116TH CONGRESS
2D SESSION

S. _____

To improve the public health response to addressing maternal mortality and morbidity during the COVID–19 public health emergency.

IN THE SENATE OF THE UNITED STATES

Ms. WARREN (for herself, Mr. BOOKER, Ms. HARRIS, Mrs. GILLIBRAND, and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To improve the public health response to addressing maternal mortality and morbidity during the COVID–19 public health emergency.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Maternal Health Pandemic Response Act of 2020''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) The World Health Organization declared COVID–19 a ''Public Health Emergency of Inter-

national Concern'' on January 30, 2020. By the beginning of August 2020, there have been over 18,000,000 confirmed cases of, and over 700,000 deaths associated with, COVID–19 worldwide.

(2) In the United States, the number of cases of COVID–19 has quickly surpassed the number of such cases in every other nation, and as of August 5, 2020, over 4,000,000 cases and 156,000 deaths have been reported by the United States alone.

(3) Long-standing systemic health and social inequities have put communities of color at increased risk of contracting COVID–19 or experiencing severe illness; age-adjusted hospitalization rates from COVID–19 are highest for American Indian and Alaska Native, Black, and Latinx people.

(4) Prior to the start of the COVID–19 pandemic, the United States was facing a maternal mortality and morbidity crisis, in which the United States has the highest maternal mortality rate in the developed world, and that rate is not improving.

(5) More than 50,000 women in the United States annually experience severe maternal morbidity, and much larger numbers experience more common harmful challenges, such as prenatal and

postpartum anxiety and depression and lack of support for meeting breastfeeding goals.

(6) Compared to white women, Black and American Indian and Alaska Native women in the United States are significantly more likely to die from pregnancy-related complications, and Black and American Indian and Alaska Native women suffer disproportionately high rates of maternal morbidity.

(7) The causes of maternal mortality and morbidity are complex and include racial, ethnic, and socioeconomic inequities; racism, bias, and discrimination; comorbidities; and inadequate access to the health care system, including behavioral health care, which are factors that have similarly contributed to the racial disparities seen in COVID–19 outcomes.

(8) The burden of morbidity and mortality in the United States for both COVID–19 and maternal health outcomes has also fallen disproportionately on Black, Latinx, and American Indian and Alaska Native communities, who suffer the most from great public health needs and are the most medically underserved.

(9) According to the Centers for Disease Control and Prevention, ''pregnant people have changes

in their bodies that may increase their risk of some infections'' and ''pregnant people have had a higher risk of severe illness when infected with viruses from the same family as COVID–19 and other viral respiratory infections, such as influenza''.

(10) As of June 25, 2020, the latest information from the Centers for Disease Control and Prevention indicates that pregnant women are more likely to be hospitalized and are at higher risk for intensive care unit admissions than nonpregnant women due to COVID–19, and Latinx and Black pregnant people have been disproportionately infected by COVID–19.

(11) Our understanding of the specific impact of COVID–19 on pregnant people is limited, in part due to a lack of robust data collection, but the COVID–19 pandemic has further strained the health care system and added another layer of fear and vulnerability for pregnant people, with disproportionate effects on people of color.

(12) As of July 30, 2020, over 14,000 pregnant people in the United States have tested positive for COVID–19 and 35 pregnant people have died as result of COVID–19.

(13) The World Health Organization states that everyone ''has the right to safe and positive childbirth experience, whether or not they have a confirmed COVID–19 infection, this includes the right to respect and dignity, a companion of choice, clear communication by maternity staff, pain relief strategies, and mobility in labor when possible and the position of choice''.

(14) A COVID–19 public health response without concerted Federal action and focus on maternal health care access and quality, research, data collection, mitigating negative socioeconomic consequences of the pandemic, and safeguarding the right to safe and positive childbirth experience will risk exacerbating the maternal mortality and morbidity crisis.

SEC. 3. DEFINITIONS.

In this Act:

(1) COVID–19 PUBLIC HEALTH EMERGENCY.—The term ''COVID–19 public health emergency'' means the period beginning on the date that the public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to COVID–19 took

effect, and ending on the later of the end of such public health emergency or January 1, 2023.

(2) CULTURALLY CONGRUENT.—The term ''culturally congruent'', with respect to care or maternity care, means care that is anti-racist and is in agreement with the preferred cultural values, beliefs, worldview, and practices of the health care consumer and other stakeholders.

(3) INDIAN TRIBE, TRIBAL ORGANIZATION, AND URBAN INDIAN ORGANIZATION.—The terms ''Indian Tribe'' and ''Tribal organization'' have the meanings given the terms ''Indian tribe'' and ''tribal organization'', respectively, in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304)), and the term ''urban Indian organization'' has the meaning given such term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

(4) MATERNAL MORTALITY.—The term ''maternal mortality'' means a death occurring during pregnancy or within one year of the end of pregnancy, from a pregnancy complication, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy.

(5) POSTPARTUM.—The term ''postpartum'' means the 1-year period beginning on the last day of a person's pregnancy.

(6) RESPECTFUL MATERNITY CARE.—The term ''respectful maternity care'' refers to care organized for, and provided to, all pregnant and postpartum people in a manner that is culturally congruent, maintains their dignity, privacy, and confidentiality, ensures freedom from harm and mistreatment, and enables informed choice and continuous support during labor, childbirth, and postpartum.

(7) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(8) SEVERE MATERNAL MORBIDITY.—The term ''severe maternal morbidity'' means an unexpected outcome caused by labor and delivery that results in significant short-term or long-term consequences to the health of the pregnant person.

SEC. 4. EMERGENCY FUNDING FOR FEDERAL DATA COLLECTION, SURVEILLANCE AND RESEARCH ON MATERNAL HEALTH OUTCOMES DURING THE COVID–19 PUBLIC HEALTH EMERGENCY.

To conduct or support data collection, surveillance, and research on maternal health as a result of the COVID–19 public health emergency, including support to

assist in the capacity building for State, Tribal, territorial, and local public health departments to collect and transmit racial, ethnic, and other demographic data related to maternal health, there are authorized to be appropriated—

(1) $100,000,000 for the Surveillance for Emerging Threats to Mothers and Babies program of the Centers for Disease Control and Prevention, to support the Centers for Disease Control and Prevention in its efforts to—

(A) work with public health, clinical, and community-based organizations to provide timely, continually updated guidance to families and health care providers on ways to reduce risk to mothers and babies and tailor interventions to improve their long-term health;

(B) partner with more State, Tribal, territorial, and local public health programs in the collection and analysis of clinical data on the impact of COVID–19 on pregnant and postpartum patients and their newborns, including among pregnant people of color; and

(C) establish regionally-based centers of excellence to offer medical, public health, and other knowledge to ensure communities, espe-

cially communities of color, can help pregnant and postpartum patients and infants get the care they need;

(2) $30,000,000 for the Enhancing Reviews and Surveillance to Eliminate Maternal Mortality program (commonly known as the ''ERASE MM program'') of the Centers for Disease Control and Prevention, to support the Centers for Disease Control and Prevention in expanding its partnerships with States and Indian Tribes and provide technical assistance to existing Maternal Mortality Review Committees; and

(3) $45,000,000 for the Pregnancy Risk Assessment Monitoring System (commonly known as the ''PRAMS'') of the Centers for Disease Control and Prevention, to support the Centers for Disease Control and Prevention in its efforts to—

(A) create a COVID–19 supplement to its PRAMS questionnaire;

(B) add questions around experiences of respectful maternity care in prenatal, intrapartum, and postpartum care;

(C) conduct a rapid assessment of COVID–19 awareness, impact on care and experiences, and use of preventive measures

among pregnant, laboring and birthing, and postpartum people during the COVID–19 public health emergency; and

(D) work to transition the survey to an electronic platform and expand the survey to a larger population, with a special focus on reaching underrepresented communities;

(4) $15,000,000 for the National Institute of Child Health and Human Development, to conduct or support research for interventions to mitigate the effects of the COVID–19 public health emergency on pregnant and postpartum people, including Black, Latinx, Asian-American and Pacific Islander, and American Indian and Alaska Native people.

SEC. 5. COVID–19 MATERNAL HEALTH DATA COLLECTION AND DISCLOSURE.

(a) DATA COLLECTION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Administrator of the Centers for Medicare & Medicaid Services, shall make publicly available, on the website of the Centers for Disease Control and Prevention, pregnancy and postpartum data collected across all surveillance systems relating to COVID–19, disaggregated by race, ethnicity, State, and Tribal location including the following:

(1) Data related to all COVID–19 diagnostic testing, including the number of pregnant people and postpartum people tested and the number of positive cases.

(2) Data related to all suspected cases of COVID–19 in pregnant, birthing, and postpartum people who did not undergo testing.

(3) Data related to all COVID–19 serologic testing, including the number of pregnant and postpartum people tested and the number of such serologic tests that were positive.

(4) Data related to treatment for COVID–19, including hospitalizations, emergency room, and intensive care unit admissions of pregnant, birthing, and postpartum people related to COVID–19.

(5) Data related to COVID–19 outcomes, including total fatalities and case fatality (expressed as the proportion of people who were infected with COVID–19 and died from the virus) of pregnant and postpartum people.

(6) Data related to pregnancy and infant health outcomes for pregnant people with confirmed or suspected COVID–19, which may include stillbirths, maternal mortality and morbidity, infant mortality,

preterm births, low-birth weight infants, and cesarean section births.

(b) TIMELINE.—The Secretary shall update the data made available under this section not less frequently than monthly, during the COVID–19 public health emergency and for at least one month after the end of the COVID–19 public health emergency.

(c) PRIVACY.—In publishing data under this section, the Secretary shall take all necessary steps to protect the privacy of people whose information is included in such data, including by complying with—

(1) privacy protections under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(2) protections from all inappropriate internal use by an entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from inappropriate uses.

(d) INDIAN HEALTH SERVICE.—The Director of the Indian Health Service and Director of the Centers for Disease Control and Prevention shall consult with Indian Tribes and confer with urban Indian organizations on data collection and reporting for purposes of this section.

(e) DATA COLLECTION GUIDANCE.—The Secretary shall issue guidance to States and local public health departments to ensure that all relevant demographic data, including pregnancy and postpartum status, are collected and included when sending COVID–19 testing specimen to laboratories, and State and local health departments and Indian Tribes are disaggregating data on COVID–19 status in data on maternal and infant morbidity and mortality. The Secretary shall ensure that the guidance is developed in consultation with Indian Tribes to ensure that it includes tribally-developed best practices on reducing misclassification of American Indian and Alaska Native people in Federal, State, and local public health surveillance systems.

SEC. 6. INCLUSION OF PREGNANT PEOPLE AND LACTATING PEOPLE IN VACCINE AND THERAPEUTIC DEVELOPMENT FOR COVID–19.

(a) IN GENERAL.—The Director of the National Institutes of Health shall—

(1) support and advance the responsible inclusion of pregnant and lactating people in COVID–19 therapeutic and vaccine clinical trials when safe and appropriate;

(2) prioritize the implementation of final recommendations made by the Task Force on Research

Specific to Pregnant Women and Lactating Women to improve the inclusion of pregnant and lactating people in clinical research when safe and appropriate, particularly as these recommendations apply to the development and issuance of safe and effective COVID–19 therapeutics and vaccines; and

(3) ensure that at least one COVID–19 vaccine developed and made available for use in the United States is suitable for pregnant people and lactating people.

(b) REQUIREMENTS.—

(1) REPORTING REQUIREMENTS.—The Director of the National Institutes of Health shall collect information from every developer of a drug or biological product for the treatment or prevention of COVID–19 in the clinical stages of development that received Federal funding from the Department of Health and Human Services and its subagencies regarding—

(A) how evidence is being generated to evaluate the safety, efficacy, and appropriate dosing of the drug or biological product among pregnant people and lactating people;

(B) plans for the systematic collection of data from people who are inadvertently exposed

to the drug or biological product while pregnant or lactating;

(C) plans for the inclusion of pregnant people and lactating people, including racial and ethnic minorities disproportionately affected by COVID–19, in clinical trials or the rationale for exclusion; and

(D) plans for performing Developmental and Reproductive Toxicology studies, or the rationale for not performing such studies.

(2) DRUG APPROVALS AND BIOLOGICAL PRODUCT LICENSING.—The Commissioner of Food and Drugs shall require a drug or biological product developer submit, as part of an application for approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensing of a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) for the treatment or prevention of COVID–19—

(A) an adequate representation of the effect of the drug or biological product on pregnant people and lactating people, either through the inclusion of pregnant people and lactating people in clinical trials when safe and appropriate or other research, or through a scientific

and ethical justification as to why pregnant people or lactating people were not included in clinical trials; and

(B) a comprehensive plan for the collection of additional evidence of safety and efficacy for pregnant and lactating people after approval under such section 505 or licensure under such section 351, or after issuance of an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3).

SEC. 7. PUBLIC HEALTH COMMUNICATION REGARDING MATERNAL CARE DURING COVID–19.

(a) PUBLIC HEALTH CAMPAIGN.—The Director of the Centers for Disease Control and Prevention shall undertake a robust public health education effort to enhance access by pregnant people, their employers, and their providers to accurate, evidence-based health information about COVID–19 and pregnancy, safety, and risk, with a particular focus on reaching pregnant people in underserved communities.

(b) EMERGENCY TEMPORARY STANDARD.—

(1) IN GENERAL.—In consideration of the grave risk presented by COVID–19 and the need to strengthen protections for employees, pursuant to

section 6(c)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(c)(1)) and notwithstanding the provisions of law and the Executive order listed in paragraph (3), not later than 7 days after the date of enactment of this Act, the Secretary of Labor shall promulgate an emergency temporary standard to protect all employees at occupational risk from occupational exposure to SARS–CoV–2.

(2) PREGNANT AND POSTPARTUM EMPLOYEES.—The emergency temporary standard promulgated under this subsection shall include consideration of the risks and needs specific to pregnant and postpartum employees.

(3) INAPPLICABLE PROVISIONS OF LAW AND EXECUTIVE ORDER.—The requirements of chapter 6 of title 5, United States Code (commonly referred to as the ''Regulatory Flexibility Act''), subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act''), the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq.), and Executive Order 12866 (58 Fed. Reg. 190; relating to regulatory planning and review), as amended, shall not apply to the standard promulgated under this subsection.

(c) TASK FORCE ON BIRTHING EXPERIENCE AND SAFE, RESPECTFUL MATERNITY CARE IN RESPONSE TO THE COVID–19 PUBLIC HEALTH EMERGENCY.—

(1) ESTABLISHMENT.—The Secretary, in consultation with the Director of the Centers for Disease Control and Prevention and the Administrator of the Health Resources and Services Administration, shall convene a task force to develop Federal recommendations regarding respectful maternity care, including safe birth care and postpartum care, during the COVID–19 public health emergency.

(2) DUTIES.—The task force established under paragraph (1) shall develop, publicly post, and update Federal recommendations in multiple languages to ensure quality, provide nondiscriminatory maternity care, promote positive birthing experiences, and improve maternal health outcomes during the COVID–19 public health emergency, with a particular focus on outcomes for communities of color and rural populations. Such guidelines and recommendations shall—

(A) address, with particular attention to ensuring equitable treatment on the basis of race and ethnicity—

(i) measures to facilitate respectful maternity care;

(ii) strategies to increase access to specialized care for those with high-risk pregnancies or pregnant individuals with elevated risk factors;

(iii) COVID–19 diagnostic testing for pregnant and laboring patients;

(iv) birthing without one's chosen companions, with one's chosen companions, and with smartphone or other telehealth connection to one's chosen companions;

(v) newborn separation after birth in relation to maternal COVID–19 status;

(vi) breast milk feeding in relation to maternal COVID–19 status;

(vii) licensure, training, scope of practice, and Medicaid and other insurance reimbursement for certified midwives, certified nurse-midwives, certified professional midwives, in a manner that facilitates inclusion of midwives of color and midwives from underserved communities;

(viii) financial support for perinatal health workers who provide non-clinical

support to people from pregnancy through the postpartum period, such as a doula, community health worker, peer supporter, lactation consultant, nutritionist or dietitian, social worker, home visitor, or a patient navigator in a manner that facilitates inclusion from underserved communities;

(ix) how to identify, address, and treat prenatal and postpartum mental and behavioral health conditions, such as anxiety, substance use disorder, and depression, which may have arisen or increased during the COVID–19 public health emergency;

(x) strategies to address hospital capacity concerns in communities with a surge in COVID–19 cases and to provide childbearing people with options that reduce potential for cross-contamination and increase the ability to implement their care preferences while maintaining safety and quality, such as the use of auxiliary maternity units and freestanding birth centers;

(xi) how to identify and address racism, bias, and discrimination in the deliv-

ery treatment and support to pregnant and postpartum people, including evaluating the value of training for hospital staff on implicit bias and racism, respectful maternity care, and demographic data collection; and

(xii) such other matters as the task force determines appropriate;

(B) identify barriers to the implementation of the guidelines and recommendations;

(C) take into consideration existing State and other programs that have demonstrated effectiveness in addressing pregnancy, birth, and postpartum care during the COVID–19 public health emergency; and

(D) identify policies specific to COVID–19 that should be discontinued when safely possible and those that should be continued as the public health emergency abates.

(3) MEMBERSHIP.—The task force established under paragraph (1) shall be comprised of—

(A) representatives of the Department of Health and Human Services, including representatives of—

(i) the Secretary;

(ii) the Director of the Centers for Disease Control and Prevention;

(iii) the Administrator of the Health Resources and Services Administration;

(iv) the Administrator of the Centers for Medicare & Medicaid Services;

(v) the Director of the Agency for Healthcare Research and Quality; and

(vi) the Director of the Indian Health Service;

(B) at least 3 State, local, or territorial public health officials representing departments of public health, who shall represent jurisdictions from different regions of the United States with relatively high concentrations of historically marginalized populations, to be appointed by the Secretary;

(C) at least 1 Tribal public health official representing departments of public health;

(D) 1 or more representatives of a community-based organization that addresses adverse maternal health outcomes with a specific focus on racial and ethnic inequities in maternal health outcomes, appointed by the Secretary, with special consideration given to organizations

led by a person of color or from communities with significant minority populations;

(E) 1 or more obstetrician-gynecologist or other physician who provides obstetric care, with special consideration for physicians who are from, or work in, communities experiencing the highest rates of COVID–19 mortality and morbidity;

(F) 1 or more nurse, such as a certified nurse-midwife, women's health nurse practitioner, or other nurse who provides obstetric care, with special consideration for nurses who are from, or work in, communities experiencing the highest rates of COVID–19 mortality and morbidity;

(G) 1 or more perinatal health workers who provide non-clinical support to people from pregnancy through postpartum period, such as a doula, community health worker, peer supporter, lactation consultant, nutritionist or dietitian, social worker, home visitor, or patient navigator;

(H) 1 or more patients who were pregnant or gave birth during the COVID–19 public health emergency;

(I) 1 or more patients who contracted COVID–19 and later gave birth;

(J) 1 or more patients who have received support from a perinatal health worker who provides prenatal and postpartum support, such as a doula, community health worker, peer supporter, lactation consultant, nutritionist or dietitian, social worker, home visitor, or a patient navigator, or a spouse or family member of such patient; and

(K) racially and ethnically diverse representation from at least 3 independent experts with knowledge or field experience with racial and ethnic disparities in public health, women's health, or maternal mortality and severe maternal morbidity.

SEC. 8. GAO REPORT ON MATERNAL HEALTH AND PUBLIC HEALTH EMERGENCY PREPAREDNESS.

Not later than 1 year after the end of the public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to COVID–19, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report on maternal health and public health

emergency preparedness, including prenatal, labor and delivery, and postpartum care during the COVID–19 public health emergency, including the following:

(1) A review of the prenatal, labor and delivery, and postpartum experiences of people during the COVID–19 public health emergency, which shall—

(A) identify barriers to accessing pregnancy, birth, and postpartum care during a pandemic;

(B) assess the extent to which public and private insurers were providing coverage for maternal health care during the public health emergency, including for telehealth services;

(C) to the extent practicable, analyze maternal and infant health outcomes by race and ethnicity (including quality of care, mortality, morbidity, cesarean section rates, preterm birth, prevalence of prenatal and postpartum anxiety and depression) during the COVID–19 public health emergency and the impact of Federal and State policy changes made in response to the COVID–19 pandemic on such outcomes;

(D) identify contributors to population-based disparities seen in COVID–19 outcomes, such as racial profiling of, and bias and dis-

crimination against Black, American Indian and Alaska Native, Latinx, and Asian-American and Pacific Islander people; and

(E) review the impact of increased unemployment, paid family leave, changes in health care coverage, and other social determinants of health for pregnant and postpartum people during the public health emergency.

(2) Consultation with maternity care providers, maternal mental and behavioral health care specialists, researchers who specialize in women's health or maternal mortality and severe maternal morbidity, people who experienced pregnancy or childbirth during the COVID–19 public health emergency, representatives from community-based organizations that address maternal health, and perinatal health workers who provide nonclinical support to pregnant and postpartum people (such as a doula, community health worker, peer support, certified lactation consultant, nutritionist or dietician, social worker, home visitor, or navigator).

(3) Recommendations to improve the public health emergency response and preparedness efforts of the Federal Government specific to maternal

health, with a particular focus on outcomes for minority women, including—

(A) ways to improve research, surveillance, and data collection of the Federal Government related to maternal health;

(B) ways for the Federal Government to factor maternal health outcomes and disparities into decisions regarding distribution of resources, including COVID–19 tests, personal protective equipment, and emergency funding;

(C) the extent to which guidelines and recommendations of the Federal Government related to maternal health care during the COVID–19 public health emergency were culturally congruent and linguistically competent for minority women; and

(D) ways to improve the distribution of public health funds, data, and information to Indian Tribes and Tribal organizations with regard to maternal health during the COVID–19 public health emergency.