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.
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”.

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 Con-
trol 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 As-
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 ex-
periences, and use of preventive measures
among pregnant, laboring and birthing, and
postpartum people during the COVID–19 pub-
lic 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 reach-
ing 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 avail-
able, 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.
(c) 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 appro-
priate, 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 in-
formation from every developer of a drug or biologi-
cal 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 re-
garding—

(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 ra-
tionale for not performing such studies.

(2) DRUG APPROVALS AND BIOLOGICAL PROD-
UCT LICENSING.—The Commissioner of Food and
Drugs shall require a drug or biological product de-
developer submit, as part of an application for ap-
proval 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 ef-
fect of the drug or biological product on preg-
nant people and lactating people, either through
the inclusion of pregnant people and lactating
people in clinical trials when safe and appro-
priate 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 Fed-
eral Food, Drug, and Cosmetic Act (21 U.S.C.
360bbb–3).

SEC. 7. PUBLIC HEALTH COMMUNICATION REGARDING MA-
TERNAL CARE DURING COVID–19.

(a) PUBLIC HEALTH CAMPAIGN.—The Director of
the Centers for Disease Control and Prevention shall un-
dertake a robust public health education effort to enhance
access by pregnant people, their employers, and their pro-
viders to accurate, evidence-based health information
about COVID–19 and pregnancy, safety, and risk, with
a particular focus on reaching pregnant people in under-
served 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 not-withstanding 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 dieti-
tian, social worker, home visitor, or a pa-
tient 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 anx-
xiety, substance use disorder, and depres-
sion, which may have arisen or increased
during the COVID–19 public health emer-
gency;

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

(xi) how to identify and address rac-
ism, bias, and discrimination in the deliv-
every 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 practi-
tioner, 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 sup-
porter, lactation consultant, nutritionist or die-
titian, 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-
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crimination against Black, American Indian
and Alaska Native, Latinx, and Asian-American
and Pacific Islander people; and

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

(2) Consultation with maternity care providers,
maternal mental and behavioral health care special-
ists, researchers who specialize in women’s health or
maternal mortality and severe maternal morbidity,
people who experienced pregnancy or childbirth dur-
ing the COVID–19 public health emergency, rep-
resentatives 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 con-
sultant, 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.