

Increasing State Health Agency Capacity to Improve 17P Utilization

Executive Summary

Preterm birth increases risk for infant health problems, long-term developmental issues, and death compared to infants who are born full term. Progesterone supplementation is one of the few interventions that have been found to effectively prevent preterm birth among women with known risk factors. A synthetic form of progesterone administered through weekly injections, 17 alpha-hydroxyprogesterone caproate (17P), has been found to reduce the recurrence of preterm birth by 33 percent. However, multiple barriers and challenges prevent some eligible women from receiving treatment. State health departments are partnering with various stakeholders to improve access to 17P by improving identification of 17P-eligible women, collaborating with Medicaid agencies, enhancing the 17P ordering and administration process, increasing provider and patient education about the importance of 17P in preventing preterm birth, and improving state 17P reimbursement policies.

Progesterone and Preterm Birth

Progesterone is a steroid hormone that plays an important role in preparing the uterus for pregnancy and maintaining a uterine environment that supports fetal growth once pregnancy is achieved. Pooled data suggest that, among women with a history of preterm birth (PTB) or with premature cervical shortening, progesterone treatments can reduce adverse outcomes like respiratory distress syndrome and admission to the neonatal intensive care unit by 43 percent, neonatal death by 52 percent, and neonatal intensive care unit admissions by 61 percent.¹ PTB, considered birth before 37 weeks gestation, increases the risk for infant health problems, long-term developmental issues, and death compared to infants who are born full term.²

- 17P has been shown to reduce the recurrence of preterm birth by 33 percent.
- Despite strong evidence supporting the use of progesterone injections like 17P, a number of challenges prevent eligible women from receiving treatment.

Starting with 2014 data, the National Center for Health Statistics changed the way PTB is measured, from the last menstrual period to obstetric estimate.³ In 2014, the U.S. PTB rate was 9.6 percent.⁴ Both the last menstrual period and obstetric estimate measures show that rates of PTB have declined since 2006, and this current rate achieves the Healthy People 2020 goal for PTB of 11.4 percent or less.⁵ Yet nearly 1 in 10 infants in the U.S. are still born preterm. While the cause of PTB is not always known, women who have already experienced PTB are more likely to have another preterm infant compared to women who have not. Despite general declines in PTB, marked disparities continue to exist. In fact, the 2013 PTB rate was significantly higher among African American infants (16.3 percent) than among Hispanic infants (11.3 percent) or non-Hispanic white infants (10.2 percent).⁶ Other PTB risk factors include carrying more than one baby at a time; problems with the uterus or cervix, including premature cervical shortening; maternal chronic health conditions such as high blood pressure, diabetes, and clotting disorders; certain infections during pregnancy; and smoking, alcohol use, or illicit drug use

during pregnancy.⁷ Preventing PTB is critical to supporting long-term infant health and development and promoting health equity. It is also an important avenue to address rising healthcare costs. PTB-related health expenses cost the United States healthcare system more than \$26 billion each year.⁸

To date, only a few interventions have been found to effectively prevent PTB among women with known risk factors. These interventions include eliminating early elective deliveries through non-medically indicated caesarean delivery and reducing induced labor, limiting multiple embryo transfers through assisted reproductive technology, promoting maternal smoking cessation, encouraging cervical cerclage (a minor procedure that stitches closed the opening of the cervix) where appropriate, and increasing access to progesterone supplementation such as 17P and vaginal progesterone.⁹

In 2012, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal and Fetal Medicine (SMFM) issued updated clinical practice guidelines for PTB risk screening and evidence-based progesterone use to prevent PTB.^{10,11} The guidelines strongly recommend using progesterone supplementation for singleton pregnancies where women experienced prior spontaneous PTBs, and vaginal progesterone for singleton pregnancies diagnosed mid-pregnancy with a short cervical length and no history of spontaneous PTB. The guidelines do not recommend progesterone treatment for women with singleton pregnancies, no history of PTB and normal or unknown cervical length, multiples pregnancies regardless of cervical length, or pregnancies with symptoms of preterm labor or premature membrane rupture, regardless of cervical length.¹²

What is 17P?

The synthetic form of progesterone known as 17P is administered through weekly injections beginning at 16-21 weeks gestation until delivery. It is available only by prescription and is intended for use among women with a singleton pregnancy and history of PTB. Among these women, 17P has been shown to reduce the recurrence of PTB by 33 percent.^{13,14} Each year, approximately 133,000 women are eligible for treatment with 17P, yet just a fraction of these women actually receive this treatment. For example, in Louisiana, just five percent of women who are eligible for 17P receive the drug.^{15,16} One study found that, nationwide, 30 percent of women eligible for 17P either receive progesterone treatment that does not align with SMFM guidance, or receive no progesterone supplementation at all.¹⁷

17P is available in two formulations. The FDA-approved injection, known by the trade name Makena, is marketed by Lumara Health (previously Ther-Rx). 17P may also be available in a non-FDA approved injection through specialty compounding pharmacies that can customize drugs to meet the specific needs of individual patients.

What is Vaginal Progesterone?

Vaginal progesterone is available as a suppository, capsule, or gel, and is used to prevent PTB in women who have a singleton pregnancy and premature cervical shortening in the second trimester with no history of PTB. Women with a short cervix have a 50 percent chance of experiencing PTB.¹⁸

The ACOG and SMFM clinical guidelines recommending vaginal progesterone were issued in 2012. Although FDA has approved vaginal progesterone products for other uses, including assisted

reproductive technology, vaginal progesterone products have not yet been FDA-approved for PTB prevention. However there is discussion among practitioners about the appropriate use of vaginal progesterone for this purpose.^{19, 20} Clinical practice varies, and some practitioners are prescribing vaginal progesterone to prevent PTB in accordance with the ACOG and SMFM guidelines. There is precedence for this level of care: in fact, many drugs are regularly prescribed during pregnancy without specific label indication, such as sulfate for pre-eclampsia.²¹ State health agencies, health plans, providers, and other partners can explore and collaborate to increase provider awareness of the guidelines, establish and strengthen cervical length screening systems, establish policies covering screening and treatment, and ensure availability of the drug for appropriate patients. Still, at this time, only Makena has been approved by the FDA specifically to prevent PTB.

Availability and Access Challenges

Despite the strong evidence supporting 17P use, a number of challenges prevent some eligible women from receiving treatment.

Cost, Safety, and Quality

Medicaid Health Plans of America encourages Medicaid health plans to adopt evidence-based use of progesterone to prevent preterm birth.²² However, the price of Makena poses a budgetary challenge for some states. The cost of Makena varies by state, and Lumara Health negotiates price directly with state Medicaid agencies to address these cost barriers. However, some states are choosing to cover compounded formulations, which tend to be significantly less expensive than Makena. Private insurers' coverage policies for 17P also vary significantly: some support the use of compounded versions of the drug but also reimburse providers who choose to prescribe Makena, while others cover both Makena and compounded formulations.²³

The Drug Quality and Security Act of 2013 (DQSA) increased regulatory oversight of compounding of human drugs. Compounded drug products are not FDA approved, which means that they do not undergo premarket FDA review of safety, effectiveness, or manufacturing quality. The Federal Food, Drug, and Cosmetic Act, as amended by DQSA, limits the circumstances under which a drug may be legally compounded if there is an FDA-approved product available. Specifically, under section 503A of the law, a pharmacist may not compound, regularly or in inordinate amounts, any drug product that is essentially a copy of a commercially available drug product. Section 503A also states that a drug must be compounded based on the receipt of a valid prescription for an identified individual patient. Under section 503B of the law, a compounder registered with FDA as an outsourcing facility may not compound any drug product that is essentially a copy of one or more approved drug products. A drug product compounded by an outsourcing facility is not "essentially a copy" if the FDA-approved drug product appears on FDA's drug shortage list at the time of compounding, distributing, and dispensing. An outsourcing facility is not required to obtain prescriptions for identified individual patients for its compounded drugs, although it may do so.

States considering using compounded 17P or compounded vaginal progesterone should understand these legal limitations, and it is suggested that the state board of pharmacy be consulted to determine the level of state oversight and the compounder's compliance record. States may also consult FDA's

[website](#) for more information on 17P compounding, a list of specific compounders, and other details about FDA's activities implementing DQSA.^{24,25}

Ensuring Adherence to Treatment

Once 17P-eligible women are identified, they and their providers may face challenges to successful 17P treatment. Some of these challenges are logistical, including ordering, procuring, stocking, and storing the injections, and billing and payment. Because 17P is administered as a series of injections requiring weekly office visits, ensuring adherence to the treatment plan can also be challenging. Providing patients with information on the importance of consistent, timely treatment and also actively working with them to address barriers to receiving the injections can help. For example, health plans can use case managers to help increase attendance at prenatal visits. Eliminating other barriers by helping patients with transportation issues and ensuring that they do not need to go to a pharmacy to pick up the injection before their office visits may help increase adherence. Local health departments can also partner with clinics to support quality case management and patient-centered care to ensure completion of the full course of treatment. Effectively addressing these challenges will require partnerships and open, consistent communication between physician leaders, Medicaid agencies, private insurers, managed care networks, public health agencies, and patients.²⁶

State and Territorial Health Agencies' Role in Promoting 17P Access and Use, and Steps Taken

State and territorial health agencies are uniquely positioned to take a leadership role in promoting access to and use of 17P, and are currently engaging in activities to create meaningful systems changes to increase 17P use.

Leveraging Data to Improve Screening and Identification of Eligible Women

Many pregnant women, particularly in the Medicaid population, first seek prenatal care after the gestational age indicated for PTB risk screening and 17P treatment. When women do present for prenatal care early in their pregnancy, they may not be aware that a prior PTB increases their risk for a second PTB, and therefore may not bring this to the attention of their physician. As the following state examples show, using data to promote early identification of pregnant women is critical to expanding risk screening and connecting women who are appropriate for 17P to case management and enhanced clinical and community services:²⁷

By improving identification of 17P-eligible women, collaborating with Medicaid agencies, enhancing the ordering and administration process, improving education, and partnering with key stakeholders, state health agencies are increasing access to 17P for eligible women across the country.

- In September 2014, **Louisiana** linked its vital records data with its statewide Medicaid data. A weekly report of women who have had a previous PTB and are potentially eligible for 17P, is generated from these linked records. This list is shared with Medicaid managed care plans and helps to ensure

that these women are easily identified upon registering with their plan, which allows plans to conduct immediate outreach.

- In **North Carolina**, the [Pregnancy Medical Home](#) program through Community Care of North Carolina includes a focus on increasing screening for 17P eligibility as well as case management for women with Medicaid who are receiving 17P treatment.
- In 2013, the **Ohio** Perinatal Quality Collaborative (OPQC) initiated the statewide Progesterone Project to promote identification and treatment for women with a history of PTB and those identified as having a short cervix on ultrasound in the current pregnancy. OPQC is working with providers to identify eligible women through increased use of data from obstetrical history screening tests. OPQC also provides educational materials to prenatal caregivers including physicians, nurses, and pharmacists about the social and medical risk factors for PTB to improve identification of progesterone-eligible women.
- In **Texas**, the Better Birth Outcomes workgroup, a partnership between the Health and Human Services Commission (Texas' state Medicaid agency) and the Department of State Health Services, agreed to provide Medicaid managed care plans access to birth records and historical claims data for all women entering the Medicaid program. This data sharing began in August 2014 and allows for immediate identification of 17P-eligible women. Managed care contracts require plans to report quarterly on both birth volume and the number of clients that started 17P treatment.

Working with Medicaid

Medicaid coverage for 17P is determined separately by each state Medicaid agency. Nationwide, 45 percent of all births are covered by Medicaid, making this publically financed payer an indispensable partner in the pursuit of increased 17P utilization.²⁸ Many states credit their relationship with Medicaid as an essential component of their efforts to increase access to 17P:

- **Iowa** credits the establishment of a new Medicaid code to administer 17P in clinics funded by state Title V Maternal and Child Health programs in part to the existing relationship between the Iowa Department of Public Health and the state's Medicaid agency. This relationship, built upon mutual respect, allows the two agencies to have continual discussions on ways to increase access to 17P for Medicaid-eligible women.
- **Louisiana** is the first state to create a progesterone pay for performance measure for Medicaid managed care plans. Louisiana's Medicaid managed care plans must now increase the percent of eligible women receiving 17P from the current 5 percent requirement to 20 percent. Plans have \$2 million at stake through the new measures, and could lose up to \$250,000 if they do not meet the progesterone-specific goal.
- The **Ohio** Perinatal Quality Collaborative is working with Ohio Medicaid, Medicaid managed care companies, and pharmacies and manufacturers to reduce financial barriers to 17P.

Easing the Ordering Process to Increase 17P Availability

Ordering 17P to a clinic is not as simple as ordering more common medications like antibiotics or allergy prescriptions: it can be complicated, costly, and time-consuming for providers. Some managed care organizations within the same state will each require the use of a different form, creating additional paperwork for providers. Lumara Health offers assistance to state Medicaid agencies and their contracted managed care organizations regarding the ordering and adjudication process to address this challenge, but additional guidance and resources may be needed to help providers and patients

understand how to obtain and bill for 17P. Lumara Health's [website](#) also includes information and tools to help providers order Makena.

- The **Louisiana** Department of Health and Hospitals' Birth Outcomes Initiative and the Louisiana Hospital Association have partnered to improve access to 17P and streamline the ordering process through the [17P Louisiana Resource Center](#) website. The website includes a section called "How to Order 17P" and includes specific instructions for individual health plans, including information for Medicaid and uninsured patients. Hoping to incentivize providers to order and administer 17P, Louisiana is working to increase the reimbursement rate for compounded 17P. Louisiana Medicaid covers both Makena and compounded 17P to make it easier for physicians to prescribe the drug when needed.
- The **Ohio** Perinatal Quality Collaborative successfully worked with medical directors and pharmacists from Medicaid managed care plans to remove the requirement for prior authorizations for all progesterone products, including compounded 17P, when available.
- The **South Carolina** Birth Outcomes Initiative (SCBOI) developed the [Universal 17P Authorization Form](#), which allows physicians to order either Makena or compounded 17P using the same form. The form is used for all managed care plans in the state, and clearly indicates that the decision to prescribe either Makena or compounded 17P is in the hands of the physician. Some compounding pharmacies in the state have stopped producing the compounded product, so if the compounded product is not available when prescribed, Medicaid managed care plans must pay for Makena instead.
- **Texas** simplified the 17P ordering process by amending the pharmacy benefit prior authorization requirement. This change streamlines the process for both Makena and compounded 17P formulations. Managed Medicaid plans must therefore either adopt the state's prior authorization requirement or create a simpler authorization.

Improving 17P Delivery and Administration

Clinicians administer 17P through a series of injections, requiring weekly office visits and creating barriers for many eligible women related to transportation, child care, work, and other logistical challenges. Home administration of 17P by qualified individuals can help eliminate such barriers for women struggling with transportation or time to get to physicians' offices. However, obstacles to home administration exist, including the limited number of allowed home visits under Medicaid, Medicaid codes that are associated with a length of time, and unbillable travel time to and from a patient's home.

- In **Iowa**, Title V Maternal and Child Health agencies are Medicaid providers and can bill for home administration of 17P to Medicaid-eligible women. Because home administration of 17P happens relatively quickly, and Iowa Medicaid uses a home visit timed code with a 31-minute minimum visit, 17P administrations given at home were often not being reimbursed by Medicaid. Iowa Department of Public Health worked with the state's Medicaid agency to set up a new code that allows state Title V agencies and clinics to bill for 17P at a clinic setting, such as a Special Supplemental Nutrition Program for Women, Infants, and Children clinic, where women already receive services from the Title V program. Medicaid also reimburses a woman's transportation to these clinic appointments, as well as care coordination, thus improving the administration of 17P for Medicaid eligible women in the state.

- In **Louisiana** all risk-bearing Medicaid managed care plans in the state now cover home administration of 17P. This practice has more than quadrupled 17P use for Medicaid patients in the state.
- **South Carolina** managed care plans contract with an organization, Alere, which offers 17P home administration. However, Alere uses a bundled code for home administration of 17P, which means that the state cannot accurately track how much Makena is used or how much of the compounded product is being administered. The state is working on modifications to the system that will allow it to better understand this data.

Provider and Patient Education

Providers play a critical role in educating women about 17P and its ability to prevent subsequent PTB, and sharing evidence with providers supporting 17P use for appropriate patients and information about its availability may help identify eligible women. Providers also need to be aware of reimbursement policies in their states so that they can appropriately prescribe 17P. Several states have taken steps to educate providers and patients about 17P to further these goals:

- **Iowa** is planning regional meetings throughout the state to talk to providers about the availability of Medicaid reimbursement for 17P administration for Medicaid-eligible women. Iowa is also working with the March of Dimes to distribute patient education materials to Neonatal Intensive Care discharge coordinators to educate women who have recently experienced PTB and help them understand how progesterone can reduce their risk of future PTB.
- **Louisiana** partnered with the Louisiana Hospital Association to conduct provider education throughout the state to ensure that providers were aware of the state's incentives for 17P administration. Louisiana's 17P efforts has led Lammico, a lead malpractice insurer in the state, to create [free continuing medical education](#) for providers on all forms of progesterone, allowing them to get 10 percent off their annual malpractice dues.
- Physician champions who are part of **North Carolina's** Pregnancy Medical Home program play an important role in educating their peers about 17P consensus practice on [clinical pathways](#). The program holds webinars and in-person meetings to inform clinicians about the pathways and their implementation, and the state also provides clinicians with [patient education brochures](#) in English and Spanish so that they can better explain 17P treatment to eligible mothers and families.
- In **Ohio**, OPQC has begun to engage practitioners throughout the state through in-person meetings. OPQC members provide physicians with [patient education materials](#) and direct sonographers to credentialing organizations. OPQC is also working with physician offices by monitoring the number of women delivering prematurely and how many of those women are receiving progesterone.
- Through a grant funded by the March of Dimes, the Medical University of **South Carolina** has also made great efforts to educate providers on appropriate use and access to 17P through the [Progesterone Outreach Program](#). This project was funded for three years, 2009-2011, and its activities reached more than 1,150 perinatal professionals.
- The **Texas** perinatal quality collaborative hosted a Grand Rounds on 17P, "Healthy Texas Babies: prevention of subsequent preterm deliveries in high-risk OB patients 17P" to support 17P provider education.

Partnerships

Partnerships represent important opportunities for state health departments to leverage outside organizations' expertise. State health agency staff consistently mention partnerships with other governmental agencies and state and local groups when asked about important components of success in increasing 17P access and use:

- **Iowa** credits the positive relationship with Medicaid for the establishment of a new Medicaid code allowing for 17P administration in Title V Maternal and Child Health clinics.
- **North Carolina** stressed the need for positive relationships among payers, healthcare providers, clinic managers, 17P distributors, public health leaders and community organizations. The University of North Carolina at Chapel Hill's Center for Maternal and Infant Health, the North Carolina Division of Public Health, the North Carolina Perinatal Health Committee of the Child Fatality Task Force, and the North Carolina Division of Medical Assistance have worked collaboratively to prioritize access to 17P in the state. These partners have also worked closely with pharmacies to improve 17P access and to serve all women. North Carolina recognizes that it can only realize the full benefit of 17P treatment for mothers and babies through a collective approach. The Center for Maternal and Infant Health convened a major meeting of stakeholders in September 2015 to review a wealth of new data, including interviews with mothers and case managers, and develop strategies to improve access and treatment completion for all 17P-eligible women.
- Much of the work to increase access to 17P and progesterone in **Ohio** is happening through the Ohio Perinatal Quality Collaborative, which involves partners from Ohio's Medicaid Technical Assistance and Policy Program, Best Evidence for Advancing Childbirth in Ohio Now, Ohio Colleges of Medicine Government Resource Center, Centers for Education & Research and Quality, Ohio Department of Health, Ohio Department of Medicaid, Ohio Hospital Association, CDC, Ohio Collaborative to Prevent Infant Mortality, Ohio Children's Hospital Association, Ohio March of Dimes, and Ohio Better Birth Outcomes.
- The **South Carolina** Birth Outcomes Initiative, which is housed at the Department of Health and Human Services, has served as a platform for projects on many maternal and child health issues, including access to 17P and progesterone. The monthly meetings frequently include more than 100 stakeholders from groups such as the South Carolina Hospital Association, March of Dimes, Blue Cross Blue Shield of South Carolina and the South Carolina Department of Health and Environmental Control.
- The **Texas** Better Birth Outcomes group that pioneered the state's data sharing agreement to improve early identification of 17P-eligible women is comprised of the Health and Human Services Commission (Texas' state Medicaid agency) and the Department of State Health Services, and often partners with March of Dimes. Texas' state health official was very involved with the creation of Better Birth Outcomes. The Department of State Health Services is also involved in the Texas Collaborative for Healthy Mothers and Babies, the state's perinatal quality collaborative that also has a focus on 17P.

National Efforts

HRSA Maternal and Child Health Bureau's CoIIN on Infant Mortality

HRSA's Maternal and Child Health Bureau launched a comprehensive initiative to combat infant mortality in the southern United States in 2012. The initiative is known as the Collaborative Innovation and Improvement Network (CoIIN) on Infant Mortality. This work leveraged the existing efforts of state

health officials in regions IV and VI and the [ASTHO President’s Challenge](#) to reduce preterm births by eight percent by 2014. Working with partners, including ASTHO, the Association of Maternal and Child Health Programs, the March of Dimes, the National Institute for Children’s Healthcare Quality (NICHQ), CityMatCH, and CDC’s Division of Reproductive Health, the Infant Mortality CoIIN leveraged collaborations across, within, and between states and federal and non-federal agencies and organizations to successfully serve as a mechanism for states to accelerate improvement in infant mortality reduction.

Early findings from the 2012 Infant Mortality CoIIN indicate that there has been a 30 percent decline in non-medically indicated early deliveries and a 12 percent decline in smoking during pregnancy in participating states.²⁹ While not all of the decline can be directly attributed to the Infant Mortality CoIIN, it is clear that the initiative provided a platform to accelerate momentum and improvement in these areas. Bolstered by the positive early findings, the Infant Mortality CoIIN is now being applied across the United States. One of the state-identified strategy areas for improvement is on preventing PTB, with a focus on increased access to 17P. The March of Dimes working with NICHQ to support states that are interested in increasing access to 17P through the Infant Mortality CoIIN. As states begin their Infant Mortality CoIIN work, they may identify and implement other best practices and partnerships to improve access to 17P.

Conclusion

State and territorial health agencies are critical partners in assuring that eligible women receive access to 17P. By using data to better identify 17P-eligible women, collaborating with Medicaid agencies, enhancing the 17P ordering and administration process, improving provider and patient education, and partnering with key stakeholders, these agencies are improving access to 17P for eligible women across the country. However there is still a long way to go in assuring access for all eligible women, and there are still many issues to consider regarding access to 17P. It is crucial that state and territorial health agencies continue to explore issues related to program changes, using data to drive action, policies and partners, and remain engaged in the important work of improving access to 17P to prevent preterm births.

Additional Resources

State or Organization	Resource
Louisiana	17P Resource Center
American Congress of Obstetricians and Gynecologists	2012 Practice Bulletin: Prediction and Prevention of Preterm Birth
ASTHO and Louisiana	ASTHO State Story: Louisiana Public Health and Medicaid Team Up to Increase 17P Access and Reduce Preterm Birth
Louisiana	Lammico free continuing medical education
Lumara Health	Makena Care Connection
North Carolina	Mombaby.org , includes information about the NC 17P Initiative and resources – including patient education booklets.

Issue Brief



State or Organization	Resource
North Carolina	NC Pregnancy Medical Home and clinical pathways
Lumara Health	Ordering and financial information website for providers
March of Dimes and the Medical University of South Carolina	Progesterone Outreach Program
Ohio	Progesterone Project: Every Week Matters
Ohio	Progesterone Project: Every Week Matters Patient Education
March of Dimes	Progesterone Treatment to Prevent Preterm Birth
Lumara Health	The Growth You Can't See
South Carolina	Universal 17P Authorization Form
National Academy of State Health Policy	<i>In development:</i> State 17P Reimbursement Policies Chart

¹ Sotiriadis A, Papatheodorou S, Makrydimas G. “Perinatal outcome in women treated with progesterone for the prevention of preterm birth: a meta-analysis.” *Ultrasound Obstet Gynecol.* 2012. 40:257-266.

² Behrman RE, Stith Butler A, eds. “Preterm birth: causes, consequences, and prevention.” Washington, DC: National Academies Press; 2006.

³ Martin J, Osterman M, Kirmeyer S, Gregory E. Measuring gestational age in vital statistics data: Transitioning to the obstetric estimate. *National vital statistics reports*; 64(5). National Center for Health Statistics. 2015. Available at: http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_05.pdf. Accessed 8-20-2015.

⁴ Hamilton B, Martin J, Osterman M, Curtin S. “Births: Preliminary data for 2014.” *National Vital Statistics Reports*; 64(1). National Center for Health Statistics. 2015. Available at http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_06.pdf. Accessed 8-20-2015.

⁵ <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=26>

⁶ Martin J, Hamilton B, Osterman M, et al. “Births: Final data for 2013.” *National Vital Statistics Reports*; 64(1). Hyattsville, MD: National Center for Health Statistics. 2015. Available at http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_01.pdf. Accessed 3-4-2015.

⁷ CDC. “National Prematurity Awareness Month.” Available at <http://www.cdc.gov/Features/PrematureBirth/>. Accessed 3-4-2015.

⁸ CDC. “Preterm Birth.” Available at: <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm>. Accessed 1-21-2014.

⁹ Chang H, et al. “Preventing preterm births: analysis of trends and potential reductions with interventions in 39 countries with very high human development index.” *Lancet.* 2013. 381: 223–34

¹⁰ American College of Obstetricians and Gynecologists (ACOG). “ACOG practice bulletin no.130: prediction and prevention of preterm birth.” *Obstet Gynecol.* 2012 Oct;120(4):964-73. Available at: http://www.mhpa.org/_upload/ACOGPracticeBulletinNo130_PredictionandPreventionofPretermBirth_Oct2012.pdf. Accessed 6-2-2015.

¹¹ Society for Maternal-Fetal Medicine Publications Committee et al. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. *Am J Obstet Gynecol.* 2012;206):376-86. doi: 10.1016/j.ajog.2012.03.010. Erratum in: *Am J Obstet Gynecol.* 2013 Jan;208(1):86.

¹² Medicaid Health Plans of America. “Preterm Birth Prevention: Evidence-Based Use of Progesterone Treatment Issue Brief and Action Steps for Medicaid Health Plans, November 2014.” Available at http://www.mhpa.org/_upload/PTBIssueBrief111714MHPA.pdf. Accessed 3-5-2015.

- ¹³ Meis PJ, Klebanoff M, Thom E, *et al.* "Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate." *N Engl J Med.* 2003. 348:2379-2385. Available at <http://www.nejm.org/doi/full/10.1056/NEJMoa035140>. Accessed 1-30-2014.
- ¹⁴ UNC Center for Maternal & Infant Health. "Preventing preterm birth: Progesterone treatment (17P) important information you need to know." Available at <http://mombaby.org/PDF/17P%20Factsheet.pdf>. Accessed 1-21-2014.
- ¹⁵ Petrini JR, Callaghan WM, Klebanoff M, *et al.* "Estimated effect on 17 alpha-hydroxyprogesterone caproate on preterm birth in the United States." 2005. 105(2): 267-272. Available at <http://www.ncbi.nlm.nih.gov/pubmed/15684150>. Accessed 1-30-2014.
- ¹⁶ Louisiana 2015 Medicaid Quality Management Statistics and Reporting.
- ¹⁷ Lumara Health data on file.
- ¹⁸ March of Dimes. "Preterm Labor." Available at: <http://www.marchofdimes.org/pregnancy/progesterone-treatment-to-prevent-preterm-birth.aspx#>. Accessed 3-6-2015.
- ¹⁹ Iams JD. Clinical practice. Prevention of preterm parturition. *N Engl J Med.* 2014 Jan 16;370(3):254-61.
- ²⁰ Iams JD. Identification of Candidates for Progesterone. Why, Who, How, and When? *Obstetrics & Gynecology,* 2014;123:1317-26.
- ²¹ Medicaid Health Plans of America. "Preterm Birth Prevention: Evidence-Based Use of Progesterone Treatment Issue Brief and Action Steps for Medicaid Health Plans, November 2014." Available at <http://www.mhpa.org/upload/PTBIssueBrief111714MHPA.pdf>. Accessed 3-5-2015.
- ²² Medicaid Health Plans of America. "Preterm Birth Prevention: Evidence-Based Use of Progesterone Treatment Issue Brief and Action Steps for Medicaid Health Plans, November 2014." Available at <http://www.mhpa.org/upload/PTBIssueBrief111714MHPA.pdf>. Accessed 3-5-2015.
- ²³ Appleby J. "Insurance Policies Favoring Compounded Drugs For High-Risk Pregnancies Draw Scrutiny." *Kaiser Health News.* October 30, 2012. Available at: <http://kaiserhealthnews.org/news/compounded-pregnancy-drugs/>. Accessed 3-6-2015.
- ²⁴ FDA. "Hydroxyprogesterone Caproate (17P)." Available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm402614.htm>. Accessed 3-3-2015.
- ²⁵ FDA. "Compounding." Available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>. Accessed 1-21-2014.
- ²⁶ Appleby J. "Insurance Policies Favoring Compounded Drugs For High-Risk Pregnancies Draw Scrutiny." *Kaiser Health News.* October 30, 2012. Available at: <http://kaiserhealthnews.org/news/compounded-pregnancy-drugs/>. Accessed 3-6-2015.
- ²⁷ Medicaid Health Plans of America. "Preterm Birth Prevention: Evidence-Based Use of Progesterone Treatment Issue Brief and Action Steps for Medicaid Health Plans, November 2014." Available at <http://www.mhpa.org/upload/PTBIssueBrief111714MHPA.pdf>. Accessed 3-5-2015.
- ²⁸ Markus A, Andres E, West K *et al.* Medicaid Covered Births, 2008 through 2010, In the Context of the Implementation of Health Reform. *Women's Health Issues,* September 2013, 23:5:e273-e280.
- ²⁹ Lee, V. The Collaborative Improvement & Innovation Network (CoIIN) to Reduce Infant Mortality: Success & Lessons Learned from Regions IV and VI. Presentation from North Carolina State Health Director's Conference, January 22, 2015. Available at: <http://www.ncpublichealth.com/shd/presentations/2015/0122-2-3/1-22-2015-145-245-LeeCollaborativeImprovement%28SalonA%29.pdf>. Accessed 6-5-2015.

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