (PASD) Team whose members have expertise to assume responsibility for the diagnosis and management of pregnant or postpartum patients with suspected or unanticipated placenta accreta spectrum disorder, including;

(A) the multidisciplinary team must be comprised of a minimum of an obstetric anesthesiologist, obstetrician/gynecologist or maternal-fetal medicine physician, surgeon or surgeons with expertise in pelvic, urologic and gastroenterological surgery, interventional radiologist, blood bank/transfusion medicine service specialist, and neonatologist, and experienced nursing and operating room personnel;

(B) all team members must have full hospital privileges and a representative of the team must be available at all times for on-site consultation and management, and to arrive at the patient bedside within 30 minutes of an urgent request in attending to a patient with placenta accreta spectrum disorder;

The subcommittee received feedback from stakeholders and public comment that questioned whether it was sufficient for a "representative" of the team to arrive at patient bedside within 30 minutes of an urgent request. After additional deliberation,

The subcommittee recommends altering the language related to the multidisciplinary team to highlight primary and secondary components of the PASD team with the following alteration of the proposed language related to team composition and urgent request response.

"(#__) Placenta Accreta Spectrum Disorder Team. The facility shall have a Placenta Accreta Spectrum Disorder (PASD) Team whose members have expertise to assume responsibility for the diagnosis and management of pregnant or postpartum patients with suspected or unanticipated placenta accreta spectrum disorder, including the following elements;

(A) the multidisciplinary team must be comprised of:
1) a primary response team consisting of a minimum of these components: an anesthesiologist with training and/or experience in obstetric anesthesia , obstetrician/gynecologist or maternal-fetal medicine physician, surgeon or surgeons with expertise in pelvic, urologic and

gastroenterological surgery, a neonatologist, and experienced nursing and operating room personnel; and

2) a secondary response team consisting of a minimum of these components: a radiologist with critical interventional radiology skills and blood bank/transfusion medicine service specialist.
(B) all team members must have full hospital privileges; and:

1) a representative of each component of the primary response team must be available at all times for on-site consultation and management, and to arrive at the patient bedside within 30 minutes of an urgent request in attending to a patient with placenta accreta spectrum disorder;

2) a representative of each component of the secondary response team must be available at all times for on-site consultation and management and be able to arrive at the patient's bedside for an urgent request to attend to a patient with placenta accreta spectrum disorder within a time frame commensurate to the clinical situation and consistent with current standards.

This language modification was approved at the PAC meeting on 10/6/2021 and incorporated into the proposed maternal rule change.

LEVEL IV PLACENTA ACCRETA SPECTRUM DISORDER TEAM – TEAM CAPABILITIES:

The subcommittee would like to highlight to the PAC that, while all level IV maternal facilities should have the described elements in the proposed draft maternal rules, it is important to recognize that all maternal Level IV facilities may not care for the most advanced types of PASD (eg percreta). This is an important consideration to ensure that women with advanced PASD cases are referred to facilities with the highest level of capability related to PASD care. Analogous conditions are evident in the neonatal rules where only some level IV centers have advanced capability for ECMO and others do not. Similarly, while all level IV maternal centers have a full complement of medical and surgical specialists and subspecialists, not all level IV centers may have capability to care for advanced maternal cardiac surgical cases. The subcommittee believes this is a critical consideration as the revised maternal rules are implemented and updated facility survey process begins related to PASD. Without these considerations, level IV maternal facilities who may not possess the advanced expertise needed for the specific case, may avoid referral or transport to facilities with the necessary expertise commensurate with the patient's need. This could cause unintended consequences and increases risk for maternal and neonatal adverse outcomes.

FOSTERING TELEMEDICINE:

HB-1164 notes that the rules created for patient safety practices for the evaluation, diagnosis, treatment, and management of placenta accreta spectrum disorder include:

"(3) foster telemedicine medical services, referral, and transport relationships with other hospitals assigned a maternal level of care designation under Section 241.182 for the treatment and management of placenta accreta spectrum disorder;"

This introduction of telemedicine into the maternal rules related to PASD specifically is problematic as the current maternal rules do not include any requirements for telemedicine for any maternal condition or level of care. The only mention of telemedicine in the current maternal rules is in the section on "Survey Team" as noted below:

(d) The survey team shall evaluate the facility's compliance with the designation criteria by:

(1) reviewing medical records; staff rosters and schedules; documentation of QAPI Program activities, including peer review; the program plan; policies and procedures; and other documents relevant to maternal care;

(2) reviewing equipment and the physical plant;

(3) conducting interviews with facility personnel and surveyors may meet privately with individuals or groups of personnel; and

(4) evaluating appropriate use of telemedicine capabilities where applicable.

The subcommittee was concerned introducing the concept of "fostering telemedicine" specific to PASD but not other conditions. Telemedicine is not widely used in the state by maternal centers adding a requirement for telemedicine capacity may be a significant burden on facilities. The subcommittee recommends that if verbiage is introduced into the maternal rules or should be generically introduced either under "Designation Requirements" for all levels of care of introduce into the level III and level IV centers.