Report on Benefits of Prenatal Surgical Procedures to Treat Birth Defects

As Required By:

House Bill 606

84th Legislature,
Regular Session, 2015

Texas Health and Human Services Commission

December 2016
Executive Summary

This report serves as a preliminary overview outlining recent trends of emerging fetal surgical interventions currently practiced in Texas. Per House Bill 606, 84th Legislature, Regular Session, 2015 key components required for the report are 1) an analysis of costs comparing procedures by payer, 2) potential cost differentials that may occur as a result of prenatal versus postnatal interventions, and 3) an analysis of survival, outcomes, and quality of life for individuals who received prenatal versus postnatal treatment.

Prenatal Interventions

One half of 1 percent of infants born in Texas each year are diagnosed with 1 or more congenital malformations (approximately 22,000 defects per 400,000 deliveries). Some of these birth defects are profound and not survivable. Others may cause varying degrees of disability, can be corrected after birth, or may not be apparent or impact the individual's daily life.

Fetal surgery is a relatively new, multidisciplinary, field which continues to evolve as an increasing body of data from clinical trials becomes available, improvements of sophisticated diagnostic tools and surgical techniques necessary for performing in-utero interventions develop, the understanding of fetal and placental anatomy improve, and the impact on maternal-fetal outcomes is better understood.

Two procedures are becoming standard surgical practice: laser ablation to treat twin-twin transfusion syndrome (TTTS), and open fetal surgery to correct myleomeningocele (MMC) or spina bifida. Laser ablation surgeries correct placental blood flow defects that place fetal identical twins at risk of development or death. The first laser ablation surgeries began in the late 1980's. Texas Children's Hospital (TCH) has been performing these surgeries since 2007 and Children's Memorial Hermann Hospital (CMHH) has been providing this surgery since 2011. The TTTS fetal intervention findings include:

- Approximately half of all pregnancies evaluated for TTTS undergo the surgery
- Approximately 100 TTTS procedures a year are performed in Texas
- Over 70 percent of TTTS surgeries result in both twins surviving, and another 20 percent successfully deliver one of the twins
Surgery to correct MMC has only become a recognized surgical alternative since 2011. Uncorrected spina bifida, a neural tube defect in which the spinal cord forms but a portion of the structures surrounding the spinal cord remain open, can lead to problems with locomotion, neural tube herniation, learning disabilities, and rarely, death. An extensive three-center trial carried out through 2011 established the efficacy of open womb fetal surgery to correct spina bifida before delivery. Both Texas fetal centers began offering prenatal MMC interventions in 2011. Between 2012 and 2014, approximately 15 MMC surgeries per year have been performed in Texas. Myelomeningocele fetal intervention findings include:

- One-third of pregnancies evaluated for prenatal MMC surgery undergo the surgery (approximately 15 per year).
- The number of prenatal MMC surgeries has steadily increased since 2012, while the number of postnatal surgeries declined over the same period.
- Preliminary outcomes data suggest that only 10 percent of infants treated prenatally require shunts within the first year of life. Over one-third of infants with postnatal repairs will require shunting to prevent spinal cord fluid buildup.

Several additional fetal interventions are undergoing investigational trials. These include fetoscopic repair of MMC, fetal cardiac interventions, and fetal endoscopic tracheal occlusion for surgical intervention for treatment of severe congenital diaphragmatic hernia (CDH). Of these, CDH repair is considered by both CMHH and TCH as an intervention that will soon become a standard of care.

Congenital diaphragmatic hernia occurs when the fetal diaphragm does not completely develop and a small opening remains present, which allows abdominal organs to move into the thorax. In severe cases, lung development is impacted. Infant mortality can be as high as approximately 50 percent. Fetal tracheal occlusion is being investigated as a technique which temporarily closes the trachea, blocking amniotic fluid in the lungs to help them develop and allowing the lungs to develop and increase the chances of survival at birth. Congenital diaphragmatic hernia repairs, although not routine, are currently performed by TCH as part of an investigational pilot study with approximately four interventions per year from 2012 to 2014. CMHH began performing CDH repairs beginning in 2016 and has completed three procedures at the time of this report.
Evaluation of Fetal Surgery Costs

The examination of cost differences by payer and by timing of the intervention require information on actual cost reimbursements to health entities responsible for providing these services. Insurance and health plan payer reimbursements are negotiated individually by health care providers and may be proprietary, limiting the availability of cost data for analyses. The Health and Human Services Commission (HHSC) is working with CMHH and TCH to obtain summary reimbursement information for the procedures examined in this report.

Cost data for the Medicaid program, including the interventions addressed for this report are limited. Prior to July 2015, most procedures that identified specific physician services for fetal surgeries were not a paid benefit for mothers over age 21, and as of November 2016, procedures that identify specific physician services for in utero surgery to correct MMC or congenital diaphragmatic hernia are not Medicaid benefits.

Evaluation of Fetal Surgery Outcomes

Our ability to assess long-term outcomes depends, in part, on the type of intervention performed and the ability to monitor patients over time. Both Texas fetal centers are able to report perinatal survival, but there is significant loss to follow-up among patients who don't require postnatal care. An approach for subsequent research will be to examine linked administrative files, such as the Department of State Health Services hospital discharge and ambulatory care files, to develop longitudinal health histories of individuals receiving fetal surgery which can be utilized to examine health outcomes over time.

Next Steps

Given these limitations, HHSC plans additional reports. An analysis to be published in 2017 will examine cost differences and outcomes in addition to more complete enumeration of procedures. The HHSC will continue to work with the two Texas fetal centers to obtain summary reimbursement cost data to evaluate cost differentials by payer type and by surgery. We will also utilize THCIC charge data to determine if these data provide insights on payer and surgical timing cost differentials.
A second report tentatively scheduled for 2019 will examine longer term trends and post-natal outcomes by identifying individuals who have received fetal and postnatal surgeries and monitoring their health status and costs using Medicaid and THCIC administrative data available to HHSC, and follow them for up to five years after the intervention was performed.
The 84th Texas Legislature, Regular Session, 2015, passed House Bill 606 (H.B. 606), requiring a study on the benefits of prenatal surgical procedures to treat birth defects. The bill directed the Texas Health and Human Services Commission (HHSC) to evaluate the benefits of prenatal surgical procedures for Texas and the state's Medicaid program, and to provide a written report to the Governor, Lieutenant Governor, Speaker of the House of Representatives, House Committee on Public Health, and Senate Committee on Health and Human Services. The bill states:

"The commission shall conduct a study to evaluate the benefits of prenatal surgical procedures to treat birth defects.\(^1\)

The procedures studied must include:

1. fetoscopic placental laser ablation (FPLA);
2. maternal-fetal surgery; and
3. any other type of prenatal surgical procedure that is or becomes the standard of practice for treating a birth defect.

The study must analyze:

1. the difference in average total cost to the Medicaid program, private health benefit plan coverage, and individuals and other payers between conducting a prenatal surgical procedure and a postnatal procedure to treat a birth defect, including any continuing treatments needed after either procedure; and
2. any improvement in survival rates, long-term outcomes, and quality of life for children with birth defects following a prenatal surgical procedure as compared to a postnatal procedure to treat a birth defect."
Goals of This Study

This report serves as a preliminary overview outlining recent trends of emerging fetal surgical interventions currently practiced in Texas. In addition to identifying these trends, H.B. 606 directed HHSC to examine 1) costs comparing procedures by payer, 2) potential cost differentials that may occur as a result of prenatal versus postnatal interventions, and 3) survival, outcomes, and quality of life for individuals who received prenatal versus postnatal treatment.

The examination of cost differences by payer and by timing of the intervention require information on cost reimbursements to health entities responsible for providing these services. Data detailing the amount hospitals and ambulatory care facilities charge for inpatient and outpatient services are reported to the Texas Health Care Information Collection (THICIC). However, charges may differ significantly from actual costs. Insurance and health plan payer reimbursements are negotiated individually by health care providers and may be proprietary, limiting the availability of cost data for analyses. The HHSC has requested summary reimbursement information for the procedures examined in this report from both Children's Memorial Hermann Hospital (CMHH) and Texas Children's Hospital (TCH) fetal centers. At the time of this report, our request for these data is under consideration by both centers.

Cost data for the Medicaid program, including the interventions addressed in this report, are available for covered procedures. Medicaid claims and encounters are records of financial transactions between providers and the Medicaid program. They are used as a justification for payment, based on the listed procedures that have been provided to a Medicaid participant. However, prior to July 2015 some procedures that identify specific physician services for fetal surgeries were not a paid benefit for mothers over age 21 (refer to Table 1, page 16). Procedures may have been performed with prior authorization but were either denied claims (paid amount = $0.00) or billed under different, general procedure codes. These practices reduced HHSC's ability to assess costs for specific procedures. As of November 2016, procedures that identify specific physician services for certain in utero surgeries including the correction of myelomeningocele (MMC) or congenital diaphragmatic hernia (CDH) are not Medicaid benefits.

The HHSC's ability to assess postnatal outcomes depends, in part, on the type of intervention performed and the ability to monitor patients over time. Both Texas fetal centers are able to
report perinatal survival, but there is significant loss to follow-up among patients who don't require postnatal care. For example, with TTTS, while it may be critical for certain patients to be closely monitored prior to and immediately following surgery, in many cases delivery and postnatal care can be accomplished where the patient resides. Although prenatal surgeries to correct MMC defects may require long-term monitoring and evaluation, only a half-decade of MMC prenatal intervention data are available for Texas and the average annual number of procedures is 15. Because most of the individuals will be discharged to areas of the state - or elsewhere - away from the fetal centers, many of these individuals may also be lost to follow-up. HHSC will explore the use of Medicaid and THCIC data to follow patients longitudinally.

To address current data limitations, HHSC plans additional reports: 1) an analysis to be published in 2017 will examine cost differences and outcomes, in addition to a more complete enumeration of procedures, and 2) a report tentatively scheduled for 2019 will examine longer term trends and postnatal outcomes by identifying individuals who have received prenatal surgeries and monitoring their health status and costs using Medicaid and THCIC administrative data available to HHSC.

In addition to the above, H.B. 606, passed in conjunction with H.B. 2131, 84th Legislature, Regular Session, 2015 (H.B. 2131), provides baseline data to inform the establishment of Centers of Excellence for Fetal Diagnosis and Therapy. Specifically, the Department of State Health Services (DSHS), in consultation with the Perinatal Advisory Council,4 is responsible for the designation of centers of excellence for fetal diagnosis and therapy. Centers that have been so designated will be able to provide "comprehensive maternal, fetal, and neonatal health care for pregnant women with high-risk pregnancies complicated by one or more fetuses with anomalies, with genetic conditions, or with compromise caused by a pregnancy condition or by exposure."
Prenatal Surgical Procedures to Treat Birth Defects

Despite the complexity of the human organism, only one half of 1 percent of infants born in Texas each year are diagnosed with 1 or more congenital malformations (approximately 22,000 defects per 400,000 deliveries). Some of these birth defects are profound and not survivable. Others may cause varying degrees of disability, can be corrected after birth, or may not be apparent or impact the individual's daily life.

Fetal surgery is a relatively new, multidisciplinary, field which continues to evolve as an increasing body of data from clinical trials becomes available, improvements of sophisticated diagnostic tools and surgical techniques necessary for performing in-utero interventions develop, the understanding of fetal and placental anatomy improve, and the impact on maternal-fetal outcomes is better understood. The first invasive procedures (for intra-uterine blood transfusion) occurred in 1963. Until 1994, surgeries for fetal defects were considered risky and potentially lethal. Improved imaging techniques since the 1980's have led to earlier and more accurate diagnoses. The growth of fetal surgery, while relatively rapid, had historically lacked the rigor to inform "definitive conclusions about care and policy." Previous research focused on perinatal outcomes. Postnatal impacts of the surgery on the child, as well as the effects of fetal surgery on the mother, were secondary research foci.

More recent research has been deliberate and based on both animal models and on large randomized controlled human trials as opposed to retrospective clinical trials. Fetal centers have developed standards of care, developed medical training programs, established specialized collaborative teams, and have incorporated bioethical protocols as standard practice.

The ethics and rationale for performing fetal interventions has become a critical concern for determining which individuals are candidates for fetal surgery. Fetal interventions, unlike other surgeries, impact two patients; the fetus and the mother. The fetus, like any other individual, is at risk of complications arising from the procedure. The mother, who may or may not suffer from complications of the pregnancy, may ultimately be at risk of post-surgical complications that impact her health or ability to deliver the current or subsequent pregnancies. For this reason, medical ethicists and social workers are critical components of any fetal surgical team.
Maternal-fetal medicine is widely practiced throughout Texas, with facilities practicing this specialty providing various needle-based diagnostic and therapeutic services including amniocentesis, amnioreduction, fetal blood transfusion, fetal biopsies, and various shunting procedures. However, at this time (November 2016) these facilities are not equipped to provide advanced fetal interventions.

With implementation of H.B. 2131, fetal centers will be designated by the state. Qualified centers must be a health care entity that: "(1) offers fetal diagnosis and therapy through an extensive multi-specialty clinical program that is affiliated and collaborates extensively with a medical school in this state and an associated hospital facility that provides advanced maternal and neonatal care; (2) demonstrates a significant commitment to research in and advancing the field of fetal diagnosis and therapy; (3) offers advanced training programs in fetal diagnosis and therapy; and (4) integrates an advanced fetal care program with a program that provides appropriate long-term monitoring and follow-up care for patients."

Further, centers must have the "ability to monitor short-term and long-term patient diagnostic and therapeutic outcomes; and provide to the DSHS annual reports containing aggregate data on short-term and long-term diagnostic and therapeutic outcomes as requested or required by the department and make those reports available to the public."

Currently, Texas has two fetal centers, both in Houston, which have treated the majority of fetal surgical interventions anticipated by H.B. 606: Texas Children's Hospital (TCH) and Children's Memorial Hermann Hospital (CMHH). The Fetal Center at CMHH began performing TTTS laser photocoagulations and MMC interventions in 2011. The TCH Fetal Center was established in 2001 and began performing TTTS laser photocoagulations and MMC interventions in 2007 and 2011, respectively. TCH has also performed fetoscopic MMC repairs. The first procedure was performed in July of 2014. A third institution, University of Texas Southwestern Medical Center in Dallas, performed one fetal surgery (TTTS) in 2011 but none since.

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\(^1\) As of November 2016, the Perinatal Advisory Council has not officially designated any Centers of Excellence for Fetal Diagnosis and Therapy.
Although several anomalies arising during fetal development have become, or are, treatable via fetal surgery, most are considered experimental and not routine. However, two congenital conditions that currently benefit from prenatal intervention are TTTS and MMC or spinal bifida.\textsuperscript{17} Procedures developed to treat these conditions are becoming standard practice and have become well established within major maternal-fetal centers.

Twin-twin transfusion syndrome is a condition of the placenta in which identical (monozygotic) twins share a single chorionic membrane, but have separate amniotic sacs.\textsuperscript{18} Although the majority of monozygotic twins develop normally, about 10 to 20 percent will develop abnormal blood vessel connections within the placenta which cause the twins to share blood flow.\textsuperscript{19} If the blood flow is shared asymmetrically one twin will become a "donor" pumping much of the shared blood to the "recipient." This imbalance can lead to intrauterine growth restriction or death of the donor twin as well as other possible complications to the recipient twin. If the condition is unmanaged and the condition severe, both twins have an increased likelihood of dying. If both twins survive, they may experience severe neurologic compromise and organ failure.

Treatment options include amnioreduction to relieve pressure and uterine size, termination of the non-viable twin, or fetoscopic laser ablation of the shared vessels. In nonselective ablation, all vessels crossing the dividing membrane are ablated, whereas selective ablation is limited to certain vessels connecting the fetuses.\textsuperscript{18} Odibo et al. demonstrated that selective laser photocoagulation was a cost effective alternative to amnioreduction and that overall outcomes, including perinatal survival, were improved.\textsuperscript{20}

A related condition is twin reversed arterial perfusion (TRAP) sequence. In this case an acardiac/acephalic twin receives all of its blood supply from a normal twin, or "pump" twin. The increased demand on the heart of the pump twin may result in cardiac failure of the normal twin. The goal of fetal TRAP surgery, as for TTTS twins, is to interrupt blood supply. In this instance the blood supply to the non-viable twin is blocked.

Spinal bifida (myelomeningocele) is a neural tube defect in which the spinal cord forms but a portion of the structures surrounding the spinal cord remain open.\textsuperscript{21} The condition occurs in about 30 to 40 deliveries per 100,000/year in Texas (Figure 1). Although MMC is rarely fatal,
individuals may suffer a range of complications from incontinence to cognitive impairment and paraplegia.

Prior to 2011, standard therapy was, and remains, postnatal surgical closure of the MMC followed by shunting for hydrocephalus if needed. In March 2011, The New England Journal of Medicine published the results of the Management of Myelomeningocele Study (MOMS) — a relatively large randomized trial of prenatal versus postnatal repair of MMC conducted at three maternal-fetal centers. Although the MOMS study was designed to examine results among 200 candidates, it was concluded early because results demonstrated significantly improved outcomes among the experimental (prenatal surgery) group when compared to the postnatal surgery control group. Findings showed that prenatal intervention contributed to a significant reduction in the need for cerebrospinal shunting (a common complication of postnatal MMC repair) and significantly improved locomotor outcomes. The surgery was not without complications. Maternal morbidity and pregnancy complications were more frequent among the prenatal surgery group. Deliveries among the prenatal surgery group occurred earlier, and as a result, a greater number of infants born from this group suffered respiratory distress. As a result

*Data for 2014 are provisional
Source: Birth Defects Epidemiology and Surveillance Branch, Texas Department of State Health Services
of this study, prenatal MMC surgery has become an acceptable alternative for mothers who meet the criteria for fetal repair.

Werner et al. suggest that when compared to postnatal surgeries, prenatal MMC surgery saves over $2 million per 100 cases repaired. Further, approximately 40 fewer newborns require shunts, over 20 fewer neonates need long term care per 100 prenatal surgeries when compared to the same number of postnatal repairs, and motor function among patients with prenatal interventions is significantly improved over postnatal repairs. However, the number of pregnancy complications (uterine rupture and dehiscence) was over 25 percent higher among pregnancies that underwent prenatal MMC repair.23

Measuring Fetal Interventions in Texas

No single information source adequately describes fetal surgical intervention in Texas. Fetal surgeries evaluated in this report have only been practiced in Texas for less than a decade and for a limited number of rare conditions TTTS, MMC open surgeries, and surgeries to correct CDH. Data required to carry out the analyses mandated by H.B. 606 are distributed among various entities and in varying formats. Key data, such as non-Medicaid provider cost reimbursement, are proprietary and may not be available to HHSC. Other data necessary for evaluating postnatal outcomes may be difficult to obtain. Assuming a successful intervention, there may be little need for a mother and child to remain in the proximity of the fetal center. Administrative data use specific medical codes to document procedures and conditions for billing purposes. The code sets that are used may vary among the different data sets making definitive identification of conditions at best difficult or ambiguous. Finally, many of the procedures anticipated by H.B. 606 are limited or new to Medicaid, and some, such as prenatal MMC are not benefits.

This report includes combined data provided by TCH and CMHH on the frequency and type of procedures performed at their facilities from 2012 through 2014. An analysis of HHSC data from 2012 through 2015 of fetoscopic procedures utilized to treat TTTS and surgical procedures required for prenatal treatment of MMC/Spina Bifida is also included. Key THCIC data analyzed by HHSC are only available through September 2015. In addition, some interventions paid for as Medicaid benefits were only made available beginning July 2015.
The information below describes the data sources, limitations, and challenges of identifying and linking the information necessary to achieve the requirements of H.B. 606.

**Data Sources**

HHSC identified four primary data sources to assess conditions that are treatable by fetal surgery and to address the legislation's requirements. These data sources are listed here in order from the least to the most detailed information on fetal surgical procedures:

1) The Texas Birth Defects Registry (BDR). The registry is maintained by the Birth Defects Epidemiology and Surveillance (BDES) Branch at the DSHS. The registry uses active surveillance to collect data from a variety of sources to identify a wide array of congenital anomalies among newborn and older children born in Texas. These data provide baseline information from which we can estimate the potential demand for several of the fetal therapies described in this report.

2) The Texas Hospital Inpatient and Outpatient Discharge Datasets. DSHS collects data on health care activity in Texas hospitals. DSHS requires all hospitals and ambulatory surgical centers (ASCs) except those that are statutorily exempt to submit a standardized administrative claims dataset on inpatient and outpatient discharges to THCIC. The inpatient and outpatient datasets include admission and discharge dates, discharge status, diagnosis and procedure codes, demographics and payer type. The Inpatient and Outpatient Research Data Files include identifiers which enable HHSC to identify and link specific individuals over multiple visits and years. All-payer administrative data potentially allow the comparison of specific therapies by payment type.

3) Medicaid claims and encounters data. The HHSC partners with the Texas Medicaid & Healthcare Partnership (TMHP) to maintain claims and encounters data for services provided to pregnant women participating in the Medicaid program as well as infant and child participants. From these data, HHSC can identify individuals (both pregnant

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ii Exempt hospitals include those located in a county with a population less than 35,000, or those located in a county with a population more than 35,000 and with fewer than 100 licensed hospital beds and not located in an area that is delineated as an urbanized area by the United States Bureau of the Census (Section 108.0025). Exempt hospitals also include hospitals that do not seek insurance payment or government reimbursement (Section 108.009). Type of hospitals included in the data are community hospitals, acute care facility, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, children's or pediatric hospitals, and long term care hospitals
women and children) who received therapies related to the procedures specified in H.B. 606 as well as information on prenatal interventions that impact the fetus. Data consist of demographic variables, diagnoses, procedures and provider reimbursements. Unlike the birth defects registry and hospital discharge data, Medicaid data are limited to eligible, low-income or disabled population.

4) Texas Children's Hospital and Children's Memorial Hermann Hospital Clinical Data. The HHSC has been collaborating with the two Texas fetal centers (both located in Houston) since August 2015 to obtain key information necessary to augment the data available from the Medicaid and THCIC administrative files. These data are provided directly from each center's records and serve as the baseline for any comparisons made in this and subsequent studies. Each center has provided information on individuals who have been evaluated for fetal surgical interventions, the actual numbers of procedures carried out between January 1, 2012 through December 31, 2014, and perinatal outcomes of the procedures. HHSC continues to work with the centers towards acquiring aggregate reimbursement data and long term outcomes.

Case Ascertainment

Each data set available for analysis is derived in a different manner. The Texas fetal centers use a combination of patient registries, billing data (for physicians and hospitals), and chart reviews to identify patients and outcomes. Fetal centers also have information on the severity of the conditions or other factors that determine whether a patient is a candidate for a fetal procedure that is unavailable elsewhere.

Identification of fetal surgeries from Health and Human Services administrative data sources such as hospital discharge data and Medicaid administrative data require characterizing applicable procedure and diagnosis codes into surgery types. International Classification of Diseases, Clinical Modification (ICD-9-CM) Volume 3 includes codes for surgical procedures. Inpatient hospital discharge data use ICD-9-CM procedure codes. Medicaid institutional claims and encounters may also utilize ICD-9-CM procedure codes, however payments for Medicaid benefits are not tied to these codes. The outpatient hospital discharge data use Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System
(HCPCS) codes. Medicaid claims and encounters include CPT and HCPCS codes; payments are based on these if they are a benefit. Table 1 lists the procedure codes, their description and their benefit history in Texas Medicaid.

Tying specific information from the HHS administrative data to the data provided by the fetal centers is challenging. The procedure codes used by fetal centers and physicians may not be specific to any surgery type. For example, the CPT code for "Unlisted fetal invasive procedure" (CPT = 59897) can be used for several procedures of varying complexity. The surgical procedure code for the "Correction of Fetal Defect" (ICD-9-CM Procedure Code = 75.36) is also used to identify fetal surgeries without information on the type or complexity of the procedure. These codes encompass a wide range of interventions, from minimally invasive fetoscopic procedures to open procedures.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Date Procedure Became a Medicaid Benefit</th>
<th>Changes to Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>59072</td>
<td>Umbilical cord occlusion</td>
<td>1/1/2011: Limited to ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
<tr>
<td>59074</td>
<td>Fetal fluid drainage (e.g., vesicocentesis, thoracentesis, paracentesis), including ultrasound guidance</td>
<td>5/1/2005: Benefit for ages 10 - 55 years</td>
<td>none</td>
</tr>
<tr>
<td>59076</td>
<td>Fetal shunt replacement, including ultrasound guidance</td>
<td>5/1/2005: Benefit for ages 10-55 years</td>
<td>none</td>
</tr>
<tr>
<td>59897</td>
<td>Unlisted fetal invasive procedure, including ultrasound guidance, when performed</td>
<td>7/1/2004: Benefit for ages 10-55 years</td>
<td>none</td>
</tr>
</tbody>
</table>

**Healthcare Common Procedure Coding System (HCPCS) Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Date Procedure Became a Medicaid Benefit</th>
<th>Changes to Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2400</td>
<td>Repair, congenital diaphragmatic hernia in the fetus using temporary tracheal occlusion, procedure performed in utero</td>
<td>Not a Benefit</td>
<td>Not applicable</td>
</tr>
<tr>
<td>S2401</td>
<td>Repair, urinary tract obstruction in the fetus, procedure performed in utero</td>
<td>1/1/2011: Benefit for ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
<tr>
<td>S2402</td>
<td>Repair, congenital cystic adenomatoid malformation in the fetus, procedure performed in utero</td>
<td>1/1/2011: Benefit for ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
<tr>
<td>S2403</td>
<td>Repair, extralobar pulmonary sequestration in the fetus, performed in utero</td>
<td>1/1/2011: Benefit for ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
<tr>
<td>S2404</td>
<td>Repair, myelomeningocele in the fetus, procedure performed in utero</td>
<td>Not a Benefit</td>
<td>Not applicable</td>
</tr>
<tr>
<td>S2405</td>
<td>Repair of sacrococcygeal teratoma in the fetus, procedure performed in utero</td>
<td>1/1/2011: Benefit for ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
<tr>
<td>S2409</td>
<td>Repair, congenital malformation of fetus, procedure performed in utero, not otherwise classified</td>
<td>1/1/2011: Benefit for ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
<tr>
<td>S2411</td>
<td>Fetoscopic laser therapy for treatment of twin-to-twin transfusion syndrome</td>
<td>1/1/2011: Benefit for ages 10-20 years</td>
<td>7/1/2015: Expanded to ages 10-55 years</td>
</tr>
</tbody>
</table>

**ICD-9-CM Procedure Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Medicaid payments are not based on ICD-9-CM Procedure Codes; they are informational only.</th>
</tr>
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<tbody>
<tr>
<td>75.31</td>
<td>Amnioscopy</td>
<td></td>
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<tr>
<td>75.36</td>
<td>Correction of Fetal Defect</td>
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To refine estimates of the types of surgery performed, the accompanying ICD-9-CM diagnosis codes are examined. These codes indicate the treated condition and suggest information about corresponding treatments. The principal diagnosis is the condition that is primarily responsible for the patient receiving services. Secondary diagnoses list conditions that are also present at the time of the visit. For the hospital inpatient and outpatient discharge data, there are up to 25 diagnoses (including the principal diagnosis) that can be listed for 1 hospital stay. For Medicaid data, the first 10 diagnoses listed on a claim were examined for potential indicators for fetal surgery.

As with the procedure codes, diagnosis codes can be unspecific or ambiguous used for multiple conditions treatable by fetal surgery. For example, "Other known or suspected fetal abnormality, not elsewhere classified" (ICD-9-CM = 655.83) can indicate conditions that might require a needle-based procedure or a birth defect requiring fetal invasive surgery. Furthermore, diagnosis codes do not indicate the severity of the condition or other factors that may dictate whether a fetal surgery is indicated for the condition.

Data Limitations

Despite the wide array of data available for addressing the requirements of H.B. 606, each information system has limitations due to timeliness or data completeness:

Timeliness - Administrative reporting lags are built into key HHS data systems to ensure completeness specific to each data universe.

- Texas Birth Defects Registry protocols necessitate a lag for the surveillance for staff to monitor many data systems and visit medical facilities, but data are 95 percent complete within 24 months. (Although incomplete, provisional data on 2014 deliveries were made available by the birth defects registry for this report).
- The THCIC inpatient and ambulatory data have an approximately one year lag before they are reported and are released every quarter. These data are currently available through the third quarter of 2015 (July - September).
- Although Medicaid administrative claims and encounters are updated weekly, typically, HHSC analyses of these data must allow at least an eight month lag to allow for all
transactions to be adjudicated and complete. HHSC has chosen to cut off the analysis of Medicaid data at September 30, 2015, for this report. This is because on October 1, 2015, the code set for providers in hospitals changed to the 10th revision of the ICD-10-CM which may affect the reporting of trends and rates.

Data completeness - Each of the data systems utilized for this report were developed for specific purposes; monitoring birth defects, payment for Medicaid services, and enumeration of hospital and ambulatory service utilization. Although overlap of information exists among each system, key components are excluded creating challenges in comparing information from one source to another.

- The TTTS is not a reportable condition monitored by the BDR. Further, less severe instances of TTTS that can be managed without surgical intervention cannot be tabulated for analyses. Statewide estimates of TTTS based on the numbers of twins born each year suggest that only 25 percent of twins are considered candidates for laser ablation (see page 19).
- Birth defects detected and diagnoses that are refined after a child's first birthday are not included in the registry. Diagnoses that are made outside of Texas or in Texas facilities that BDES staff does not access, such as prenatal diagnostic facilities and private physicians' offices are excluded from the registry.
- Although the information claims and encounters contain, such as diagnosis, type and date of service, is useful for this analysis, surveillance is not the intended purpose. This is especially apparent when using Medicaid data to assess birth defects and prenatal surgeries. Since some fetal procedures were not paid Medicaid benefits for all ages until July 2015, surgeries provided before were likely billed under different procedure codes complicating HHSC's ability to assess trends and costs at this time.
- The primary shortcoming of the THCIC data universe is that it only collects charges and not actual hospital costs or provider reimbursement. Further, the inpatient discharge data primarily use ICD-9-CM surgical procedure codes, which do not specifically detail which type of fetal surgery is being performed.
- For both THCIC and Medicaid data, the lack of information about condition severity makes it difficult to compare prenatal surgeries to cases where prenatal surgery did not occur because the cases may not be similar.
Results

Twin-to-twin Transfusion Syndrome

Annually, approximately three percent of all Texas births are twins;\textsuperscript{25} about one-third of these are identical twins. The proportion of twins with monochorionic placentas is about two thirds, and from these approximately 15 percent will be diagnosed with TTTS.\textsuperscript{20} From 2012 through 2014, on average, 12,000 twins were born annually in Texas; approximately 400 twins per year present with TTTS (Table 2). Less than one quarter of the expected number of twins born in Texas with TTTS will undergo laser ablation to correct the defect (Tables 3 and 4).

| Table 2: Expected Number of Twin-to-twin Transfusion cases in Texas, 2012-2014 |
|---------------------------------|----------------|----------------|----------------|
|                                 | 2012   | 2013   | 2014   | Total 2012-2014 |
| Number of Twin Births in Texas  | 11,735 | 12,181 | 12,583 | 36,499          |
| Estimated number Texas resident twins with TTTS | 383    | 398    | 411    | 1,192           |

Source: Department of State Health Services, Center for Health Statistics

The number of actual cases identified by the data available to HHSC is lower than the estimated expected number of TTTS. There will be undetectable cases because of fetal loss as well as cases which are not severe enough to warrant diagnoses or procedures that can be identified within the Medicaid or THCIC data. The number of TTTS surgeries occurring in Texas, as identified by HHS data sources is reported in Table 3.
Table 3: Frequency of Fetal Surgeries for TTTS (HHS Data Sources)

<table>
<thead>
<tr>
<th></th>
<th>THCIC Hospital Discharge Data</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Total 2012-2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
<td>2013</td>
<td>2014</td>
<td>2015¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inpatient²</td>
<td>20</td>
<td>17</td>
<td>31</td>
<td>20</td>
<td></td>
<td>68</td>
</tr>
<tr>
<td>Outpatient³</td>
<td>59</td>
<td>70</td>
<td>79</td>
<td>65</td>
<td></td>
<td>208</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>79</td>
<td>87</td>
<td>110</td>
<td>85</td>
<td></td>
<td>276</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Medicaid Claims and Encounters Data</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Total 2012-2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
<td>2013</td>
<td>2014</td>
<td>2015¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inpatient claims/encounters²</td>
<td>26</td>
<td>25</td>
<td>20</td>
<td>11</td>
<td></td>
<td>82</td>
</tr>
<tr>
<td>HCPCS code⁴</td>
<td>26</td>
<td>33</td>
<td>31</td>
<td>19</td>
<td></td>
<td>109</td>
</tr>
<tr>
<td><strong>Total⁵</strong></td>
<td>52</td>
<td>58</td>
<td>51</td>
<td>30</td>
<td></td>
<td>191</td>
</tr>
</tbody>
</table>

Notes:
1 Data do not include 4th quarter of 2015. In October 2016, medical coding and billing for health services were updated from ICD-9 to ICD-10. Because of the code set changes, the cut-off date for current analysis of HHS data is September 30, 2015.
2 Inpatient fetal surgeries are identified using ICD-9 Procedure Codes 75.36 (Fetal Invasive Procedure) or 75.31 (Amnioscopy) combined with one of the following ICD-9 Diagnosis Codes:
   - 678.03 (Twin-to-twin Transfusion Syndrome);
   - 663.83 (Other umbilical cord complications, velementous cord) or 762.3 (Placental transfusion syndrome affecting fetus), when combined with multiple gestation
   - V91.00 - V91.02, V91.11 (Twin or triplet gestation with monochorionic or unspecified number of placenta)
3 The number of uniquely identified women discharged from the fetal centers with a diagnosis of TTTS and a revenue code related to surgery (Revenue Code = 0360, 0361, or 0369)
4 Paid claims for HCPCS code = S2411 or 59897 accompanied by a diagnosis of multiple gestation or TTTS
5 Medicaid recipients may have been identified using both definitions; the total count does not represent distinct individuals.

Sources:
Texas Hospital Inpatient Discharge Research Data file, [Quarter 1, 2012 - Quarter 3, 2015]. Texas Department of State Health Services, Center for Health Statistics, Austin, Texas. [November 1, 2016]. Health and Human Services Commission (AHQP Claims Universe, TMHP; Encounters Best Picture Universe, TMHP)

Quintero et al.²⁶ noted a relationship between the severity of perinatal morbidity and twin survival based on a five stage progression of sonographic and clinical characteristics of TTTS pregnancies. Stage I pregnancies were the least severe and rarely require surgical intervention whereas Stage V TTTS pregnancies were characterized by significant fetal and placental abnormalities; often with the death of one or both twins. By identifying the Quintero stage of
TTTS during twin development, the maternal-fetal team can monitor the severity of the condition and the appropriate intervention to manage the outcome of the pregnancy.

Twin survival among infants treated in Texas was high after laser ablation; between 2012 through 2014 among all laser ablations performed by both CMHH and TCH, 71 percent of both twins survived and in 18 percent of all procedures at least 1 twin survived.

Surgeries that correct TTTS are performed on the more severe cases, between Stage II to Stage IV - and that in itself is a fraction of the total number of TTTS pregnancies. Less severe pregnancies can be clinically managed and the mother may never go beyond her doctor or maternal-fetal specialist. Still, from 2012 through 2014, approximately half of all women evaluated by the two fetal centers for TTTS were treated by laser ablation. The reported number of TTTS cases reported by the fetal centers and their distribution by Quintero stage is shown in Table 4 and depicted in Figures 2 and 3.

Table 4: Frequency of Fetal Surgeries for TTTS (Fetal Center Data)

<table>
<thead>
<tr>
<th>Annual Average 2012-2014</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultations</td>
<td>198</td>
</tr>
<tr>
<td>Selective Laser Photocoagulation</td>
<td>95</td>
</tr>
<tr>
<td>By Quintero stage</td>
<td></td>
</tr>
<tr>
<td>Stage II</td>
<td>21</td>
</tr>
<tr>
<td>Stage III</td>
<td>40</td>
</tr>
<tr>
<td>Stage IV</td>
<td>22</td>
</tr>
<tr>
<td>Radiofrequency Ablation</td>
<td>10</td>
</tr>
<tr>
<td>Bipolar Cord Coagulation</td>
<td>1</td>
</tr>
</tbody>
</table>

TTTS Pregnancies outcome (% Survival to live birth)

|                                |          |
|                                | 71%      |
| % both twins survive           |          |
| % neither twin survives        | 11%      |

Source: Texas Children's Hospital (unpublished data)
Children's Memorial Hermann Hospital (unpublished data)
Figure 2: Selective Laser Photocoagulation by Quintero Stage, Fetal Centers, 2012-2014

Source: Texas Children's Hospital (unpublished data)
Children's Memorial Hermann Hospital (unpublished data)

Figure 3: Twin Survival After Selective Laser Photocoagulation at Texas Fetal Centers, 2012-2014

Source: Texas Children's Hospital (unpublished data)
Children's Memorial Hermann Hospital (unpublished data)
Spina Bifida

According to the Texas Birth Defects registry, approximately 150 cases of spina bifida occur per year (Figure 1). Cases include live births, spontaneous fetal deaths, and induced pregnancy terminations. Ninety percent of spina bifida (without anencephaly) cases delivered during 1999-2013 were live births, 3.84 percent spontaneous fetal deaths, 5.84 percent induced pregnancy terminations, and 0.14 percent unspecified non-live births.5

The majority of spina bifida cases are post-natal repairs; maternal or fetal complications prevent prenatal surgery on the fetus. Ninety-two percent of spina bifida surgeries among neonates, identified from hospital inpatient stays in which the birth occurred or stays in which the infant was transferred to another facility on their birth date, were performed within two days of delivery (Table 5).

Table 5: Distinct count of inpatient discharges for newborn infants1 who have spinal surgery2, by day of spinal surgery, 2012 - 2015

<table>
<thead>
<tr>
<th>Days since birth</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ 0</td>
<td>12</td>
<td>17</td>
<td>10</td>
<td>9</td>
<td>48</td>
</tr>
<tr>
<td>+ 1</td>
<td>42</td>
<td>30</td>
<td>34</td>
<td>17</td>
<td>123</td>
</tr>
<tr>
<td>+ 2</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>+ 3</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>+ 4</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>≥ 5</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>65</strong></td>
<td><strong>53</strong></td>
<td><strong>57</strong></td>
<td><strong>30</strong></td>
<td><strong>205</strong></td>
</tr>
</tbody>
</table>

Notes:

1 Discharges for newly born infants were identified from hospital inpatient stays in which the birth occurred - defined as having the admission diagnosis of live birth (ICD-9-CM = V30 - V39) - or inpatient stays where the admission date is the same date as the patient date-of-birth. Patient transfers after their birth date are not included.

2 Spinal surgery discharges were defined as inpatient stays where the principal procedure code is "Operations on Spinal Cord and Spinal Canal Structures" (ICD-9-CM Procedure Code = 03.xx)

Source:
Texas Hospital Inpatient Discharge Research Data file, [Quarter 1, 2012 - Quarter 3, 2015]. Texas Department of State Health Services, Center for Health Statistics, Austin, Texas. [November 1, 2016].
Table 6: Frequency of Fetal Surgeries for Spina Bifida (Fetal Center Data)  

<table>
<thead>
<tr>
<th></th>
<th>Annual Average 2012-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consults</td>
<td>53</td>
</tr>
<tr>
<td>Candidates for repair</td>
<td>20</td>
</tr>
<tr>
<td>Prenatal repair</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: Texas Children's Hospital (unpublished data)  
Children's Memorial Hermann Hospital (unpublished data)

From 2012 through 2014 the 2 fetal centers evaluated an average of 50 candidates per year for prenatal MMC surgery. Of these, fewer than 40 percent were considered surgical candidates. Three quarters of qualified candidates (approximately 15 per year) underwent prenatal surgery to correct the condition. (Table 6). The number of MMC surgeries occurring in Texas, as identified by HHS data sources is reported in Table 7.

Table 7: Frequency of Fetal Surgeries for MMC/Spina Bifida (HHS Data)

<table>
<thead>
<tr>
<th>Data Source</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>THCIC Hospital Discharge Data&lt;sup&gt;2&lt;/sup&gt;</td>
<td>4</td>
<td>13</td>
<td>14</td>
<td>17</td>
<td>31</td>
</tr>
<tr>
<td>Medicaid HCPCS code&lt;sup&gt;3&lt;/sup&gt;</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>16</td>
</tr>
</tbody>
</table>

Notes:
<sup>1</sup> Data do not include 4<sup>th</sup> quarter of 2015.
<sup>2</sup> Inpatient fetal surgeries are identified using ICD-9 Procedure Codes 75.36 (Fetal Invasive Procedure) or 75.31 (Amnioscopy) combined with an ICD-9 Diagnosis Codes of 655.03 (CNS malformation of fetus)
<sup>3</sup> Paid claims for HCPCS code = S2404 or 59897 accompanied by a diagnosis of 655.03 (CNS malformation of fetus)

Sources:
Texas Hospital Inpatient Discharge Research Data file, [Quarter 1, 2012 - Quarter 3, 2015]. Texas Department of State Health Services, Center for Health Statistics, Austin, Texas. [November 1, 2016]. Health and Human Services Commission (AHQP Claims Universe, TMHP; Encounters Best Picture Universe, TMHP)

Data from the Texas fetal centers suggest that, for the MMC surgeries they perform, infants with postnatal repairs are three times more likely (36.9 percent) than infants who underwent prenatal MMC repairs to require shunts (11.4 percent). However, these data only take into account postnatal surgeries that occur at CMHH and TCH, the fraction of infants who experienced postnatal MMC repair and require shunts is unknown from the data we currently have.
Other fetal procedures

House Bill 606 also directs HHSC to evaluate "any other type of prenatal surgical procedure that is or becomes the standard of practice for treating a birth defect." In addition to prenatal interventions for TTTS and MMC, both fetal centers report that fetal endoscopic tracheal occlusion (FETO) is a prospective, if not current, candidate for surgical intervention for treatment of severe CDH.

Congenital diaphragmatic hernia occurs when the fetal diaphragm does not completely develop and a small opening remains present which abdominal organs can move into the thorax. In severe cases lung development is impacted. Infant mortality can be as high as approximately 50 percent.

There are approximately 100 cases of CDH in Texas per year (Figure 4). Treatments for the most severe CDH cases are performed in-utero using fetoscopy to place a balloon in the fetal trachea, blocking amniotic fluid in the lungs to help them develop and increase survival at birth. However, CDH surgeries in Texas are uncommon at this time and clinical trials are ongoing.27,28 Congenital diaphragmatic hernia repairs, although not routine, are currently performed by TCH as part of an investigational pilot study with approximately four interventions per year from 2012 through 2014.29 Children's Memorial Hermann Hospital began performing CDH repairs beginning in 2016 and has completed three procedures at the time of this report.30
Summary

This report provided a preliminary overview outlining recent trends of emerging fetal surgical interventions currently practiced in Texas. The interventions specified by H.B. 606 included 1) fetoscopic placental laser ablation which is utilized to correct twin-twin-transfusion syndrome; 2) maternal-fetal surgery which includes a number of surgical interventions that impact both the mother and fetus. Open surgical repair to correct complications of spina bifida is becoming a standard practice; and 3) any other type of prenatal surgical procedure that is or becomes the standard of practice for treating a birth defect. These include FETO interventions to correct congenital diaphragmatic hernia and fetoscopic repair of MMC.

In addition to identifying these procedures H.B. 606 directs the HHSC to examine 3 key aspects of prenatal surgical procedures; 1) an analysis of costs comparing procedures by payer, 2) potential cost differentials that may occur as a result of pre- versus post-natal interventions and 3) and an analysis of survival, outcomes and quality of life for individuals who were treated pre-versus post-natally.

Source: Birth Defects Epidemiology and Surveillance Branch, Texas Department of State Health Services
Evaluation of Fetal Surgery Trends

Two procedures are becoming standard surgical practice; laser ablation to treat TTTS and open fetal surgery to correct MMC or spina bifida. The first laser ablation surgeries began in the late 1980's. Texas Children's Hospital has been performing these surgeries since 2007 and CMHH has been providing this surgery since 2011. The TTTS fetal intervention findings include:

- Approximately half of all pregnancies evaluated for TTTS undergo the surgery.
- Approximately 100 TTTS procedures a year are performed in Texas.
- Over 70 percent of TTTS surgeries result in both twins surviving, another 20 percent successfully deliver one of the twins.

Surgery to correct MMC has only become a recognized surgical alternative since 2011. Both Texas fetal centers began offering prenatal MMC interventions beginning in 2011. Between 2012 through 2014, approximately 15 MMC surgeries per year have been performed in Texas. MMC fetal intervention findings include:

- One-third of pregnancies evaluated for prenatal MMC surgery undergo the surgery (approximately 15 per year).
- The number of prenatal MMC surgeries has steadily increased since 2012 whereas there has been a small, but concomitant, decline in postnatal surgeries.
- Preliminary outcomes data suggest that only 10 percent of infants treated prenatally require shunts within the first year of life. Over one-third of infants with post-natal repairs will require shunting to prevent spinal cord fluid buildup.

Several additional fetal interventions are undergoing investigational trials. These include fetoscopic repair of MMC, fetal cardiac interventions, and FETO for surgical intervention for treatment of severe CDH. Of these, CDH repair is considered by both CMHH and TCH as an intervention that will soon become a standard of care.

Evaluation of Fetal Surgery Costs

The examination of cost differences by payer and by timing of the intervention require information on actual cost reimbursements to health entities responsible for providing these
services. Insurance and health plan payer reimbursements are negotiated individually by health care providers and may be proprietary, limiting the availability of cost data for analyses. We are working with CMHH and TCH fetal centers to obtain summary reimbursement information for the procedures examined in this report. As of the time that this report was being prepared, our requests for these data are still under consideration by both centers.

Cost data for the Medicaid program, including the interventions addressed for this report are limited. Prior to July 2015 most procedures that identify specific physician services for fetal surgeries were not a paid benefit for mothers over age 21 and as of November 2016, in utero surgery to correct MMC or CDH are not Medicaid benefits. Therefore, actual costs of the interventions addressed by the requirements of this report would be limited to Medicaid clients and only if the procedure has been available as a Medicaid benefit.

**Evaluation of Fetal Surgery Outcomes**

The HHSC's ability to assess postnatal outcomes depends, in part, on the type of intervention performed and the fetal center's ability to monitor its patients over time. Both Texas fetal centers are able to report perinatal survival, but there is significant loss to follow-up among patients who don't require postnatal care. For example, with TTTS, while it may be critical for certain patients to be closely monitored prior and immediately post-surgery, in many cases delivery and postnatal care can be accomplished where the patient resides. Although prenatal surgeries to correct MMC defects may require long-term monitoring and evaluation, only a half-decade of MMC prenatal intervention data are available for Texas and the average annual number of procedures is 15. Because most of the individuals will be discharged to areas of the state - or elsewhere - away from the fetal centers, many of these individuals may also be lost to follow-up. Further, comparisons cannot be made for Medicaid at this time because in utero MMC surgery is not currently a covered benefit.

**Next Steps**

Given these limitations, HHSC plans additional reports. An analysis to be published in 2017 will examine cost differences and outcomes in addition to more complete enumeration of procedures. The HHSC will continue to work with the two Texas fetal centers to obtain summary
reimbursement cost data. We will also utilize THCIC charge data to determine if these data provide insights on payer and surgical timing cost differentials.

A second report tentatively scheduled for 2019 will examine longer term trends and post-natal outcomes by identifying individuals who have received fetal and postnatal surgeries and monitoring their health status and costs using Medicaid and THCIC administrative data available to HHSC, and follow them for up to five years after the intervention was performed.
References

1 "Birth defect" has the meaning assigned by Chapter 87, Section 87.001 of the Texas Health and Safety Code.


4 established under Section 241.187, H.B. 2131, 84th Legislature, Regular session, 2015


7 Moise, K. (2016). What’s on the Horizon for Fetal Surgery? Presentation to the University of Texas at Austin, Dell Medical School. https://www.youtube.com/watch?v=pwKHcV5jl30


11 Fearon, D. Ethics of Fetal Medicine. med.brown.edu/pedisurg/Fetal/Seminar/SyllabusPages/2Ethics.pdf accessed 11/1/16


13 Kenneth Moise, M.D., *Co-Director, The Fetal Center, CMHH* [Personal Communication]
15 Haley Jackson, M.P.H. Senior Project Manager, Women's Services, Texas Children's Hospital. [Personal Communication].
24 Chapter 108 of the Texas Health and Safety Code; Chapter 421 of Title 25, Part 1 of the Texas Administrative Code.
27 Fetosopic Endoluminal Tracheal Occlusion (FETO) for Congenital Diaphragm Hernia https://clinicaltrials.gov/ct2/show/study/NCT02596802
29 Haley Jackson, M.P.H. Senior Project Manager, Women's Services, Texas Children's Hospital. [Personal Communication].
30 Courtney Rupp, Practice Manager, The Fetal Center, Children's Memorial Hermann Hospital [Personal Communication]