I. Background and Summary

Nearly two-thirds of full-benefit members in the South Carolina Department of Health and Human Services' (SCDHHS) Healthy Connections Medicaid program are minor children, making Medicaid the primary or secondary health payer for nearly three-fifths of all children in the state and nearly two-thirds of all South Carolina births. SCDHHS has undertaken several efforts to improve maternal and child health to support positive birth outcomes for mothers and children statewide.

- SCDHHS employs Healthcare Effectiveness Data and Information Set (HEDIS)-based withhold measures to incentivize Medicaid managed care organizations (MMCOs) to focus on prenatal care, neonatal primary care and childhood immunizations.
- The South Carolina Birth Outcomes Initiative (BOI) leverages payer policy to reduce pre-term births, support vaginal delivery, encourage breast-feeding, and address perinatal behavioral health and substance use disorders.
- In 2016, South Carolina launched a nursing home visitation pay-for-success program in cooperation with Nurse-Family Partnership, Social Finance, The Children's Trust Fund of South Carolina, and other stakeholders to improve outcomes for high-risk first time mothers and their families.
- SCDHHS also provides state-funded only grants and services to augment innovation efforts and pursue interventions not authorized for federal participation. An example of this is the Managing Abstinence in Newborns (MAiN) program, developed in partnership with the Greenville Health System.

While these interventions have proven to benefit Medicaid members, the portfolio of services offered to address prenatal and infant health is incomplete. Today's maternal health initiatives are limited to Medicaid full-benefit members and some interventions, such as MAiN, which seeks to mitigate an already negative birth outcome, Neonatal Abstinence Syndrome (NAS). SCDHHS has traditionally offered family planning services to South Carolinians not eligible for Medicaid, but whose children would be Medicaid eligible. Such family planning services are focused almost exclusively on contraceptive and related care, with a primary goal of preventing pregnancies.

Accordingly, South Carolina Medicaid's interventions for children are nearly completely focused on the period from conception to early development, and interventions for mothers are focused nearly completely on reproductive health and the brief prenatal period. This narrow approach no longer aligns with clinical evidence or nationally accepted treatment guidelines. A broader approach, one that ensures the delivery of high quality care during the preconception period, is an essential component of ensuring that the mothers, infants and children entrusted to Medicaid's care can achieve their highest level of health and well-being.

II. Maternal Health and Birth Outcomes

Every year, 57,000 children are born in South Carolina.[1] Two-thirds of these births are covered by the Medicaid program, leading to full-benefit eligibility for the infant.[2] Historically, South Carolina Medicaid covers nearly two-thirds of infants and toddlers in South Carolina; generally decreasing the relative share of the population to about half of all non-disabled high school aged minors. The Medicaid population, however, is not a representative measure of the state's population, as the program disproportionately supports the disabled, impoverished, those in foster care and other populations known to be at-risk for adverse life events and traditionally poorer health

[1] According to an analysis of data from the SCDHEC Birth Certificate Data, the birth rate in South Carolina surged in 2006-2009, with a peak in 2008 of over 63,000 births. Following the Great Recession, the birthrate has stabilized between 56,500 and 58,500 births per year.
[2] SCDHEC Birth Certificate Data. http://www.scdhec.gov/VitalRecords/Statistics. Accessed March 10, 2018.

outcomes. This is demonstrated most acutely in the state's birth outcomes. The Centers for Disease Control and Prevention (CDC) reports that the top five causes of infant death in 2015 were:[3]

- Birth defects,
- Preterm birth and low birth weight,
- Sudden infant death syndrome,
- Maternal pregnancy complications and
- Injuries.

While SCDHHS recognizes that some birth defects cannot be prevented or mitigated through prenatal care, established evidence indicates that many, such as neural tube defects, Fetal Alcohol Spectrum Disorder (FASD) and cleft palate, correlate with maternal health and prenatal behavior.[4] Therefore, three of the top five sources of infant mortality are directly related to prenatal care and maternal health, either wholly or in part. In the same year, South Carolina ranked (lower number is worse) sixth in preterm birth, fifth in rate of low birthrate and 13th in cesarean delivery rate.[5] The state also ranked 36th (lower is better) in the nation for infant mortality at a prevalence of 7.0 per 1,000 births.[6] Although this rate represents record lows for the state, in part due to collaborative payer and provider policies implemented over the past decade, South Carolina continues to underperform with respect to the rest of the nation.

South Carolina Medicaid offers full-benefits eligibility for non-disabled pregnant women with incomes of up to 185 percent of the federal poverty level (FPL) and non-pregnant mothers with incomes of up to 67 percent FPL. An additional family planning supplement program, with a benefit that is limited to contraception, pregnancy planning and select family planning-related benefits, is available for women and men with incomes of up to 185 percent of FPL. With these benefits combined, a family eligible for Medicaid benefits has the tools to access comprehensive care for children, appropriately plan for additional pregnancies and access prenatal care once a woman becomes pregnant through at least 60 days postpartum, depending on the family's income. This continuum of services, however, assumes appropriate utilization of family planning services and disciplined adherence to a family planning regime. The data do not indicate such a disciplined approach to family planning is taken nationwide.

Over the past decade, research indicates that between 45-55 percent of all pregnancies in the United States are unplanned.[7] Wholly unwanted pregnancies trend just below 14 percent, annually, with the remainder of unanticipated pregnancies regarded as mistimed.[8] When data are analyzed for relevance to the Medicaid population, the rate of unintended pregnancies skyrockets:

- Three-quarters of mothers under the age of 20 report their pregnancy was unplanned.
- For families under 100 percent of FPL, 60 percent of all pregnancies are reported as unplanned.

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[3] CDC. Causes of Infant Mortality. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm. Accessed January 2, 2018.
[4] CDC. Commit to Healthy Choices to Help Prevent Birth Defects. https://www.cdc.gov/ncbddd/birthdefects/prevention.html. Accessed December 4, 2017.
[5] CDC, Stats of the State of South Carolina. https://www.cdc.gov/nchs/pressroom/states/southcarolina/southcarolina.htm. Accessed March 21, 2017.
[6] Kids Count. Infant Mortality. http://datacenter.kidscount.org/data/tables/6051-infant-mortality#ranking/2/any/true/573/any/12719. Accessed May 2017.
[7] Finer, L., and Zolna, M. "Declines in Unintended Pregnancy in the United States, 2008–2011." The New England Journal of Medicine, no. 374 (2016): 843-852. http://doi.org/10.1056/NEJMsa1506575.
[8] CDC. Intendedness of Pregnancy. https://www.cdc.gov/nchs/nsfg/key_statistics/i.htm#intended. Accessed March 8, 2018.

- African-American women report nearly two-thirds of all pregnancies are not planned, along with half of those experienced by Hispanic women.
- While unintended pregnancies appear to end in elective abortion, in preference over birth, at an average ratio of nearly 2-to-1, the relative use of abortion decreases along with income levels.

In addition, analysis of CDC vital statistics data indicates that the greatest decrease in the rate of unintended pregnancies was among women younger than 19, tracking along with national decrease in teen pregnancies over the past decade.[9] Similarly, while the rate of pregnancies regarded as mistimed decreased significantly in the past decade, the rate of unwanted pregnancies has remained nearly stable at 13.4% (2011-2015), down from 13.8% (2006-2010). When evaluated as a body of work, trends point to a high rate of unintended pregnancies among women in traditional Medicaid populations, but also among older women than in the past. SCDHHS has validated this hypothesis using data from the South Carolina Department of Health and Environmental Control (SCDHEC) vital statistics unit:

- The rate of births to mothers over the age of 30 increased 10.5 percent following the 2008 recession, for 3,686 more births per year to that population, despite a decrease overall of 5,740 births during the same period.
- The rate of births to mothers over the age of 35 increased 17 percent, while the rate (per 1,000) of births to mothers under the age of 20 dropped 54 percent.

The intent to become pregnant correlates with many factors, including utilization of prenatal care, postpartum depression, and proper spacing of pregnancies to mitigate complications of back-to-back pregnancies.[10,11] Once a Medicaid-eligible woman begins an unintended pregnancy, weeks of prenatal care may be lost before the pregnancy is diagnosed, the individual is motivated to enroll in Medicaid and the eligibility determination is made. While SCDHHS makes efforts to expedite eligibility determinations for pregnant women, the length of administrative delay associated with applying for benefits after a pregnancy is identified will always be greater than zero. Further, a woman who is never motivated to apply for Medicaid benefits but gives birth in a South Carolina hospital will likely be enrolled at the time of or immediately after birth. The result is a birth and medical care for which the South Carolina Medicaid program is financially responsible but had no opportunity to positively influence.

III. TARGETS FOR IMPROVEMENT

Although the consequences of poor birth outcomes are far reaching, and SCDHHS expects diversity of health improvements along with improved prenatal health, the analysis presented as part of the 1115 demonstration rational focuses on three common measures of birth outcomes: gestational age at birth, perinatal neonatal intensive care unit (NICU) involvement and prevalence of NAS.

NICU Admission. From 2008-2016, SCDHEC vital statistics data demonstrates that NICU admissions increased 28 percent, while the rate of NICU admissions per 1,000 births increased 41 percent. During this period, NICU

[9] CDC. Teen Pregnancy in the United States. https://www.cdc.gov/teenpregnancy/about/index.htm. Accessed March 10, 2018.
[10] March of Dimes. Birth Spacing and Birth Outcomes. https://www.marchofdimes.org/MOD-Birth-Spacing-Factsheet-November-2015.pdf.
[11] Abbasi, S., Chuang, C. H., Dagher, R., Zhu, J., and Kjerulff, K. (2013). Unintended Pregnancy and Postpartum Depression Among First-Time Mothers. Journal of Women's Health, 22(5), 412–416. http://doi.org/10.1089/jwh.2012.3926

admissions for neonates showed no sign of slowing down at the state's eight licensed NICU sites even as total births decreased statewide.

Gestational Age. While the number of births reported to SCDHEC decreased 9.1 percent from 2008-2016, births at a gestational age of less than 32 weeks decreased at a rate of 11.1 percent and those of a gestational age 32-36 weeks decreased at a rate of 14.5 percent. Conversely, the rate of NICU admissions per 1,000 births increased by 13.5 percent and 44.5 percent, respectively. While SCDHHS believes that the accelerated decrease of pre-term birthrates is attributable in part to the efforts of a statewide Birth Outcomes Initiative collaborative, NICU admissions among this population appear persistent. As of 2016, nearly 85 percent of all births with a gestational age of less than 32 weeks involve NICU admissions, as do over one-third of all near-term births. The relatively low rate of NICU admissions for full-term births – 18 of every 1,000 – increased to 33 per 1,000 for 638 more NICU admissions per year than in 2008 for children born from 37 to 41 weeks gestational age.

Neonatal Abstinence Syndrome. Across South Carolina's communities, a small but increasing collection of infants are the youngest victims of the nation's opioid epidemic. Comprehensive data are sparsely available, but a recent study by the CDC indicates that South Carolina's incidence of NAS has increased from 1.5 per 1,000 births to 3.9 per 1,000 hospital births from 2008 to 2013.[12] Recent scholarly studies completed and published by the principal investigators of the MAiN program found that 81 percent of all NAS births in South Carolina were paid for by the state's Medicaid program and that the cost of NAS births (total charges) has increased from $39,400 in 2000 to $93,400 in 2012.[13]

Other Indicators of Birth-Related Health Outcomes. The three indicators of birth outcomes initially evaluated for the purposes of South Carolina's Family Planning 1115 demonstration waiver comprise the highest-cost outcomes associated with poor birth outcomes but are not comprehensive of those proposed for evaluation by the waiver. Others include:

- Birth weight
- Initiation of Neonatal Special Care within 48 hours of birth (lower-acuity than NICU)
- Maternal morbidity and mortality
- Use of non-mandatory of elective caesarian section as a mode of birth
- Initiation of medically necessary caesarian
- Gestational diabetes (mother)
- Gestational hypertension (mother)
- Neonatal breast-feeding
- Postpartum depression
- Maternal substance use – tobacco, alcohol, opioids and others
- Social supports, including affirmative paternity
- Intent to become pregnant

[12] Ko, J., Patrick. S., Tong. V., Patel, R., Lind, N., and Barfield, D. Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013. CDC Morbidity and Mortality Weekly Report (2016) 65:799–802. http://dx.doi.org/10.15585/mmwr.mm6531a.
[13] Barlow, K., Cannon, A., Dankovich, K., James, A., Merritt, M., and Hudson, J. Neonatal Abstinence Syndrome: An Epidemic. GHS Proc. June 2017; 2 (1): 11-15. https://hsc.ghs.org/wp-content/uploads/2016/11/GHS-Proc-Neonatal-Abstinence-Syndrome-An-Epidemic.pdf.

IV. Maternal Health and Behavior Status

Using NAS as a proxy for maternal substance use, the experience of South Carolina infants tracks along with the nationwide opioid epidemic. South Carolina has seen some progress with respect to controlling opioid over-prescribing and SCDHHS recently announced a five-day prescription limit for opioid-naive users pursuant to South Carolina Governor McMaster's Executive Order No. 2017-43 to address initiation of opioid misuse. Despite front-end efforts to limit access and development of new addiction, it is estimated that there were nearly 700 opioid-related deaths in South Carolina in 2016, a statistically significant increase (15.3 percent) from 2015.[14] Again, an evaluation of vital statistics data indicates that births to mothers with existing disease states are on the rise (2008-2016):

- Obesity prior to pregnancy increased 13.4 percent.
- Chronic maternal hypertension increased 28 percent and pregnancy associated hypertension increased 36.5 percent.
- Pre-pregnancy diabetes increased 16.5 percent and gestational diabetes increased 40.3 percent.
- Mothers reporting an absence of prenatal care increased 29.9 percent.
- One bright spot is tobacco usage during pregnancy, the rate of which decreased 26.4 percent.

V. Addressing Preconception Maternal Health

In summary, SCDHHS has identified that although overall birth outcomes are improving statewide as the result of targeted and cooperative interventions in the payer and provider community, they remain unacceptably poor. The rate of high-acuity and high-cost interventions for neonates is increasing, and this appears to track alongside the aging of mothers and increase of poor preconception health and behaviors. SCDHHS has also identified gaps in its service portfolio for mothers of Medicaid beneficiaries that, if addressed, could improve birth outcomes for both mothers and infants.

Such an initiative is consistent with public health initiatives supported by the CDC to improve preconception care, the 6|18 initiatives to reduce tobacco use, prevent unwanted pregnancy, control blood pressure and prevent diabetes, as well as local efforts through the University of South Carolina's Arnold School of Public Health to address health disparities among rural, impoverished and minority populations.

Accordingly, SCDHHS proposes that this demonstration waiver employ a more robust and focused care model for women of childbearing age that requires the coordination of family planning and reproductive health care with primary care services and chronic disease management for both full- and limited-benefit Medicaid beneficiaries. The agency will refer to this as the preconception health, or preconception care, model.

The Preconception Care Model

Preconception health refers to the health of women and men during their reproductive years, and the preconception care model focuses on improving health, reducing or removing risk factors and identifying disease as early as possible.[15] Improving preconception health is an effective means of improving health outcomes and

[14] CDC. Drug Overdose Data. https://www.cdc.gov/drugoverdose/data/statedeaths.html. Accessed January 9, 2018.
[15] Centers for Disease Control and Prevention. 2018. Preconception Health. https://www.cdc.gov/preconception/index.html. Accessed January 9, 2018.

potentially reducing costs.[16,17] To provide this care effectively, preconception components should be integrated into primary care and provided in a medical home environment. The delivery of that care outside of the primary care medical home results in fragmented care and threatens the integrity of the delivery model. Identifying and treating chronic disease (most especially diabetes and hypertension) are critically important to ensuring high quality preconception care, but these activities are absent from the approach to family planning.

Finding the appropriate setting for the preconception care model is a challenge for the Medicaid population. A 2016 survey sponsored by the Kaiser Family Foundation indicated that women with Medicaid were more likely to have discussed reproductive health with a health provider, but were far less likely to have those conversations in a traditional doctor's office or health maintenance organization (HMO) setting, with only 57 percent of Medicaid beneficiaries discussing reproductive health in this most appropriate setting.[18] Medicaid beneficiaries are more likely than those with private insurance to access a community health center (13 percent versus 4 percent), family-planning limited service clinic (5 percent versus 2 percent) or "other place" (18 percent versus 8 percent). SCDHHS believes that the ad-hoc nature of coordination between reproductive health and primary care services for Medicaid beneficiaries represents a gap in comprehensive coverage and therefore an opportunity for health and birth outcomes improvement using payer policy and steerage to appropriate settings.

IMPLEMENTING COMPREHENSIVE PRECONCEPTION CARE

Transitioning South Carolina's Medicaid program from its current state to one that facilitates the adoption of a preconception care (PCC) model requires two important changes. First, SCDHHS intends to modify the benefit available to those qualifying for "family planning only" services to align with those services necessary to ensure quality care. While not comparable to a full-benefits service portfolio – this benefit would not cover hospitalization, a full array of behavioral health services, dental, orthopedics, vision, etc. – primary care, certain chronic disease management and obstetrics services would be more comprehensive. Second, SCDHHS must require that those providers serving Medicaid members are qualified and able to deliver the breadth of services required in the PPC model.

Alignment of Limited Benefit Program

SCDHHS has long provided family planning benefits to many South Carolinians through a demonstration waiver from 1994 until 2011, when the program transitioned to operate under state plan authority. The family planning benefit provides coverage for family planning services and supplies, as well as family-planning related services. These services include: examinations and office visits, contraception, sterilization, sexually transmitted infection (STI) treatment and screening and other screenings recommended by the United States Preventative Service Task Force (USPSTF).

To ensure that these members have access to the services necessary to achieve good preconception health, SCDHHS proposes to modify those benefits to align with the preconception care model. Specifically, office visits for these Medicaid members will incorporate a comprehensive assessment and treatment, rather than focusing

[16] Centers for Disease Control and Prevention. 2006. "Recommendations to improve preconception health and health care—United States." MMWR Recommendations and Reports 1-23. ?

[17] Weisman, C., Misra, P., Hillemeier, M., Downs, S., Chuang, H., Camacho, T., and Dyer, M. (2011). Preconception Predictors of Birth Outcomes: Prospective Findings from the Central Pennsylvania Women's Health Study. Maternal and Child Health Journal, 15(7), 829–835. http://doi.org/10.1007/s10995-009-0473-2

[18] Ranji, U., Bair Y., and Salganicoff, A. T., and Dyer, M. (2016). Medicaid and Family Planning: Background and Implications for the ACA. Kaiser Family Foundation Issue Brief. http://files.kff.org/attachment/issue-brief-medicaid-and-family-planning-background-and-implications-of-the-aca

on reproductive health. Additionally, SCDHHS proposes the addition of a limited pharmacy benefit for medications used to treat hypertension, hypercholesterolemia, diabetes, depression and substance use disorder. Pharmacotherapy serves as the cornerstone of cost-effective care in all of these conditions.

Provider Qualifications
SCDHHS proposes to leverage a focused network of providers for the provision of family planning benefits. Specific requirements for providers who participate in this network will include the ability to treat the entire scope of PPC, including regularly managing diabetes, hypertension, heart disease and depression. Providers must also either provide direct care for substance use disorder or have established relationships with treatment centers to facilitate referral.

AUTHORITIES AND WAIVERS

An analysis of the SCDHHS Medicaid State Plan and federal authorities indicates that implementation of the preconception care model, as articulated, will require amendments to policy, the Medicaid State Plan, and specific waivers approved by the Centers for Medicare and Medicaid Services (CMS). A brief analysis is provided for each major subject.

Beneficiary Eligibility
SCDHHS does not intend to change the underlying eligibility for either full-benefits or limited-benefits categories. The agency recognizes that:

- The current family planning and pregnant woman benefit limits eligibility to individuals at 185 percent of FPL.
- The Children's Health Insurance Program (CHIP), implemented in South Carolina as an extension of the Medicaid program, covers children up to 208 percent of FPL.

Therefore, individuals of childbearing age between 185-208 percent of FPL are not eligible for Medicaid, though their children would be Medicaid-eligible. These individuals do qualify for individual plans on South Carolina's federally run exchange.

Covered Services
SCDHHS proposes no new covered services for the full-benefits Medicaid population, and maintains that any services offered to the limited-benefits population will be offered as "family planning-related" services. SCDHHS will issue amendments to the state's physician services manual to amend the definitions of covered and non-covered family planning related services to account for preconception maternal health services in approved primary care settings.[19]

SCDHHS welcomes public comment related to the coverage of wraparound care management services for maternal health to support the implementation of evidence-based strategies for improved maternal health outcomes.

[19] CMS. Family Planning and Family Planning Related Services Clarification. SMDL#14-003. (April 2014). https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-14-003.pdf.

Provider Qualifications

For the purposes of adopting and enforcing these provider qualification requirements, a Section 1115 Waiver is the most appropriate vehicle, whereby the state will request a waiver of the requirements of §1902(a)(23) of the Social Security Act, and any other authorities and regulations as necessary. The CMS specifically highlights the following as acceptable objectives of Section 1115 Waivers.[20]

- Improve access to high-quality, person-centered services that produce positive health outcomes for individuals;
- Promote efficiencies that ensure Medicaid's sustainability for beneficiaries over the long term;
- Support coordinated strategies to address certain health determinants that promote upward mobility, greater independence, and improved quality of life among individuals;
- Strengthen beneficiary engagement in their personal healthcare plan, including incentive structures that promote responsible decision-making;
- Enhance alignment between Medicaid policies and commercial health insurance products to facilitate smoother beneficiary transition and
- Advance innovative delivery system and payment models to strengthen provider network capacity and drive greater value for Medicaid.

The transition from the traditional approach to family planning services to a preconception care model aligns with all of these objectives. Given the recent rescindment of 2016 sub-regulatory guidance that restricted state flexibility to implement this patient-centered primary care model, SCDHHS believes that such qualifications are consistent with current CMS attitudes regarding the integration of reproductive health and primary care.

[20] Centers for Medicare & Medicaid Services. Section 1115 Demonstrations. https://www.medicaid.gov/medicaid/section-1115-demo/index.html. Accessed February 9, 2018.