Billing Code

DEPARTMENT OF DEFENSE

Office of the Secretary

Establishing a TRICARE Childbirth and Breastfeeding Support Demonstration

AGENCY: Defense Health Agency, Department of Defense (DoD).

ACTION: Notice of demonstration project.

SUMMARY: The Assistant Secretary of Defense for Health Affairs issues this notice announcing the creation of a demonstration to cover the services of three new classes of extra-medical TRICARE-authorized providers: certified labor doulas (CLDs), certified lactation consultants, and certified lactation counselors. The demonstration also adds childbirth support services, provided by CLDs, as a benefit under TRICARE and expands the existing breastfeeding counseling benefit to include group breastfeeding counseling sessions. The demonstration will commence January 1, 2022, and will be conducted for a period of 5 years covering eligible beneficiaries in the 50 United States and District of Columbia. Eligible beneficiaries in overseas locations will be covered under the demonstration beginning January 1, 2025, until termination of the demonstration project.

FOR FURTHER INFORMATION CONTACT: Erica Ferron, 303-676-3626, erica.c.ferron.civ@mail.mil.

SUPPLEMENTARY INFORMATION:

A. Background

The purpose of the demonstration is to study the impact of adding these providers and services on cost, quality of care, and maternal and fetal outcomes for the TRICARE population, as required by Section 746 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (NDAA-2021). The demonstration will also study the appropriateness and administrative feasibility of making coverage under the TRICARE Program permanent.

In the NDAA-2021, enacted January 1, 2021 (Public Law 116-283), Congress directed the Secretary of Defense to carry out a demonstration project to evaluate the cost, quality of care, and impact on maternal and fetal outcomes of using extra-medical maternal health providers under the TRICARE Program, and to determine the appropriateness of making coverage of such providers under TRICARE permanent. Extra-medical maternal health care providers under the demonstration include doulas and lactation consultants and counselors not otherwise TRICARE-authorized providers (that is, that are not also physicians, registered nurses, certified nurse midwives, etc.).

In a recent Report to Congress (RTC), DoD reported on maternal and infant mortality rates. Military Health System (MHS) data reflects that from January 2009 to June 2018, the pregnancy-related mortality ratio (PRMR[1]), including the direct care (DC) and private sector care (PC) systems, was 7.40 deaths per 100,000 live births and statistically significantly lower than the benchmark data from National Perinatal Information Center (NPIC)[2] with a comparative rate of 11.3 deaths per 100,000 live births. During that same period, the infant mortality rate was 2.51 deaths per 1,000 live births and was statistically significantly below the NPIC rate of 4.76 per 1,000 live births. Despite generally lower rates of maternal and infant mortality compared with the United States overall and with NPIC member facilities, the MHS continues to actively

[1] PRMR is defined as CDC as the death of a woman while pregnant or within one year of pregnancy from any cause related to or aggravated by pregnancy or its management, but not from accidental or incidental causes.
[2] The NPIC is a nationwide voluntary obstetric quality improvement database.

work to decrease infant and maternal mortality.[3] Nationally, and worldwide the rates of maternal morbidity are increasing related to postpartum bleeding, high blood pressure, infection and mental health disorders. The U.S. maternal mortality rate is greater than 10 other high-income countries and the U.S. is the only developed country in the world where the maternal mortality rate has been steadily increasing. In 1987, the maternal mortality rate was 7.2 deaths per 100,000 live births. By 2018, the maternal mortality rate had increased to 17.4 per 100,000 live births, compared with 3.2 deaths per 100,000 in Germany, or 6.5 deaths per 100,000 in the United Kingdom.[4]

The risk of maternal mortality is not limited to labor and delivery. The three months immediately following birth, sometimes referred to as the "fourth trimester," account for more than half (52 percent) of pregnancy-related deaths in the U.S. (one-third of deaths occur during pregnancy and 17 percent occur on the day of delivery). Of the maternal deaths that occur postpartum, 19 percent occur one to six days postpartum and another 21 percent occur within six weeks of birth. Twelve percent are considered late maternal deaths, occurring later than six weeks post-delivery.[5] Doulas and lactation consultants and counselors provide services during pregnancy and the critical fourth trimester, potentially impacting outcomes for both the parent giving birth and the infant.

1. Childbirth Support and Doulas

Doulas are support personnel; while there are many types of doulas, some maternity related, some not, this demonstration will be limited to the services of labor doulas. Labor doulas, often referred to as birth doulas or labor assistants, provide guidance to the parent giving

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3 Office of the Secretary of Defense. "Maternal and Infant Mortality Rates in the Military Health System." July 2019. RefID 8-0153FF6.

4 Tikkanen, R., Gunja, M. Z., FitzGerald, M., & Zephyrin, L. (2020, November 18). Maternal mortality and maternity care in the United States compared to 10 other developed countries. Retrieved March 19, 2021, from https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries,

5 Tikkanen, R., Gunja, M. Z., FitzGerald, M., & Zephyrin, L. (2020, November 18). Maternal mortality and maternity care in the United States compared to 10 other developed countries. Retrieved March 19, 2021, from https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries,

birth and family through the labor and birthing process, and attend to the needs of the family shortly before delivery; during the birth, whether it be vaginal, or C-section; and immediately after delivery.[6] Labor doulas are not medical personnel and are not qualified to provide medical services, such as examination of the cervix or prescription of medications, and do not give medical advice.[7] Rather, the labor doula provides physical and emotional support, coaching, and guidance. While doulas do not provide medical services, evidence increasingly suggests health benefits may be associated with the use of childbirth support services.

DoD commissioned a technology assessment from Hayes, Inc., in late 2020 in anticipation of this demonstration that evaluated the impact of doula services on maternal and fetal outcomes. The results provided insight into areas for the Defense Health Agency (DHA) to explore in analysis of this demonstration. In particular, the evidence indicates that doula services might have a positive impact on shortened duration of labor, decreased epidural anesthesia, decreased anxiety during labor, decreased rate of stillbirths and low Apgar score in infants, and increased maternal feelings of coping well with labor and feeling that the birth experience was good. Additionally, some outcomes with mixed results, such as emergent C-section rate, warrant further study.[8]

In 2019, the American College of Obstetricians and Gynecologists (ACOG) published a committee opinion in which they recognized the value of labor doulas, stating "evidence suggests that, in addition to regular nursing care, continuous one-to-one emotional support provided by support personnel, such as a doula, is associated with improved outcomes for women in labor."[9] The opinion highlights the benefits of using doula support personnel including: shortened labor, decreased need for analgesia, fewer operative deliveries (C-sections),

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[6] DoulaTraining.net. (2021). Types of Doulas. Retrieved March 19, 2021, from http://www.doulatraining.net/types-of-doulas

[7] American Pregnancy Association. (2021, February 05). Labor and birth. Retrieved March 19, 2021, from https://americanpregnancy.org/health-pregnancy/labor-and-birth/

[8] Hayes, Inc. "Impact of Doulas on Birth Related Outcomes." Long Hayes Technology Assessment, November 16, 2020.

[9] ACOG. "ACOG Committee Opinion No. 766: Approaches to Limit Intervention During Labor and Birth." *Obstet Gynecol.* 2019 Feb;133(2):e164-e173. doi: 10.1097/AOG.0000000000003074. PMID: 30575638. ACOG piece.

and fewer reports of dissatisfaction with the experience of labor. The ACOG opinion noted that one analysis, looking at birth-related outcomes for Medicaid recipients who received prenatal education and childbirth support from trained doulas, suggested that paying for such personnel might result in substantial cost savings annually.[10]

Labor doulas are not currently licensed in any state and are not recognized by Medicare, although a few state Medicaid programs cover doula services. Medicaid reimburses doulas for their services in Oregon, Minnesota, Nebraska, and Indiana, with other states considering legislation. New York has a pilot program for doula services, launched in early 2019. Some state Medicaid programs recommend and recognize certification from approved private certifying organizations, whose certification qualifies a doula to receive Medicaid payment, while others offer their own certification. As of 2018, there were over 100 independent organizations offering some form of doula training or certification. Requirements for certification vary but typically include some combination of training workshops, reading lists, training in breastfeeding and basic childbirth education, networking to develop a doula business, and hands-on support for expectant mothers and their partner/spouse.[11]

2. Breastfeeding Support, Lactation Consultants, and Lactation Counselors

The U.S. Preventive Services Task Force (USPSTF) recommends breastfeeding counseling as a preventive service for pregnant women, new mothers, and their children, and recommends interventions both during pregnancy and after birth to support breastfeeding.[12] According to the Centers for Disease Control and Prevention (CDC), breastfeeding can reduce the risk of infants developing: asthma, obesity, type-1 diabetes, severe lower respiratory disease, acute otitis media (ear infections), sudden infant death syndrome, gastrointestinal infections, and

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[10] Kozhilmannil KB, Hardeman RR, Attanasio LB, Blauer-Peterson C, O'Brien M. Doula care, birth outcomes, and costs among Medicaid beneficiaries. Am J Publish Health 2013; 103;e113-21.
[11] Doulas of North America. (2021, March 04). Become a birth doula – certification. Retrieved March 19, 2021, from https://www.dona.org/become-a-doula/birth-doula-certification/
[12] U.S. Preventive Services Task Force. (2016). Final Recommendation Statement Breastfeeding: Primary Care Interventions (Rep.). USPSTF.

necrotizing enterocolitis for preterm infants. Breastfeeding may impact maternal health by lowering the risk of: high blood pressure, type-2 diabetes, ovarian cancer, and breast cancer.[13]

As a result of section 706 of the National Defense Authorization Act for Fiscal Year 2015 (NDAA-2015), TRICARE beneficiaries have access to up to six breastfeeding/lactation counseling sessions per birth event. These sessions are authorized in addition to any breastfeeding/lactation counseling services received as part of an inpatient maternity stay or outpatient obstetrical or well-child visit. Breastfeeding counseling must be provided by an already-authorized TRICARE provider, such as a physician, physician assistant, nurse practitioner, certified nurse midwife, registered nurse, outpatient hospital, or clinic. Despite the expanded breastfeeding benefit, internal analysis found fewer than five percent of TRICARE mothers in FY20 used breastfeeding counseling services in the 12 months following delivery. Low use of this service may be due in part to our current regulatory requirement that all services be provided by a TRICARE-authorized provider, as many lactation consultants and counselors do not have a health profession-related degree or license, and those that do are unlikely to focus on providing lactation services. Low utilization may have been further impacted by the failure to create a new provider class of lactation consultant/counselor, which meant this type of provider cannot be specifically searched for in TRICARE provider directories.

According to the U.S. Breastfeeding Committee, an independent nonprofit coalition, lactation consultants and counselors are the most educated of four lactation specialties (the other two are breastfeeding peer counselors and lactation educators).[14] Lactation consultants and counselors are health care professionals who have received specialized training to aid in breastfeeding and passed a certification exam. Lactation consultants and counselors are not licensed in most states; while some are also licensed medical professionals (such as registered

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[13] CDC. "Breastfeeding: Why it Matters." Retrieved March 25, 2020, from https://www.cdc.gov/breastfeeding/about-breastfeeding/why-it-matters.html

[14] U.S. Breastfeeding Committee. "Lactation Support Providers Descriptors Table." Accessed online on 3/21/21 at http://www.usbreastfeeding.org/page/lsp-descriptor-table.

nurses), many are not. Lactation consultants and counselors do not diagnose or assess illnesses, nor do they provide treatment for either the mother or the infant.

B. Description of Demonstration

1. Overall Demonstration Details

The demonstration is designed to evaluate the following hypotheses:

(1) Access to doulas will have a positive and measurable impact on maternal and fetal outcomes.

(2) Access to lactation consultants and lactation counselors will have the same or better impact on maternal and fetal outcomes when compared to the same services provided by other TRICARE-authorized providers.

(3) The cost of providing access to such providers is justified by the impact of the providers on maternal and fetal outcomes.

(4) It is feasible to administer the new provider classes and the services they provide.

In order to evaluate the demonstration, it is divided into two distinct parts: a childbirth support benefit and a breastfeeding support benefit. This division recognizes that the impact on maternal and fetal outcomes, costs, and administrative feasibility must be studied separately for the two benefits (that is, the evaluation may find a positive impact on outcomes for one part of the demonstration but not the other). Each provision adds a new class of extra-medical provider, while the childbirth support portion also adds a new type of benefit. An extra-medical provider as defined in the regulations (Title 32 Code of Federal Regulations (CFR), Part 199.6(c)(iv)) is an individual professional provider who provides "counseling or nonmedical therapy and whose training and therapeutic concepts are outside the medical field." Other extra-medical providers include certified marriage and family therapists, pastoral counselors, supervised mental health counselors, and Christian Science practitioners and Christian Science nurses.

a. Demonstration Scope

The demonstration will be limited to services occurring in PC. TRICARE statutory and regulatory restrictions on providers, from which the NDAA-2021 demonstration offers relief, apply to care administered under PC. By contrast, Military Medical Treatment Facilities (MTFs) under DC are not prevented from hiring such providers under existing statutory and regulatory requirements. Some MTFs already have lactation consultants on staff, from whom beneficiaries are eligible to receive services. As of the drafting of this decision paper, no MTFs had doulas on staff; however, many MTFs do permit beneficiaries to bring a doula with them during labor, whether that doula be a volunteer, paid for by the family, or reimbursed under another program. The evaluation of maternal and fetal outcomes will not be impacted by the limitation of the demonstration to PC.

b. Beneficiary Eligibility

The demonstration will be available to TRICARE Prime and TRICARE Select beneficiaries who receive care in PC under the managed care support contractors (MCSCs). TRICARE Overseas beneficiaries will be eligible to participate in the demonstration beginning January 1, 2025, when the demonstration expands to overseas locations. Not included in the demonstration will be TRICARE for Life, United States Family Health Plan (USFHP), and Continued Health Care Benefit Program (CHCBP) beneficiaries. Excluding beneficiaries not under the MCSCs or the Oversea Program (beginning January 1, 2025) reduces the administrative burden of the demonstration without having a meaningful impact on the demonstration's results (the hypothesis regarding administrative feasibility refers primarily to the management of the new provider categories and benefits, and not to the administrative variations under different TRICARE contracts, which are a known variable that does not require evaluation). Any potential permanent expansion would revisit inclusion of beneficiary categories excluded under the demonstration.

Beneficiaries will be enrolled in the demonstration automatically when accessing one or more covered services from a provider authorized under this demonstration. The contractor will

record the beneficiary's enrollment by marking the claims with a special processing code for either the childbirth support or breastfeeding counseling portion of the demonstration. Beneficiaries who are interested in participating in the demonstration will be able to contact the contractor for their area to express interest in participating and receive information on the demonstration requirements and help locating a provider, but such early contact will not be required.

2. Childbirth Support and Doulas

The childbirth support benefit both adds certified labor doulas (CLDs) as TRICARE-authorized providers and childbirth support services as a benefit. In order to be a CLD under this demonstration, doulas must be at least 18-years-old and have:

(a) A current certification as a labor doula by one of the following organizations:

i. BirthWorks International

ii. Doulas of North America (DONA) International

iii. Childbirth and Postpartum Professional Association (CAPPA)

iv. International Childbirth Education Association (ICEA)

v. toLabor

(b) Attended a training curriculum of at least 24 hours that includes the physiology of labor, labor doula training, antepartum doula training, and postpartum doula training.

(c) Attended one or more breastfeeding courses.

(d) Attended one or more childbirth education courses (e.g., Lamaze).

(e) Within the past three years, provided continuous labor support for at least three childbirths as the primary labor doula supporting the birthing parent, with a minimum of 15 hours over the three childbirths. At least two of the births must have been a vaginal birth.

(f) Within the past three years, provided antepartum and postpartum support for at least one birth.

(g) A current child, infant, and adult cardiopulmonary resuscitation (CPR) certification.

(h) A state license or certification if one is offered by the state, even if such a license or certification is optional.

(i) A national provider identification number (NPI).

A doula cannot use experience gained from their own childbirth experience, to include the labor and any associated classes, to qualify as an authorized provider under TRICARE.

The requirements for doulas selected under the demonstration were based on an analysis of over 150 doula training and certification bodies. The certification bodies selected for inclusion had a time-limited certification and were well-established with a wide-ranging footprint (i.e., national or international); included classroom training and workshops in labor physiology and other childbirth topics; required doulas to have completed at least two deliveries prior to certification; required evaluations from health care professionals for services provided during labor support or a comprehensive examination; and had an established scope of practice, code of ethics, code of conduct, or similar by which the doula is required to agree to abide. Some of our requirements for CLDs may duplicate those under the required certification; this is due to differences in certification requirements for the five selected certification bodies and to ensure a minimum level of education and experience for all CLDs under this demonstration. DoD recognizes that there may be some doulas and doula certification bodies concerned they do not meet inclusion criteria. If DoD determines it is appropriate to move forward with permanent coverage of CLDs under the TRICARE Program at the conclusion of this demonstration, interested individuals and organizations will be invited to provide feedback during notice and comment rulemaking.

TRICARE will cover up to six total antepartum and postpartum CLD visits. One continuous labor support encounter per birth event will be authorized regardless of the location of the childbirth (hospital, birthing center, home delivery, etc.). The birthing parent must be at least 20 weeks pregnant to be eligible for services, and the maternity episode-of-care must be overseen by a TRICARE-authorized provider (that is, childbirth support services are ineligible

for reimbursement if the delivery is performed or planned to be performed by other than a TRICARE-authorized provider; e.g., a lay midwife, except in emergency circumstances). No additional reimbursement will be provided for travel to the delivery location or if the doula moves with the patient from an initial location (the home or birthing center) to another location (a hospital), for long or difficult deliveries, or for false labor. Doula services will be eligible whether the labor is completed via vaginal birth or C-section, and whether or not the labor results in a live birth (doula services are excluded for elective abortions not otherwise covered by TRICARE).

Childbirth support reimbursement under the demonstration is as follows:

- Antepartum/Postpartum visits (up to six total): The six authorized antepartum or postpartum visits will be reimbursed at a rate of $46.00 per visit (for Calendar Year (CY) 2021), wage adjusted and updated annually. These visits will be untimed and no more than one visit will be eligible for reimbursement per day.
- Continuous Labor Support: Continuous labor support will be reimbursed at a national rate of 15 times the rate of the antepartum/postpartum visit rate, or $690.00 for CY 2021, wage adjusted and updated annually.

CLDs will be reimbursed the lower of the billed charge or the rates listed above. A CLD who advertises their rate at a rate lower than the TRICARE reimbursement amount but bills TRICARE for the reimbursement rate listed above (i.e., charges TRICARE beneficiaries more than they charge other clients) may be subject to the administrative remedies for fraud, waste, and abuse, pursuant to 32 CFR 199.9 and referral to the appropriate program integrity authority. Additional coding and reimbursement information will be published in the TRICARE manuals prior to the start of the demonstration, and may be updated periodically upon approval of the Director, DHA.

3. Breastfeeding Support, Lactation Consultants, and Lactation Counselors

The breastfeeding support portion of the demonstration creates two new classes of extra-medical providers: certified lactation consultants and certified lactation counselors. Certified lactation consultants under the demonstration will have a current International Board of Lactation Consultant Examiners (IBLCE) certification as an International Board Certified Lactation Consultant or a current Academy of Lactation Policy and Practice (ALPP) certification as an Advanced Nurse Lactation Consultant or an Advanced Lactation Consultant. Certified lactation counselors must hold a current certification from ALPP as a Certified Lactation Counselor. Both classes of provider will be required to be at least 18-years-old; to maintain a current adult, child, and infant CPR certification; to be licensed or certified in the state in which they practice even if such a licensure or certification is optional; and to bill under an NPI. If DoD determines it is appropriate to move forward with permanent coverage of lactation consultants and/or lactation counselors under the TRICARE Program, interested individuals and organizations will be able to provide feedback on qualification and other requirements during notice and comment rulemaking.

The breastfeeding support benefit under this demonstration conforms with the requirements of the existing breastfeeding counseling benefit as found in the TRICARE Policy Manual, Chapter 8, Section 2.6, paragraph 4.3, which authorizes coverage of up to six outpatient breastfeeding/lactation counseling sessions per birth event using current procedural terminology (CPT) codes 99401 to 99404. Cost-shares, copays, and deductibles do not apply to covered breastfeeding/lactation counseling services rendered on or after December 19, 2014. This demonstration adds coverage of group breastfeeding counseling, which may include prenatal breastfeeding education. Such services shall be included in the six total breastfeeding counseling visits currently authorized under the benefit.

Group lactation counseling/classes will be billed under CPT code 99411 Preventive Counseling, Group, 30 min, and 99412 Preventive Counseling, Group, 60 min. These codes will be paid at the TRICARE non-physician, non-facility CHAMPUS Maximum Allowable Charge

(CMAC) rate ($17.80 and $22.24, respectively, for FY21). Individual lactation counseling sessions will be reimbursed at the non-physician, non-facility CMAC under the existing CPT codes 99401 through 99404.

C. Implementation Details

The DHA will publish additional details on implementation of the demonstration in the TRICARE manuals prior to start of the demonstration. Providers interested in participating in the demonstration should contact the appropriate TRICARE contractor for their area during this period. While interested providers are not required to be network providers to participate in the demonstration, all providers must meet the eligibility requirements under the demonstration to have their services cost-shared. Provider networks overseas will begin development prior to the start of the demonstration expansion. Beneficiaries do not need to enroll or otherwise sign up to participate in the demonstration, but must meet eligibility criteria for the demonstration (e.g., must be at least 20 weeks pregnant for childbirth support services).

D. Beneficiary Survey

The NDAA-2021 mandated the Secretary administer a survey by January 1, 2022, and annually thereafter for the duration of the demonstration. The survey is required to gather information on:

(1) How many members of the Armed Forces or spouses of such members give birth while their spouse or birthing partner is unable to be present due to deployment, training, or other mission requirements; how many single members of the armed forces give birth alone; and how many members of the Armed Forces or spouses of such members use doula, lactation consultant, or lactation counselor support.

(2) The race, ethnicity, age, sex, relationship status, Armed Force, military occupation, and rank, as applicable, of each member surveyed.

(3) If individuals surveyed were members of the Armed Forces or the spouses of such members, or both.

(4) The length of advanced notice received by individuals surveyed that the member of the Armed Forces would be unable to be present during the birth; if applicable.

(5) Any resources or support that individuals surveyed found useful during the pregnancy and birth process, including doula, lactation consultant, and lactation counselor support.

The DoD intends to ask additional questions in the survey to aid in evaluation of the demonstration. Results of the survey will be reported to Congress.

E. Cost Assessment

The demonstration is anticipated to cost $51.16M in health care and administrative costs, with an additional $4.3M estimated for evaluation of the demonstration over the five-year period. Increased costs to the TRICARE Program for breastfeeding counseling are estimated at $7.05M, while $40.18M are estimated for the childbirth support benefit. The childbirth support benefit estimate includes a calculation for offsets from C-section reductions. There is substantial uncertainty surrounding the estimate, given that no commercial insurers and only a few Medicaid programs reimburse for childbirth support services. The estimate includes approximately $3.93M for administrative costs related to credentialing, billing, and contractor reporting requirements.

F. Demonstration Analysis

The DoD will evaluate the success of the demonstration project and report to Congress on the results annually. DoD intends to use an outside firm to assist in its analysis. In order to measure maternal and fetal outcomes, DoD will compare outcomes and use of services: (1) With historical data; (2) between those who choose not to use a service and those who do; and, (3) with nationwide statistics. The analysis will evaluate the childbirth support benefit by reviewing information obtained from claims data, such as C-section rates and use Pitocin, and comparing it to the same outcomes from before the demonstration started (pre/post-test), with beneficiaries who do not use the childbirth support benefit, and with national statistics. To evaluate the breastfeeding support benefit, the analysis will evaluate outcome measures (such as ear

infections for infants) for beneficiaries receiving services provided from a lactation consultant/counselor compared to the same outcome for services from an otherwise-authorized TRICARE provider, and when compared to beneficiaries who choose not to use the breastfeeding counseling benefit. The analysis will also compare outcomes to historical data and nationwide statistics. Additionally, we will ask questions on the beneficiary survey to assist in evaluating the quality of care received. The effectiveness of the demonstration will be evaluated by the impact of the demonstration on outcomes, the availability of providers under the demonstration, and beneficiary satisfaction with the providers. Cost will be evaluated by reviewing the overall cost of the demonstration, but also by capturing cost-savings due to improvements in maternal and fetal outcomes (for example, the cost savings associated with avoiding C-sections).

Throughout the demonstration, we will evaluate the effectiveness of the qualification requirements for providers and the reimbursement methodology. We will also evaluate the administrative feasibility of continuing the demonstration and/or implementing permanent coverage under the TRICARE Program. Such feasibility analysis will include: the extent to which TRICARE's contractors are able to build networks, the extent to which TRICARE beneficiaries access the benefit, whether providers under the demonstration are able to file claims for services and otherwise comply with program requirements, the presence of any provider quality concerns, and the cost for TRICARE's contractors to maintain the benefit. The DoD will add, remove, or revise outcome measures under study as needed to ensure a robust evaluation of the demonstration.

Because the providers under this demonstration are not medical providers, but instead are support personnel who work outside the medical field, no clinical care will be provided as part of this demonstration. Neither doulas nor lactation consultants/counselors are qualified to provide clinical care, and both will be required to refer the beneficiary to a qualified medical professional if they identify a medical issue requiring a change to the patient's clinical care. DoD's

evaluation will be limited to de-identified evaluation of claims records and survey responses. The ASD(HA) has determined that the demonstration is exempt from the requirements for human subjects research, pursuant to the authority provided by 45 CFR 46.104(d)(5) exempting demonstration projects by Federal Departments that evaluate public benefit programs.

Dated: October 25, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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