



SUMMARY OF PROVISIONS IMPORTANT TO MATERNAL HEALTH IN THE FISCAL YEAR (FY) 2022 FEDERAL SPENDING BILL

On March 15, President Biden signed legislation that will fund federal agencies through the end of fiscal year (FY) 2022. Included in the \$1.5 trillion bill are a number of provisions focused on maternal health. Notably, the bill includes the text of long-time SMFM priority, the **Maternal Health Quality Improvement Act (MHQIA)**. MHQIA will bolster the Alliance for Innovation on Maternal Health (AIM) Program, authorize new programs to train clinicians on implicit bias and culturally competent care, support a new initiative to improve postpartum care, create new rural obstetric networks, and much more. SMFM is thrilled MHQIA is now law and will lead efforts to guarantee programs are implemented effectively and equitably.

The FY 2022 spending bill also includes a small but critical provision to advance SMFM's goal of including more pregnant and lactating people in clinical trials. It will **fund the National Academies of Science, Engineering and Medicine (NASEM) to convene a workshop to examine real and perceived liability barriers to including pregnant and lactating people in clinical trials**. This convening was a priority of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), and the recommendations from the expert convening will help guide our future work in this space.

You can read more about these and other important provisions in the federal spending bill below.

Maternal Health Quality Improvement Act

SMFM has been lobbying for several years to enact the MHQIA, legislation that is foundational to federal efforts to reduce preventable maternal deaths. We are thrilled Congressional leaders chose to include the bill in the final FY 2022 spending package. The bill:

- Helps guarantee the continuation of the Alliance for Innovation on Maternal Health (AIM) Program by including language authorizing the program in federal statute.
- Creates a new grant program for racial and ethnic bias training for health care providers.
- Funds a study on best practices for teaching within health professional training programs to reduce and prevent discrimination.
- Establishes a new grant program for developing integrated health care services for pregnant and postpartum women and infants, with grants and reporting of study outcomes. This model of care is commonly referred to as a pregnancy medical home.
- Directs the Centers for Disease Control and Prevention (CDC) to take steps to improve maternal vaccination rates.
- Instructs the CDC to improve data on rural maternal and obstetric care.
- Incorporates the existing Rural Maternity and Obstetric Management Strategies (RMOMS) Program, which supports rural obstetric networks, into federal statute.

- Expands existing federal telehealth grant programs to include birth and postpartum services as part of telehealth networks.
- Establishes a new rural maternal and obstetric care training demonstration program to support training for family medicine physicians, obstetricians, nurse practitioners, physician assistants, midwives, doulas, and other professionals to provide maternal care services in rural community-based settings.

SMFM is thrilled MHQIA is now law and will lead the charge to guarantee programs are implemented effectively and equitably.

FY 2022 Funding for Federal Programs Impacting Maternal Health

Health Resources and Services Administration (HRSA)

HRSA is charged with providing equitable health care to underserved communities, including pregnant people, mothers, and their families. The agency also supports health infrastructure, including programs to train health professionals and distribute them to underserved areas.

- **Maternal and Child Health Block Grant: \$747.7 million (+\$35 million over FY 2021)**
The MCH Block Grant provides flexible funding to states to improve health outcomes for pregnant people, mothers, and children. State maternal and child health initiatives are often funded by the MCH Block Grant.
- **Title X Family Planning Program: \$286.5 million (equal to FY 2021 funding)**
The Title X Program provides grants to health care entities to provide individuals with comprehensive family planning and related preventive health services.
- **Healthy Start Program: \$131.8 million (+\$3.8 million over FY 2021)**
The Healthy Start Program provides grants to communities with high rates of infant mortality to support primary and preventive health care services for mothers and their infants.
- **State Maternal Health Innovation Grants: \$29 million (+\$6 million over FY 2021)**
State Maternal Health Innovation grants assist states and maternal health experts in optimizing resources to implement state-specific actions that address disparities in maternal health and improve maternal health outcomes.
- **AIM Program: \$12 million (+\$3 million over FY 2021)**
The AIM Program supports states in implementing quality improvement initiatives to reduce maternal mortality and morbidity.
- **Screening and Treatment of Maternal Depression and Related Behavioral Disorders Program: \$6.5 million (+\$1.5 million over FY 2021)**
State-based grant program that trains clinicians to screen, assess, and treat for maternal mental health conditions and provides specialized psychiatric consultation to assist clinicians.
- **RMOMS Program: \$6 million (+\$1 million over FY 2021)**
Grant program focused on improving access to and continuity of maternal and obstetrics care in rural communities.
- **Maternal Mental Health Hotline: \$4 million (+\$1 million over FY 2021)**
National voice and text hotline staffed by licensed health care professionals trained to help pregnant and postpartum people, and their family members, affected by maternal mental health and substance use disorders.

CDC

CDC is charged with protecting Americans from health, safety, and security threats by supporting core public health functions at state, local, and tribal health departments; detecting and responding to new and emerging health threats; promoting health and safety; and providing leadership in the public health workforce.

- **National Center on Birth Defects and Developmental Disabilities (NCBDDD): \$177.1 million (+\$9.25 million over FY 2021)**
NCBDDD is charged with reducing infant mortality through surveillance, research, and prevention of birth defects and infant disorders.
- **Surveillance for Emerging Threats to Moms and Babies Network (SET-NET): \$13 million (+\$3 million over FY 2021)**
SET-NET collects longitudinal health information of people exposed to a health threat during pregnancy and their infants. Data are then used to inform clinical decision-making and public health action.
- **Neonatal Abstinence Syndrome (NAS) Surveillance: \$3.25 million (+\$1 million over FY 2021)**
Grant program for state and local public health departments to collect data on the number of infants diagnosed with NAS at birth using consistent surveillance case definition.
- **Division of Reproductive Health (DRH): \$83 million (+\$20 million over FY 2021)**
DRH is charged with promoting optimal and equitable health in women and infants through public health surveillance, research, leadership, and partnership to move science to practice. [Congress directed DRH to use the funding increase in FY 2022 to support additional state maternal mortality review committees and perinatal quality collaboratives.](#)
- **National Center on Health Statistics (NCHS): \$180.4 million (+\$5 million over FY 2021)**
NCHS is the nation's principal health statistics agency, providing data on issues from birth rates to health insurance status to identify and address health issues.

National Institutes of Health (NIH)

NIH conducts and supports research to understand the basic biology of human health and disease; applies this understanding toward designing new approaches for preventing, diagnosing, and treating disease and disability; and ensures that these approaches are widely available.

- **Eunice Kennedy Shriver National Institute on Child Health Human Development (NICHD): \$1.68 billion (+\$92.7 million over FY 2021)**
NICHD investigates human development throughout the entire life process, with a focus on understanding important events that occur during pregnancy.
- **Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative: \$43.4 million (+\$30 million over FY 2021)**
The IMPROVE Initiative, spearheaded by NICHD, advances research to reduce preventable causes of maternal deaths and improve health for pregnant and postpartum individuals before, during, and after delivery.
- **National Institute of Environmental Health Sciences (NIEHS): \$842.2 million (+\$27.5 million over FY 2021)**
NIEHS conducts and funds research on the effects of the environment on human disease, including the impact of environmental exposures in pregnancy.

Other Agencies and Programs

- **Agency for Healthcare Research and Quality (AHRQ): \$350.4 million (+\$12.4 million over FY 2021)**
AHRQ conducts, supports, and disseminates scientific and policy-relevant research on promoting high-quality care, eliminating health care disparities, using information technology, and evaluating the effectiveness of clinical services.
Congress directed AHRQ to continue initiatives on improving maternal morbidity and mortality state and local data and prenatal care for pregnant individuals.
- **Pregnant and Postpartum Women Treatment Program: \$34.9 million (+\$2 million over FY 2021)**
Administered by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Pregnant and Postpartum Women Treatment program allocates funding to states to provide specialized in- and outpatient substance use disorder treatment for pregnant and parenting women.
- **Child Abuse Prevention and Treatment Act Infant Plans of Safe Care Grant: \$60 million (equal to FY 2021 funding)**
Dedicated funding to states to help implement federal requirements that all infants born with substance exposure have a plan of safe care upon hospital discharge.

Promoting the Inclusion of Pregnant and Lactating People in Clinical Trials

The FY 2022 spending bill also includes a small but critical provision to advance SMFM's goal of including more pregnant and lactating people in clinical trials. It will fund the National Academies of Science, Engineering and Medicine (NASEM) to convene a workshop to examine real and perceived liability barriers to including pregnant and lactating people in clinical trials. The bill also includes language that encourages the US Secretary of Health and Human Services to direct federal agencies to update their policies to reflect changes to the Common Rule in 2019 that removed pregnant people as a vulnerable population in federally funded research. You can find report language below. SMFM led lobbying efforts to include this funding and report language in the final FY 2022 spending bill.

FY 2022 Report Language on Inclusion of Pregnant And Lactating People In Clinical Trials

Research in Pregnant and Lactating Women.—The Committee is pleased with the progress being made by the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) in identifying and developing strategies to address gaps in knowledge and research on safe and effective therapies for pregnant and lactating women. The Committee encourages NICHD, along with other relevant Institutes and Centers, CDC, and FDA, to continue to implement PRGLAC recommendations to the extent appropriate and feasible under the legal authorities available to the Secretary.

Additionally, The Committee includes \$1,500,000 within NICHD to contract with the National Academies of Science, Education, and Medicine (NASEM) to convene a panel with specific legal, ethical, regulatory, and policy expertise to develop a framework for addressing medicolegal and liability issues when planning or conducting research specific to pregnant people and lactating people. Specifically, this panel should include individuals with ethical and legal expertise in clinical trials and research; regulatory expertise; plaintiffs' attorneys; pharmaceutical representatives with tort liability and research expertise; insurance industry representatives; Federally funded researchers who work with pregnant and lactating women; representatives of institutional review boards (IRBs); and health policy experts.

Research on Pregnant and Lactating Women.—The Committee encourages the Secretary to work with the NIH, FDA, the Office of Human Research Protections (OHRP), and other relevant agencies to

implement recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The Committee encourages the Secretary to direct NIH and FDA to implement guidance and templates surrounding the inclusion of pregnant and lactating individuals within clinical trials in order to require justification for the exclusion of these populations within clinical trials, and to clarify that exclusion of these populations within clinical trials should not be the default practice in the development and evaluation of drugs and therapeutics. The Secretary should work with OHRP and FDA to harmonize FDA regulations with changes to the protected status of pregnant women in federally funded research included in the 2018 revisions to the Federal Policy for the Protection of Human Subjects.

Pregnant and Lactating Individuals in Clinical Trials.—The Committee encourages FDA to harmonize its regulations with changes to the protected status of pregnant individuals in federally funded research included in the most recent revisions to the Federal Policy for the Protection of Human Subjects. When relevant, FDA should consider requesting that sponsors provide justification for the exclusion of pregnant and lactating individuals within clinical trials. The Committee encourages FDA to continue to collaborate with NIH and CDC to strengthen cross-agency approaches to including pregnant and lactating individuals in federally funded research.