

## **UNDER SECRETARY OF DEFENSE**

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG 2 6 2022

The Honorable Jack Reed Chairman Committee on Armed Services United States Senate Washington, DC 20510

Dear Mr. Chairman:

The Department's response to section 746 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116–283), "Extramedical Maternal Health Providers Demonstration Project," is enclosed. Section 746 requires the Secretary of Defense to establish a 5-year demonstration project to evaluate the cost, quality of care, and impact on maternal and fetal outcomes of covering the services of doulas and lactation consultants or counselors not otherwise TRICARE-authorized.

This demonstration contains two distinct parts: a childbirth support benefit and a breastfeeding support benefit. The childbirth support benefit adds a new class of extra-medical providers (a certified labor doula) and new coverage for childbirth support services, while the breastfeeding support benefit adds two new extra-medical providers (lactation consultants and lactation counselors) to the existing breastfeeding support benefit. Additionally, section 746 requires annual reports to Congress and annual beneficiary surveys. The enclosed initial report to Congress details the benefit structure, provider requirements, estimated cost, and plans for evaluating the success of the demonstration.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and families. I am sending a similar letter to the House Armed Services Committee.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure: As stated

cc:

The Honorable James M. Inhofe Ranking Member



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The Honorable Adam Smith Chairman Committee on Armed Services U.S. House of Representatives Washington, DC 20515

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The Honorable Mike D. Rogers Ranking Member

# **Report to Congressional Armed Services Committees**



In Response to: Section 746 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116–283), "Extramedical Maternal Health Providers Demonstration Project"

# August 2022

Preparation of this study/report cost the Department of Defense a total of approximately \$1,100.00 for the 2021 Fiscal Year. This includes 1,100.00 in DoD labor.

RefID: F-C648E63

## 1) Introduction

This report summarizes the implementation plan for a demonstration project mandated by section 746 of the William M. (Mac) Thornberry National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Public Law 116–283), which requires the Secretary of Defense to establish a 5-year demonstration project under TRICARE to evaluate the cost, quality of care, and impact on maternal and fetal outcomes of covering the services of doulas and lactation consultants or counselors not otherwise TRICARE-authorized, and to determine whether it would be appropriate to implement permanent coverage.

# 2) Background

The United States is the only developed country in the world where the maternal mortality rate has been steadily increasing. According to non-Department of Defense (DoD) statistics, 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 deaths 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. The risk of maternal mortality is not limited to labor and delivery. The 3 months immediately following birth, sometimes referred to as the "fourth trimester," account for more than half (52 percent) of pregnancy-related deaths in the United States (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 1 to 6 days postpartum and another 21 percent occur within 6 weeks of birth. Twelve percent are considered late maternal deaths, occurring later than 6 weeks post-delivery.

The American College of Obstetricians and Gynecologists (ACOG) published a Committee Opinion in 2018 emphasizing the importance of care during the months following delivery, noting postpartum women are at risk for "multiple physical, social, and psychological changes" resulting from lack of sleep, fatigue, pain, breastfeeding difficulties, stress, new onset or exacerbation of mental health disorders, and urinary incontinence. In the fourth trimester, in addition to the risk of death, the woman may experience high blood pressure, postpartum strokes, postpartum depression, wound infection, lactation difficulties, or chronic conditions such as seizure disorders. Because of this, ACOG recommends that postpartum care be an ongoing process rather than a single encounter with a health care provider, and that women have a postpartum team that includes health care providers, family and friends, lactation support, home visitors, and others.<sup>3</sup> In 2019, ACOG extended its support to the services of doulas, noting that "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

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<sup>&</sup>lt;sup>1</sup> Centers for Disease Control. (Undated.) Pregnancy mortality surveillance system. Retrieved October 20, 2021, from https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm.

<sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> ACOG. "ACOG Committee Opinion: Optimizing Postpartum Care." *Obstetrics & Gynecology*, 131(5): e140-50. (2018).

for women in labor."<sup>4</sup> The ACOG opinion highlights the benefits of using doula support personnel including: shortened labor, decreased need for analgesia, fewer operative deliveries (C-sections), and fewer reports of dissatisfaction with the experience of labor.<sup>5</sup>

# 3) NDAA for FY 2021 Requirements

Section 746 of the NDAA for FY 2021 (Public Law 116–283), enacted on January 1, 2021, mandated the Secretary of Defense (SecDef) carry out a 5-year extra-medical maternal health provider demonstration project. It required the SecDef to:

- Start the demonstration project no later than 1 year from enactment of the Act. The demonstration is required to provide access to doulas and lactation consultants or lactation counselors not otherwise authorized to provide services under TRICARE.
- Establish a process under which covered beneficiaries may enroll to receive services under the demonstration.
- Administer an annual survey.
- Evaluate the impact of the demonstration on cost, quality of care, and maternal and fetal outcomes.
- Submit annual reports to the Congressional Armed Services Committees, with this initial report detailing the implementation of the demonstration.

#### 4) Discussion

## A. Demonstration Implementation

The DoD implemented coverage of doulas by reimbursing for childbirth support services provided by certified labor doulas (CLDs) who are at least 18-years-old and have:

- 1. A current certification as a labor doula by one of the following organizations:
  - i. BirthWorks International;
  - ii. Doulas of North America International:
  - iii. Childbirth and Postpartum Professional Association;
  - iv. International Childbirth Education Association; or
  - v. ToLabor.
- 2. 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.
- 3. Attended one or more breastfeeding courses.
- 4. Attended one or more childbirth education courses (e.g., Lamaze).

<sup>&</sup>lt;sup>4</sup> ACOG. "ACOG Committee Opinion No. 736: Optimizing Postpartum Care." *Obstetrics & Gynecology*, 131(5): e140-50. (2018).

<sup>&</sup>lt;sup>5</sup> ACOG. "ACOG Committee Opinion No. 766: Approaches to Limit Intervention during Labor and Birth." *Obstetrics & Gynecology*, 133(2): e164-73.

- 5. Within the past 3 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.
- 6. Within the past 3 years, provided antepartum and postpartum support for at least one birth.
- 7. A current child, infant, and adult cardiopulmonary resuscitation (CPR) certification.
- 8. A State license or certification if one is offered by the State even if such a license or certification is optional.
- 9. A national provider identification number.

Doulas cannot use experience gained from their own childbirth experience, including the labor and any associated classes, to qualify for TRICARE reimbursement under this demonstration. DoD selected the requirements (1 through 9 immediately above) for doulas under the demonstration based on an analysis of over 150 doula training and certification bodies, current State Medicaid doula programs in Nebraska, Oregon, and New York, and proposed Medicaid programs in other States. The certification bodies selected for inclusion in this demonstration have a time-limited certification and are well-established with a wide-ranging footprint (i.e., national or international); include classroom training and workshops in labor physiology and other childbirth topics; require doulas to have provided support for at least two deliveries prior to certification; require evaluations from health care professionals for services provided during labor support or a comprehensive examination; and have an established scope of practice, code of ethics, code of conduct, or similar code by which doulas are required to abide. If DoD determines it is appropriate to move forward with permanent coverage of doulas under the TRICARE program, DoD will afford interested individuals and organizations the ability to submit feedback on provider qualifications and other requirements during notice and comment rulemaking.

DoD is covering up to six total antepartum and postpartum visits as well as one continuous labor support visit. DoD is reimbursing the antepartum and postpartum visits at \$46.00 per visit for Calendar Year (CY) 2022. DoD is covering one continuous labor support visit per pregnancy reimbursed at a 15 times the antepartum/postpartum visit reimbursement amount, or \$690.00, for CY 2022. These rates will be adjusted by locality and updated annually. DoD will monitor the demonstration for concerns over provider participation and may implement reimbursement changes as needed. Any such changes would be reported to Congress in future years through the Department annual reports.

DoD implemented coverage of lactation consultants and lactation counselors by creating provider requirements for the two new extra-medical providers and covering their services under the existing breastfeeding counseling benefit, which covers up to six breastfeeding/lactation counseling visits per birth event. To qualify under the demonstration, lactation consultants and lactation counselors are required to be at least 18 years old and hold a current infant, child, and adult CPR certification. Lactation consultants are required to have a current certification as an International Board Certified Lactation Consultant from the International Board of Lactation Consultant Examiners or as an advanced nurse lactation consultant or advanced lactation

consultant from the Academy of Lactation Policy and Practice (ALPP). Certified lactation counselors must hold a current certification from ALPP as a Certified Lactation Counselor.

The breastfeeding support benefit under this demonstration conforms to the requirements of the existing breastfeeding benefit under TRICARE, which authorizes coverage of up to six outpatient breastfeeding/lactation counseling sessions per birth event. The demonstration adds coverage of group breastfeeding counseling, which may include prenatal breastfeeding education. Group counseling services shall be included in the six total breastfeeding counseling visits currently authorized under the TRICARE benefit for either 30 minutes or 60 minutes (\$17.80 or \$22.24, respectively, for CY 2021).

# B. Demonstration Enrollment and Eligibility

The Assistant Secretary of Defense for Health Affairs (ASD(HA)) announced the demonstration in a Federal Register (FR) notice that published on October 29, 2021 (86 FR 60006). The demonstration is limited to services occurring in private sector care (PC). TRICARE statutory and regulatory restrictions on providers, from which the NDAA for FY 2021 demonstration offers relief, apply to care administered under PC. The demonstration began across the 50 United States and the District of Columbia on January 1, 2022, with coverage expanding overseas starting January 1, 2025.

The demonstration is available to TRICARE Prime and TRICARE Select beneficiaries who receive care in PC under the managed care support contractors (MCSCs). TRICARE Overseas Program (TOP) 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 are TRICARE for Life, United States Family Health Plan, and Continued Health Care Benefit Program beneficiaries. Excluding these beneficiaries reduces the administrative burden of the demonstration and will not have a meaningful impact on the demonstration's results. Any potential permanent expansion of this demonstration will revisit inclusion of beneficiary categories currently excluded under this implementation plan.

The NDAA for FY 2021 requires DoD to develop a process under which covered beneficiaries may enroll in the demonstration. DoD considered a traditional enrollment process that would require action on the part of the beneficiary to proactively sign up to participate by contacting MCSCs prior to receiving services under the demonstration. However, DoD rejected this approach because the beneficiaries most likely to benefit from this demonstration could be considered to be a vulnerable population for which extra administrative requirements might be onerous. Examples of this vulnerable population include a parent giving birth alone with few support resources or a parent who has recently given birth and has an infant whom she is unable to breastfeed. A requirement for a beneficiary to proactively sign up could impact the type of beneficiaries who opt to participate in the demonstration, which could skew analysis of the impact of the demonstration on maternal and fetal outcomes. Beneficiaries who are more involved in their health care and have existing support may have better outcomes overall and may also be more likely to be able to navigate administrative processes surrounding such a proactive enrollment requirement. Instead, DoD considers beneficiaries to be automatically enrolled in the demonstration when accessing one or more covered services from a provider

authorized under this demonstration. By choosing to engage the services of a doula, lactation consultant, or lactation counselor, the beneficiary is choosing to avail herself of services uniquely available under the demonstration and is also, therefore, voluntarily enrolling in the demonstration by making that choice. While Congress required an enrollment process under which covered beneficiaries may enroll in the demonstration, Congress also focused on the needs of single parents and parents giving birth alone in its survey requirements, suggesting Congress was also focused on the needs of DoD's most vulnerable beneficiaries. DoD's enrollment process meets the requirements of the NDAA for FY 2021 while also ensuring that confounding variables are not introduced into the analysis of maternal and fetal outcomes.

# C. Survey Administration

Section 746 of the NDAA for FY 2021 requires a beneficiary survey to be administered by January 1, 2022, and annually thereafter. DoD interprets survey administration to include several steps: (1) collecting e-mail addresses for eligible beneficiaries; (2) distribution of the survey to eligible participants; and (3) analyzing response data. DoD will perform this process each quarter, though DoD may choose to analyze the data less often than quarterly. DoD is in the process of getting its survey approved. Based on the described methodology and survey approval requirements, DoD expects to be able to inform Congress of survey results for baseline CY 2021, CY 2022, and the first two quarters of CY 2023 in the report to Congress due on January 1, 2024.

#### D. Demonstration Evaluation

The demonstration is designed to evaluate the following hypotheses:

- Access to doulas will have a positive and measurable impact on maternal and fetal outcomes.
- 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.
- The cost of providing access to such providers is justified by the impact of the providers on maternal and fetal outcomes.
- It is feasible to administer the new provider classes and the services they provide.

The evaluation will be divided into two distinct parts: the childbirth support benefit and the 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). DoD will evaluate the success of the demonstration project and report to Congress on the results annually. DoD intends to use an outside contractor to assist in its analysis due to the complexity of evaluating the mandated elements. In order to measure maternal and fetal outcomes, DoD will compare outcomes and use of services: (1) with

historical data (pre/post-test); (2) between those who choose not to use a service and those who do; and (3) with nationwide statistics. The analysis will evaluate outcome measures from claims data such as C-section rates, use of Pitocin, or ear infections for infants.

Additionally, DoD 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, DoD will evaluate the effectiveness of the qualification requirements for CLDs and lactation consultants and lactation counselors and the reimbursement methodology. DoD will evaluate the administrative feasibility of continuing the demonstration 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. 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 is being provided as part of this demonstration. Neither doulas nor lactation consultants or counselors are qualified to provide clinical care, and both are 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.

## E. Report to Congress

This initial report to Congress details DoD's implementation of the required extramedical maternal provider demonstration project, as required by section 746 of the NDAA for FY 2021. DoD will provide a report to Congress annually thereafter for the duration of the demonstration.

#### 5) Initial Cost Estimate

The demonstration is anticipated to cost \$51.16 million (M) in health care and administrative costs, with an additional \$4.3M estimated for the statutorily-required evaluation of the demonstration over the 5-year period. Increased costs to the TRICARE Program for breastfeeding counseling are estimated to be \$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. The \$4.3M in evaluation costs are necessary to ensure DoD is able to report on all items required by section 746 for future reports to Congress, which requires DoD to report on:

- The number of covered beneficiaries enrolled in the demonstration.
- The number of enrolled covered beneficiaries who have participated in the demonstration.
- The results of the required survey.
- The cost of the demonstration.
- An assessment of the quality of care provided to participants in the demonstration.
- An assessment of the impact of the demonstration on maternal and fetal outcomes.
- An assessment of the effectiveness of the demonstration.
- Recommendations for adjustments to the demonstration project.
- The estimated costs avoided as a result of improved maternal and fetal outcomes due to the demonstration project.
- Recommendations for extending the demonstration project or implementing permanent coverage under the TRICARE program of extramedical maternal health providers.
- An identification of legislative or administrative action necessary to make the demonstration project permanent.

### 6) Conclusion

This demonstration is designed to meet the requirements of section 746 of the NDAA for FY 2021, which require DoD to establish a 5-year demonstration project to evaluate the cost, quality of care, and impact on maternal and fetal outcomes of covering the services of doulas and lactation consultants or counselors not otherwise TRICARE-authorized, and to determine whether it would be appropriate to implement permanent coverage. DoD will submit to the Committees on Armed Services of the Senate and the House of Representatives a report on the cost of the demonstration and the effectiveness of the demonstration project in improving quality of care and the maternal and fetal outcomes of covered beneficiaries enrolled in this demonstration. Additionally, surveys will be administered to collect required information established in section 746 of the NDAA for FY 2021. While there is significant uncertainty in the final costs, DoD anticipates the demonstration to cost approximately \$55.5M over the 5 years to include health care, administration, and evaluation costs.