May 29, 2020

Submitted electronically to: ruralmaternalrfi@cms.hhs.gov

Dr. Nina Brown-Ashford
Acting Director, CMS Office of Minority Health
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for Information Regarding Maternal and Infant Health Care in Rural Communities

Dear Dr. Brown-Ashford:

The National Alliance of State Pharmacy Associations (NASPA), the American Association of Colleges of Pharmacy (AACP), the American Pharmacists Association (APhA), the American Society of Health-System Pharmacists (ASHP), and the National Community Pharmacists Association (NCPA) appreciate the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) Request for Information Regarding Maternal and Infant Health Care in Rural Communities. Pharmacist-provided maternal health services can improve health care access, quality, and outcomes for women and infants in rural communities and can reduce health disparities between rural and urban communities and within rural communities.

Pharmacists are a vital and accessible member of the healthcare team. Establishing pharmacist-provided maternal health services may lead to significant savings to the healthcare system. Pharmacists are well-equipped to provide these services and are more accessible than other healthcare providers. Research shows that pharmacists add significant value to the healthcare system. That value is, as of yet, largely unrealized in maternal health services. To decrease infant and maternal mortality, preterm birth, and unintended pregnancies, states should look to pharmacists as a capable workforce, ready to implement solutions.

Successful broad-scale implementation of pharmacist-provided maternal health services will require partnerships between providers, payers, and community-based pharmacists. For these services to be provided, payment of pharmacists' reasonable fees for the service of assessment of a patient for the purposes of prescribing or referral must be included. States should work with pharmacists to increase access to contraceptive, preconception, and early prenatal care to reduce Medicaid expenditures from unintended pregnancies and preterm birth.

Infant and maternal mortality, preterm birth, and unintended pregnancies are significant public health issues. Changes to the healthcare system allowing provision of primary care services by pharmacists are needed. Allowing pharmacists to provide primary care services to pregnant women and those capable of pregnancy will positively impact public health. Through these comments, we seek to provide answers to the questions outlined in the RFI regarding how pharmacist-provided maternal health services can improve access, quality, and outcomes for women and infants.

1. **What barriers exist in rural communities in trying to improve access, quality of care, and outcomes in prenatal, obstetrical, and postpartum care?**

Current barriers in rural communities to access, quality of care, and outcomes in prenatal, obstetrical, and postpartum care include a lack of providers, inappropriate or no use of contraceptives, unhealthy behaviors and lack of education for improvement, high pre-term birthrate, and maternal death rate.

Lack of Providers

Access is a routine barrier to healthcare services. The Association of American Medical Colleges (AAMC) predicts a shortage of up to 55,000 primary care physicians by 2032.[1] If current underserved populations begin to utilize healthcare services at the same rate as populations with fewer barriers to care, this number could be significantly higher. Growth in the nurse practitioner and physician assistant workforce will alleviate some of the projected shortage; however, only a little over 20% of these providers practice in primary care. Meanwhile, there are over 311,200[2] pharmacists in the U.S., many of whom are underutilized in their capacity to contribute to addressing these unmet health care needs.[3] Implementing comprehensive pharmacist-provided maternal health services can benefit a significant number of patients.

Inappropriate or No Use of Contraceptives

Contraceptives are effective at preventing pregnancy. Women who use them consistently and correctly account for 5% of all unintended pregnancies, while 41% and 54% of all unintended pregnancies can be attributed to those who use contraceptives inconsistently and not at all (or have a gap in use of a least one month), respectively.[4] To assist with this issue, 11 U.S. jurisdictions have passed statutes or implemented regulations that allow pharmacists to independently prescribe contraceptives: California, Colorado, District of Columbia, Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, Virginia, and West Virginia. Additionally, 11 states have broad collaborative practice authority allowing pharmacists to prescribe contraceptives under a collaborative practice agreement with another provider: Illinois, Michigan, Minnesota, Montana, Nebraska, South Carolina, South Dakota, Tennessee, Vermont, Washington, and Wisconsin.[5]

Unhealthy Behaviors

Unhealthy behaviors and delays in prenatal care may affect the health of the baby. Poor mental and physical health during childhood, behavioral issues, and lower educational attainment have been associated with children born from an unintended pregnancy.[6] A retrospective study of fetal-infant mortality in a Healthy Start community in Michigan showed that obesity, inadequate weight gain and

[1] AAMC. New Findings Confirm Predictions on Physician Shortage. *Press Release*. April 23, 2019. Available at: https://www.aamc.org/news-insights/press-releases/new-findings-confirm-predictions-physician-shortage
[2] U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. Available at: https://www.bls.gov/oes/current/oes291051.htm
[3] *See* Gums, John. Can pharmacists help fill the growing primary care gap? UF News. January 5, 2016. Available at: http://news.ufl.edu/articles/2016/01/can-pharmacists-help-fill-the-growing-primary-care-gap.php
[4] Guttmacher Institute. "Contraceptive Use in the United States." *Fact Sheet.* July 2018. Accessed 8 January 2020. https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states
[5] NASPA. "Pharmacist Prescribing: Hormonal Contraceptives." May 24, 2019. Available at: https://naspa.us/resource/contraceptives/
[6] Logan C, Holcombe E, Manlove J and Ryan S. "The Consequences of Unintended Childbearing: A White Paper." Child Trends, Inc. May 2007. Accessed 8 January 2020. https://pdfs.semanticscholar.org/b353/b02ae6cad716a7f64ca48b3edae63544c03e.pdf

anemia contribute as much to fetal and infant mortality as maternal substance abuse.[7] Pharmacists are an easily accessible source of information and education for pregnant women. According to the 2019 NCPA Digest, 57% of independent community pharmacies offer blood pressure monitoring, 33% provide diabetes disease state management training, and 23% provide tobacco cessation services. Eleven percent of independent community pharmacies provide enhanced services specifically related to weight management.[8]

High Pre-Term Birthrate and High Maternal Death-Rate

Pre-term births have been on the rise since 2014, and preterm and low birth weight account for almost 20% of infant deaths.[9] Of the 15 states with preterm birth rates greater than 10.3%, there were five that saw an increase from 2017 to 2018: Alabama, Illinois, Mississippi, Nebraska, and Texas. Louisiana was the highest of the 15 states with a high percentage of preterm birth at 12.99% reported in 2018.[10] Hospital costs for a preterm birth are more than 10 times that of a term birth.[11] The CDC has identified reducing preterm birth as a national public health priority and recommends providing women access to health care before and between pregnancies.[12]

In 2016, there were 16.9 deaths per 100,000 live births from pregnancy-related complications. Unfortunately, there are significant racial/ethnic disparities. There were 42.4 deaths per 100,000 live births in black, non-Hispanic women and 30.4 deaths per 100,000 live births among American Indian/Alaskan native non-Hispanic women.[13] The mortality rate in rural areas tends to be higher than it is in cities and suburbs.[14] Between 2011 and 2015, there were 23.3 deaths per 100,000 births in Tennessee and 19.4 in Kentucky.

Pharmacists can play a key role in reducing the risk of high pre-term birthrate and high maternal death rate by serving as a bridge to appropriate care for pregnant women, ensuring access by prescribing prenatal vitamins and administering progesterone, and determining presumptive eligibility for Medicaid benefits when necessary.

2. What opportunities are there to improve the above areas (i.e., access, quality and outcomes)?

There are many opportunities to improve access, quality of care, and outcomes in prenatal, obstetrical, and postpartum care due to lack of providers, inappropriate or no use of contraceptives, unhealthy behaviors and lack of education for improvement, high pre-term birthrate and maternal death rate by

[7] Kothari, Catherine & Wendt, Annie & Liggins, Oemeeka & Overton, Jacqueline & Sweezy, Luz. (2011). Assessing Maternal Risk for Fetal-Infant Mortality: A Population-Based Study to Prioritize Risk Reduction in a Healthy Start Community. Maternal and child health journal. 15. 68-76. 10.1007/s10995-009-0561-3.

[8] 2019 NCPA Digest. Available at: http://www.ncpa.co/pdf/digest/2019/2019-digest.pdf

[9] CDC. "Premature Birth." 17 October 2019. Accessed 13 January 2020. https://www.cdc.gov/reproductivehealth/features/premature-birth/index.html

[10] USDHHS. CDC. NCHS NVSS. *National Vital Statistics Reports. Births: Final Data for 2018. Supplemental tables.* 27 November 2019; 68 (13). Accessed 20 January 2020. https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13_tables-508.pdf#I19

[11] McLaurin KK, Wade SW, Kong AM, Diakun D, Olajide IR and Germano J. "Characteristics and health care utilization of otherwise healthy commercially and Medicaid insured preterm and full-term infants in the US." *Pediatric Health, Medicine and Therapeutics.* 2019:10;21–31. Accessed 22 January 2020. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6455110/pdf/phmt-10-021.pdf

[12] https://www.cdc.gov/reproductivehealth/features/premature-birth/index.html

[13] CDC. "Pregnancy Mortality Surveillance System." 10 October 2019. Accessed 20 January 2020. https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm

[14] Simpson, April. Rural America Has a Maternal Mortality Problem. Midwives Might Help Solve It. PEW Stateline. August 16, 2019. Available at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/08/16/rural-america-has-a-maternal-mortality-problem-midwives-might-help-solve-it

increasing pharmacists roles in the process. Approximately 95 percent of people live within five miles of a pharmacy.[15] Additionally, due to store hours and approachability of the pharmacy counter, pharmacists are the most accessible healthcare professional in many communities. In fact, for many underserved Americans, pharmacists are the only health professional they can access. Pharmacists offer immediate care that is close and convenient to home, and they are a bridge between our communities and providers, triaging medication and health needs, recommending needed vaccinations, and both administering those vaccines or referring patients for further follow-up. Developing a CMS Maternal Services Set for Pharmacists would greatly improve access to the services and education necessary to improve maternal and infant health, especially in rural areas. Opportunities exist in the following areas: pharmacist-provided care, pharmacists' presumptive eligibility designation, expansion of Medicaid covered services, adoption of the Women's Preventive Services Initiative Recommendations for Well-Woman Care and pharmacists' roles in those services.

Pharmacist-Provided Care

Comprehensive pharmacist-provided maternal health services address preconception, interconception, pregnancy, and postpartum health. Each stage of maternal health has unique needs. Education and screening should begin as early as 13 years of age and continue for the life of the patient. While all women can benefit from pharmacist services, not just those in their child-bearing years, pharmacist-provided maternal health services focus on those who are planning for pregnancy or are capable of pregnancy. Primary care services, including women's health, can be provided by pharmacists to help alleviate the shortage of primary care physicians.[16]

Pharmacists' Presumptive Eligibility Designation

The vast majority of women have coverage for maternal health services. Medicaid and private insurance covered 42.3% and 49.6% of all births in 2018, respectively. Around 4% of births were self-pay, which is generally considered uninsured. Black and Hispanic women are more likely to be covered under Medicaid (65.3% and 58.9%, respectively) than white, non-Hispanic women.[17] Some uninsured women may be eligible for Medicaid benefits. Presumptive eligibility is a Medicaid policy that allows states to authorize specific types of entities to screen for eligibility based on gross income and temporarily enroll pregnant women in Medicaid. This gives pregnant women immediate access to care and gets the process started for ongoing coverage. If the state designates, a pharmacist can determine presumptive eligibility. As part of a comprehensive maternal health services program, the ability to determine presumptive eligibility would be a significant patient benefit.

Expansion of Medicaid Covered Services

Family planning is a mandatory benefit under Medicaid. However, there is considerable variability in the services covered. Federal law generally allows states to pay for "family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who

[15] Patient Access to Pharmacists' Care Coalition. "The Value of Pharmacy." n.d. Accessed 9 March 2020. https://pharmacistscare.org/access-to-care/the-value-of-pharmacy/#:~:text=
[16] Jain SH. "Can Pharmacists Help Reinvent Primary Care in the United States?" Forbes. 10 October 2018. Accessed 8 January 2020. https://www.forbes.com/sites/sachinjain/2018/10/10/can-pharmacists-help-reinvent-primary-care-in-the-united-states/#2307a69f590b
[17] USDHHS. CDC. NCHS NVSS. *National Vital Statistics Reports. Births: Final Data for 2018.* 27 November 2019; 68 (13). Accessed 8 January 2020. https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf

desire such services and supplies."[18] In all states, Medicaid covers contraceptives. Some states have extended family planning services to include over-the-counter (OTC) supplies and drugs, counseling, and sexually transmitted infection (STI) screening and treatment.

Pharmacist-Provided WPSI Services

Provisions in the Affordable Care Act (ACA) require health plans to cover preventive services at no cost to the beneficiary.[19] For women this includes prenatal care; contraception; counseling and screening for sexually transmitted infections (STIs) and human immunodeficiency virus (HIV); lactation support; and screening for anxiety, gestational diabetes, and postpartum diabetes mellitus. In response to these provisions within the ACA, the Health Resources and Services Administration (HRSA) in conjunction with the Institutes of Medicine (IOM) developed the Women's Preventive Services Guidelines.[20] From that work, the American College of Obstetricians and Gynecologists (ACOG) launched the Women's Preventive Services Initiative (WPSI) – a coalition of health professional and consumer organizations tasked with developing, reviewing, and updating recommendations for women's preventive healthcare services.[21] If adopted by HRSA, women will have a comprehensive set of preventive services with full coverage under their health plan.

The WPSI focuses on well-woman care for women of all ages. Most of the preventive services identified are non-invasive and do not involve a physical examination. Pharmacists are already providing many of these services and making therapeutic recommendations at the request of their patients. Table 1 provides a list of preventive services identified by the WPSI that pharmacists are capable of providing to women of all ages. Some services may require additional training and resources to ensure competence and appropriate referrals to other healthcare providers for follow-up care.

Pharmacists are uniquely positioned in the community to offer these services to patients who may not seek routine medical care from a physician or other provider. Many of the services identified by WPSI align with the United States Preventive Services Task Force (USPSTF) recommendations. The USPSTF works to improve the health of Americans "by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications."[22]

Recommendations made by USPSTF are for preventive services that are offered in the primary care setting or services referred by a primary care provider. These recommendations are intended to help the provider and patient decide what preventive services are best. For example, folic acid is known to prevent neural tube defects.[23] Women who are planning or are capable of pregnancy should take a daily folic acid supplement. Pharmacists have the knowledge to make this recommendation and many practice in environments where the product is readily available. Making this recommendation at the pharmacy level will help ensure the patient is able to follow through with the recommendation.

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[18] Ranji U, Bair Y and Salganicoff A. "Medicaid and Family Planning: Background and Implications of the ACA." Kaiser Family Foundation. 3 February 2016. Accessed 13 January 2020. https://www.kff.org/report-section/medicaid-and-family-planning-medicaid-family-planning-policy/#endnote_link_148385-1

[19] Healthcare.gov. Preventive care benefits for women. Accessed May 24, 2020. Available at: https://www.healthcare.gov/preventive-care-women/

[20] HRSA. Women's Preventive Services Guidelines. December 17, 2019. Accessed May 2020. Available at: https://www.hrsa.gov/womens-guidelines/index.html

[21] Women's Preventive Services Initiative. ACOG. Accessed May 2020. Available at: https://www.womenspreventivehealth.org/

[22] U.S. Preventive Services Task Force. "About the USPSTF." March 2019. Accessed 16 January 2020. https://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf

[23] CDC. "Folic Acid & Neural Tube Defects: An Overview." November 9, 2017. Accessed May 2020. Available at: https://www.cdc.gov/ncbddd/birthdefectscount/basics.html

Table 1. Women's Preventive Services Initiative Recommendations for Well-Woman Care[24]

Prevention Services*	
Alcohol screening & counseling	Aspirin to prevent cardiovascular disease (CVD) & colorectal cancer (CRC)
Blood pressure screening	Breast cancer risk assessment
Contraceptive counseling & methods	Depression screening
Diabetes screening	Folic acid supplementation
Healthful diet & activity counseling	Hepatitis B and C risk assessment
HIV risk assessment	Immunizations
Interpersonal violence screening	Lipid screening
Obesity screening	Osteoporosis screening
Prevention of falls	Skin cancer counseling
STI prevention counseling	Substance use screening & counseling
Tobacco screening & counseling	Urinary incontinence screening
Prevention Services During Pregnancy	
Aspirin therapy to prevent preeclampsia	Breastfeeding counseling, service & supplies
Contraceptive counseling & methods	Depression screening
Folic acid supplementation	Gestational diabetes screening
Interpersonal violence screening	Tobacco screening & counseling
Prevention Services Postpartum	
Breastfeeding counseling, service & supplies	Contraceptive counseling & methods
Depression screening	Diabetes screening
Folic acid supplementation	Interpersonal violence screening
Tobacco screening & counseling	

*Prevention services apply to women of all ages regardless of pregnancy status.

3. What initiatives, including community-based efforts, have shown a positive impact on addressing barriers or maximizing opportunities?

Family planning services identified in Healthy People 2020 include reproductive and contraceptive services; pregnancy testing and counseling; preconception health services; prenatal care; infertility services; education, screening, testing, treatment, counseling, and referral for STIs and HIV; breast and pelvic exams; and breast and cervical cancer screening. Pharmacists are already providing many of these services, including contraception, preconception health services such as smoking cessation, progesterone administration to reduce recurrent preterm birth, pre- and post-exposure prophylaxis (PrEP and PEP) for HIV, and patient referral for screening and definitive treatment.[25,26] A study in Oregon, the first state to authorize pharmacists to independently prescribe hormonal contraceptives, showed significant benefit to the state Medicaid program when pharmacists were involved. Within the first two years of the policy change, pharmacists wrote 10% of new prescriptions for hormonal contraceptives, with 74% of those patients not using any form of birth control in the month prior to the pharmacist's prescription. The study also showed that pharmacists prevented more than 50 unintended

[24] NASPA. "Maternal Health Services Set for Pharmacists." Accessed May 2020. https://naspa.us/maternal-health/
[25] March of Dimes. "Progesterone (17P) To Reduce Recurrent Preterm Birth." n.d. Accessed 13 January 2020. https://www.marchofdimes.org/professionals/progesterone-17p-to-reduce-recurrent-preterm-birth.aspx
[26] California Pharmacists Association. "SB 159 (Wiener) – PrEP & PEP – Pharmacists' Authority to Furnish." 8 October 2019. Accessed 13 January 2020. https://cpha.com/wp-content/uploads/2019/10/PrEP-PEP-Fact-Sheet-10-8-2019.pdf

pregnancies and saved the state $1.6 million in public costs.[27] A 2010 study in North Carolina showed that administration of subcutaneous medroxyprogesterone acetate by community pharmacists was not only feasible but showed continuation rates and patient satisfaction comparable to the family planning clinic.[28]

Pharmacists are trained to provide comprehensive, quality health care services. Studies have shown positive outcomes when pharmacists are involved in the management of chronic medical conditions, and immunization rates have improved since pharmacists have been authorized to administer vaccines.[29] Pharmacists are providing medical screening, health and wellness counseling, medication management services, and patient education. Primary care services, including women's health, can be provided by pharmacists to help alleviate the shortage of primary care physicians.[30]

Community pharmacy staff members are also being utilized to provide increased access in rural communities. Pharmacy technicians and delivery drivers are being trained as community health workers to conduct patient needs assessments – care coordination, medications, social services, and more. The Centers for Disease Control and Prevention defines community health workers as liaisons with resources in the communities they serve. They play a vital role in improving health by providing a connection between health systems and community resources, as well as education on how to reduce behavioral health risk factors. Many pharmacy technicians were already performing many of these responsibilities; however, they are now receiving the training aligned with community health worker education. These technicians and delivery drivers could be helpful in increasing the availability of pregnancy and infant-related health care and the ability of individuals to receive maternal health services.

Approximately 5% of pregnant women use one or more addictive substances, which include alcohol, tobacco and illicit drugs. The use of one of these substances is associated with at least a two times higher incidence of stillbirth.[31] Use of these substances during pregnancy can also lead to preterm birth, low birthweight, birth defects, small head circumference, neonatal abstinence syndrome (NAS), or sudden infant death syndrome (SIDS). Substance use is the leading cause of maternal death in the U.S. Pharmacists are well-trained to provide smoking cessation counseling and education, and in 12 states are able to independently prescribe smoking cessation therapies.[32] In a study including over 1,400 participants, researchers showed that pharmacist-provided smoking cessation interventions have quit rates on par with other healthcare professionals.[33]

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[27] Tracy Brawley. Pharmacist-prescribed birth control reaches new users, saves Oregon $1.6M. OHSU News. May 9, 2019. Accessed May 2020. Available at: https://news.ohsu.edu/2019/05/09/pharmacists-prescribed-birth-control-reaches-new-contraceptive-users-saves-oregon-1-6-million-in-public-costs#:~:text=Pharmacist%2Dprescribed%20birth%20control%20reaches%20new%20users%2C%20saves%20Oregon%20%241.6M,-New%20data%20shows&text=In%202016%2C%20Oregon%20became%20the,without%20a%20traditional%20clinic%20visit.

[28] Picardo C, Ferreri S. Pharmacist-administered subcutaneous depot medroxyprogesterone acetate: A pilot randomized controlled trial. Contraception. 2010;82(2):160–167.

[29] U.S. Public Health Service. Office of the Chief Pharmacist. "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General 2011." December 2011. Accessed 9 March 2020. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

[30] Jain SH. "Can Pharmacists Help Reinvent Primary Care in the United States?" Forbes. 10 October 2018. Accessed 8 January 2020. https://www.forbes.com/sites/sachinjain/2018/10/10/can-pharmacists-help-reinvent-primary-care-in-the-united-states/#2307a69f590b

[31] National Institute on Drug Abuse. "Substance Use in Women: Substance Use While Pregnant and Breastfeeding." July 2018. Accessed 21 January 2020. https://www.drugabuse.gov/publications/substance-use-in-women/substance-use-while-pregnant-breastfeeding

[32] National Alliance of State Pharmacy Associations. "Pharmacist Prescribing: Tobacco Cessation Aids." 22 November 2019. Accessed 9 March 2020. https://naspa.us/resource/tobacco-cessation/

[33] Shen X, et al. Quitting patterns and predictors of success among participants in a tobacco cessation program provided by pharmacists in New Mexico. J Manag Care Pharm. 2014;20(6):579-87.

The CMS Innovation Center recently awarded funding to 10 states under the Maternal Opioid Misuse (MOM) Model. Medicaid pays most of the costs associated with NAS and covers the largest portion of hospital costs for maternal substance use.[34] CMS has identified access to comprehensive services during pregnancy and postpartum, fragmented systems of care, and a shortage of maternity care and substance use treatment providers to be significant barriers to delivering well-coordinated, high-quality care to pregnant and postpartum women with Opioid Use Disorder (OUD). All states allow pharmacists to dispense naloxone without a patient-specific prescription in some capacity.[35] States participating in the MOM model can expand access to care through pharmacist services beyond the dispensing of naloxone, however. Colorado, Tennessee, and West Virginia, three recipients of MOM Model funding, can leverage state laws that allow pharmacists to prescribe medication-assisted treatment (MAT) within their MOM Model.

4. **How can CMS/HHS support these efforts?**

Access to pharmacist provided contraception services may have a significant impact on unintended pregnancy rates; however, pharmacists need to be reimbursed for consultations related to family planning services for this to be a sustainable service. Improved access to family planning services may decrease preterm births, reduce pregnancy-related complications and increase prenatal care in the first trimester. Pharmacist-provided family planning services are a component of a more comprehensive approach to improve women's health.

Implementing comprehensive pharmacist-provided maternal health services in community pharmacies is a public health necessity. Successful implementation requires states to allow pharmacists to practice at the fullest extent of their education and training. This includes prescriptive authority for all licensed pharmacists, the ability to order and interpret relevant tests, immunize, make and receive patient referrals, and determine Medicaid presumptive eligibility. Several states have reduced the regulatory barriers to allow pharmacists to use their education and training to improve access to primary care services. This allows pharmacists to do what they are trained to do while still protecting patients through standard of care regulations. Allowing pharmacists to provide additional services that may reduce maternal morbidity or preterm birth in conjunction with services they are already providing can create significant savings for state Medicaid programs and improve access to care.

Payment

Payment for preventive services is a concern of all providers. The ACA mandates that certain preventive services must be provided at no cost to the patient. This includes OTC medications that are included in USPSTF recommendations. For those medications to be covered they must be "prescribed by a health care provider."[36] Standing orders, practice protocols, or an expanded scope of practice at the state level may allow coverage of OTC medications and pharmacists to receive some compensation for these services. At this time the best opportunity for pharmacists' payment for many of these services being provided in a community pharmacy, specifically those related to education and therapy

[34] CMS. "Maternal Opioid Misuse (MOM) Model." Updated 19 December 2019. Accessed 27 January 2020. https://innovation.cms.gov/initiatives/maternal-opioid-misuse-model/

[35] National Alliance of State Pharmacy Associations. "Pharmacist Prescribing: Naloxone." 17 January 2019. Accessed 9 March 2020. https://naspa.us/resource/naloxone-access-community-pharmacies/

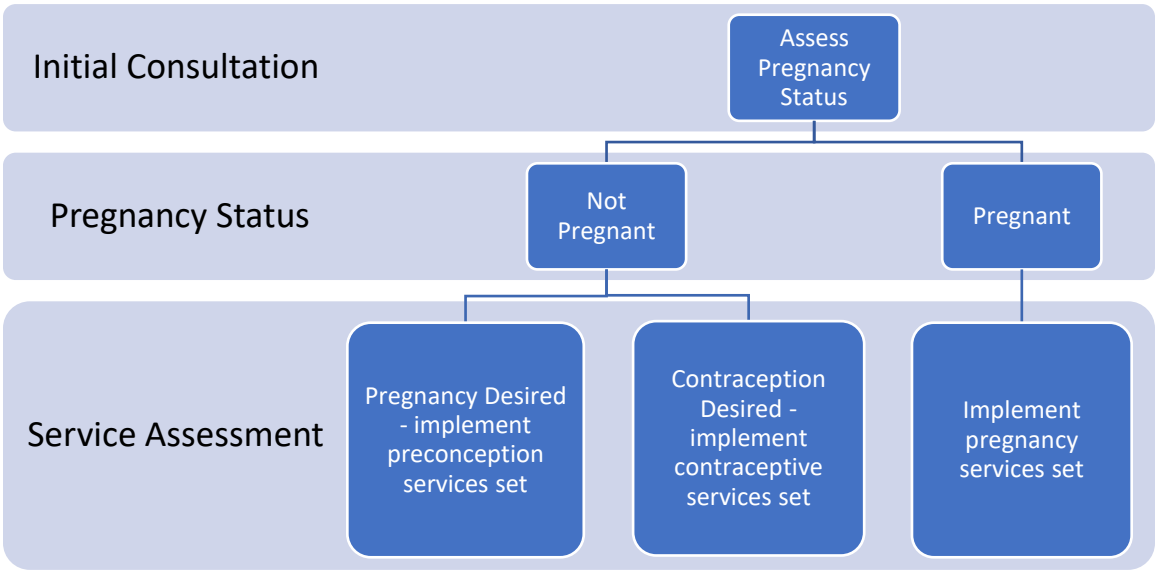
[36] Centers for Medicare & Medicaid Services. The Center for Consumer Information & Insurance Oversight. "Affordable Care Act Implementation – FAQs – Set 12." n.d. Accessed 16 January 2020. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12

recommendations, is through medication management services.[37] However, additional opportunities need to be explored to pay pharmacists' reasonable fees for the service of assessment of a patient for the purposes of prescribing or referral.

Research has shown that investment in family planning services saves $7.09 for every public dollar spent.[38] The vast majority of the savings are the result of preventing unplanned pregnancy. However, significant savings were also identified from Pap and human papillomavirus (HPV) testing and vaccines. Pharmacists are trained to provide contraceptive services and immunizations that positively impact public health by decreasing unplanned pregnancy and preventing cancer caused by HPV.

Comprehensive pharmacist-provided maternal health services will address preconception, interconception, pregnancy, and postpartum health. Each stage of maternal health has unique needs. Education and screening should begin as early as 13 years of age and continue for the life of the patient.[39] While all women can benefit from pharmacist services, not just those in their child-bearing years, the pharmacist-provided maternal health services set focuses on those who are planning or capable of pregnancy. Figure 1 outlines the maternal health services that may be provided based on pregnancy status.

Figure 1. Pharmacist-Provided Maternal Health Services Program[40]



[37] DiPietro Mager NA and Bright DR. "Delivering Preconception Medication Therapy Management Services in the Community Pharmacy." Community Pharmacy Foundation. 2015 June 30. Accessed 23 January 2020. https://www.communitypharmacyfoundation.org/resources/grant_docs/CPFGrantDoc_62211.pdf

[38] Frost JJ, Sonfield A, Zolna MR and Finer LB. "Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program." *The Milbank Quarterly.* 2014; 92(4):667-720. Accessed 8 January 2020. https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080

[39] NASPA. "Maternal Health Services Set for Pharmacists." Accessed May 2020. https://naspa.us/maternal-health/

[40] NASPA. "Maternal Health Services Set for Pharmacists." Accessed May 2020. https://naspa.us/maternal-health/

Regardless of pregnancy status there are several screenings that should be completed during a maternal health consultation. Based on recommendations from WPSI, women 13 – 49 years of age should be provided the following preventive services (see Appendix A for details):

- Alcohol screening and counseling
- Blood pressure screening
- Depression screening, including postpartum depression
- Diabetes screening, if history of gestational diabetes or overweight/obese
- Folic acid supplementation for all women capable of pregnancy
- Healthful diet and activity counseling, if overweight/obese or history of phenylketonuria (PKU)
- Hepatitis B and C screening
- HIV risk assessment and screening
- Immunizations
- Interpersonal violence screening
- Medication management services and adherence counseling
- Obesity screening
- Skin cancer counseling, if fair skin, light hair and eye color, freckles, or sunburn easily
- STI screening and prevention counseling
- Substance use screening and counseling
- Tobacco screening and counseling

Screening tools exist for many of these conditions. Incorporating existing screening tools, such as the Patient Health Questionnaire (PHQ-9) for depression and the Alcohol Use Disorders Identification Test (AUDIT), are short assessments that can be used to identify patients at risk.[41] The maternal health consultation addresses many public health issues by identifying risk factors or undiagnosed medical conditions. This allows patients to be referred for early intervention and receive treatment when indicated.

Medication management services are services that pharmacists routinely provide with most encounters focusing on chronic medical conditions. Women capable of pregnancy have chronic medical conditions and some of the medications used to treat those conditions are contraindicated in pregnancy. Pharmacists have the expertise needed to create a treatment plan based on the benefits and risks of medication therapy. In some cases, the patient's chronic medical condition may present a greater risk to the baby if left untreated. Pharmacists will collaborate with the prescriber to tailor the medication regimen to minimize the risk to both mother and child.

Preconception and Interconception Services

Addressing reproductive health needs that provide the best chance for a healthy and successful pregnancy begins long before conception. When meeting with a patient who is not pregnant, the initial consultation with the pharmacist should address general well-being and health. This initial encounter may be part of medication management services. In addition to the screening and counseling recommended above, women who desire pregnancy also should be assessed for the following:

- Pregnancy spacing and need for contraception;

[41] Pfizer Inc. "Patient Health Questionnaire (PHQ-9)." 1999. Accessed 9 March 2020. https://www.integration.samhsa.gov/images/res/PHQ%20-%20Questions.pdf

- Medication management services to assess for potentially teratogenic medications and to ensure adequate control of chronic medical conditions prior to conception; and
- Thyroid level monitoring in women with hypothyroidism.

Preconception and interconception care are services that pharmacists are already providing, but some may not realize the importance or the impact a seemingly simple OTC recommendation may have on a future pregnancy. Adequate preconception care can have lifelong implications for the infant and mother. Pharmacists can provide education; make recommendations for supplements; administer recommended immunizations and prescribed medications; provide tobacco cessation therapies; provide alcohol and substance use screening and counseling; assess for adequate control of chronic medical conditions; make recommendations to minimize the risk of complications from teratogenic medications; and refer patients to other providers for more invasive and specialized services.

Contraceptive Services

Contraceptive services are within the pharmacist scope of practice in multiple states and the District of Columbia.[42] During the consultation and assessment with the patient when providing contraception, pharmacists have an opportunity to provide the preventive health services previously discussed. Additional services the pharmacist may provide during the consultation for contraception include:

- Adherence assessment to contraceptive methods;
- Breastfeeding counseling, services and supplies for postpartum women; and
- Diabetes screening, if previous gestational diabetes without history of diabetes mellitus.

Pregnancy Services

Women who are pregnant should begin receiving prenatal care in the first trimester. The first prenatal visit is usually 8 – 10 weeks after the last menstrual period.[43] Pharmacists can ensure that newly expectant mothers are taking a prenatal vitamin and appropriate folic acid supplementation before the first prenatal visit. Women who are at risk for complications during pregnancy may also benefit from more frequent monitoring than routine follow-up appointments, such as blood pressure monitoring in women with a history of preeclampsia. Additional services that pregnant patients can receive from a pharmacist include:

- Aspirin to prevent preeclampsia, when indicated;
- Blood pressure monitoring;
- Breastfeeding counseling, services and supplies;
- Pertussis vaccine administration between 27 and 36 weeks gestation;
- Prenatal vitamin supplementation;
- Progesterone administration to reduce recurrent preterm birth, when prescribed; and
- Vitamin D supplementation.

Pregnant women who do not have a primary care physician or obstetrician should be referred for prenatal care during their first consultation with a pharmacist. Appendix B illustrates the decision-making process on what services to provide during each stage of maternal health based on pregnancy status and desire to become or prevent becoming pregnant.

[42] NASPA. "Pharmacist Prescribing: Hormonal Contraceptives." May 24, 2020. Available at: https://naspa.us/resource/contraceptives/
[43] American Pregnancy Association. "What to Expect at Your First Pregnancy Appointment." n.d. Accessed May 2020. Available at: https://americanpregnancy.org/planning/first-prenatal-visit/#:~:text=If%20you%20did%20not%20meet,you%20know%20you%20are%20pregnant!

Maternal Substance Use Disorders

We urge CMS to expand the MOM Model and access to pharmacists' medication-assisted treatment (MAT) services to improve maternal and infant health and decrease costs associated with NAS and hospital costs for maternal substance use disorders. We believe that utilizing pharmacists' expertise in the provision of a variety of MAT services is an important step toward the Administration's goal of "tackl[ing] the scourge of the opioid epidemic that is destroying so many individuals, families, and communities." Our organizations view MAT as an important component of a multipronged approach to addressing substance use disorder by improving access to treatment. We support efforts to expand access to MAT, such as increasing DATA-waivered physician's prescribing caps and allowing additional practitioners to obtain a DATA waiver. Allowing pharmacists to be data-waived providers for buprenorphine is also consistent with intent of the Administration's deregulatory efforts due to the hindrance that federal, as opposed to state, regulations have on pharmacists' ability to improve care by preventing them from increasing patient access to needed treatment in each state.

Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.[44,45] Pharmacists' responsibilities for MAT and substance use disorder ("SUD") treatment may include treatment plan development, patient communication, care coordination, adherence monitoring and improvement activities, among others. A DATA-waived pharmacist working under a CPA in a state that permits prescribing of controlled substances would also be able to initiate buprenorphine and make dosage adjustments, which would greatly increase access to MAT and address treatment gaps. As mentioned above, there are currently 49 states along with the District of Columbia that allow pharmacists to enter into CPAs[46] with physicians and other prescribers to provide advanced care to patients, which may include components of MAT. In addition, according to the Drug Enforcement Agency ("DEA"), pharmacists are mid-level practitioners like PAs and NPs, and states[47] may allow pharmacists to prescribe Schedule II-V controlled substances under a CPA.[48] Consequently, under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are unable to prescribe certain Schedule III medications, such as buprenorphine, because federal laws and regulations do not allow their eligibility for a DATA waiver. Leveraging pharmacists' medication expertise in the treatment of OUD could have a dramatic impact on maternal health outcomes and reducing the impact of NAS.

[44] DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, Journal of the American Pharmacists Association, 55(2), 187-192, available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264

[45] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy,* 36(2), 312-321.

[46] *See* Centers for Disease Control and Prevention (2017), *Advancing Team-Based Care Through Collaborative Practice Agreements,* available at: https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf

[47] States that allow pharmacists to prescribe controlled substances when working under a collaborative practice agreement: California, Massachusetts (hospital only), Montana, New Mexico, North Carolina, Ohio, and Washington.

[48] *See* Drug Enforcement Agency, Mid-Level Practitioners Authorization by State, available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

Conclusion

We appreciate the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) Request for Information Regarding Maternal and Infant Health Care in Rural Communities. Pharmacist-provided maternal health services can improve health care access, quality, and outcomes for women and infants in rural communities and can reduce health disparities between rural and urban communities and within rural communities. If you have any questions related to our comments, please contact Allie Jo Shipman, NASPA Director, State Policy (ajshipman@naspa.us; 803-257-1818), Jasey Cárdenas, AACP Associate Director, Strategic Engagement (jcardenas@aacp.org; 703-887-9532), Mike Baxter, APhA Senior Director, Regulatory Policy (mbaxter@aphanet.org; 202-459-8963), Jillanne Schulte Wall, ASHP Senior Director, Health and Regulatory Policy (jschulte@ashp.org; 301-664-8698), or Shion Chang, NCPA Associate Director, Policy and Regulatory Affairs (shion.chang@ncpa.org; 703-600-1178).

Sincerely,

National Alliance of State Pharmacy Associations
American Association of Colleges of Pharmacy
American Pharmacists Association
American Society of Health-System Pharmacists
National Community Pharmacists Association

Appendices

Appendix A. Pharmacist Provided Maternal Health Services

Preventive Service	Description and Rationale
Alcohol screening and counseling	Screening should be done at least annually for women 18 years of age and older for alcohol misuse using a validated screening tool and may be considered for adolescents. Counseling should be provided to anyone engaged in risky or hazardous behaviors to reduce intake and misuse. Approximately 1/3 of the population is affected by alcohol misuse, which is the 3rd leading cause of preventable deaths in the U.S.
Aspirin to prevent preeclampsia, when indicated	Aspirin 81mg daily should be recommended for pregnant women at high risk of preeclampsia starting after 12 weeks gestation. Patients should also be referred to an obstetrician or other provider trained in obstetrics for follow-up. Risk factors include a history of preeclampsia, intrauterine growth restriction, or preterm birth; placental abruption or fetal death; maternal comorbidities such as pregestational diabetes, chronic hypertension, renal disease, and autoimmune diseases; and multifetal gestation. Low-dose aspirin has been shown to decrease the risk of preeclampsia, a hypertensive disorder in pregnancy that can lead to significant maternal complications and death.
Blood pressure screening	The frequency of blood pressure screening varies with age and risk factors. Women 18 – 39 years of age who do not have any risk factors for hypertension should be checked at least every 3 – 5 years. Women 40 years of age and older or those with risk factors should be screened annually. The WPSI recommends annual screening for women 13 – 21 years of age. High blood pressure is a major risk factor for heart failure, heart attack, stroke, and chronic kidney disease. Screening and early treatment reduces the incidence of these cardiovascular events.
Breastfeeding counseling, services and supplies	Pregnant and postpartum women should be provided with comprehensive lactation support services. These services include counseling and education on the benefits of breastfeeding as well as assessing and ensuring access to necessary equipment and supplies. Additional training may be required to provide these services. The health benefits of breastfeeding are well known; however, half of all women in the U.S. stop breastfeeding within 6 months.
Contraception	Females 13 years of age and older should routinely be screened for contraception needs to prevent unintended pregnancy. Services include initiation a of contraceptive, adherence assessment and education, and assessment for any changes to contraceptive method.
Depression screening, including postpartum depression	Screening should take place annually in adolescents and adults using a validated depression screening tool. Individuals with positive results should be referred to their primary care provider for further assessment and treatment. Depression is a leading cause of disability and is common among pregnant and postpartum women.

Preventive Service	Description and Rationale
Diabetes screening	Women 40 – 70 years of age and overweight or obese and those with a history of gestational diabetes should be screened every 3 years for the development of type 2 diabetes mellitus. Women with a history of gestational diabetes should be screened for at least 10 years after pregnancy. Pregnant women with gestational diabetes have a higher risk of maternal and fetal complications and developing type 2 diabetes mellitus.
Folic acid supplementation or prenatal vitamins	All women who are capable of becoming pregnant should take 400 – 800 mcg of folic acid daily. Women who have had a previous pregnancy affected by a neural tube defect or are at high risk of having a baby with a neural tube defect may need higher doses. Neural tube defects occur early in pregnancy and may lead to disabilities in or death of the baby.
Healthful diet and activity counseling	Adult women who are overweight or obese and have risk factors for CVD should receive counseling to promote a healthy diet and physical activity to decrease the risk of complications from CVD. Women with PKU should be counseled on the benefits of a low phenylalanine diet before conception and during pregnancy. High phenylalanine levels are associated with mental retardation.
Hepatitis B and C screening	Adult women and adolescents should be screened for risk factors associated with hepatitis B and C infections. Those with risk factors should be referred for testing. Hepatitis B and C can lead to cirrhosis, liver failure, or liver cancer.
HIV risk assessment and screening	Adult women and adolescents should be assessed at least annually for HIV risk factors. Individuals at risk and those who are pregnant should be referred for testing. Screening for HIV infection helps identify those who are unaware they are infected and may miss the benefits of early treatment. Pharmacists who are able to provide PEP and PrEP therapy should do so if indicated. Initiation of therapy prior to delivery can reduce the risk of transmission to the baby in HIV positive women.
Hypothyroidism	Prior to conception thyroid levels should be monitored more frequently and medication doses may need to be adjusted. Recommending monitoring should be included in every preconception visit. Adequate thyroid levels reduce the risk of spontaneous abortion, stillbirth, low birth weight and neurological problems.
Immunizations	All patients should be assessed annually for vaccination needs. Women capable of conception should be assessed for Hepatitis B and Mumps, Measles and Rubella (MMR) vaccination status and be vaccinated if indicated. Pregnant women should receive a tetanus, diphtheria and pertussis (TDaP) vaccine with every pregnancy between 27 and 36 weeks gestation and an annual influenza vaccine. Patients should also be counseled on the benefits of vaccinating other family members and caregivers.
Interpersonal violence screening	Adult women and adolescents should be screened at least annually for interpersonal and domestic violence. Referral for intervention services should be made when victims are identified. Interpersonal and domestic violence are common among women and are frequently undetected.

Preventive Service	Description and Rationale
Medication management services and adherence assessment	A comprehensive medication review should be conducted annually and with a change in pregnancy status or desire to become pregnant. Whenever possible, medications contraindicated during pregnancy should be discontinued, changed to a medication with lower teratogenic potential, or dose reduced in women trying to conceive or at risk of becoming pregnant. Medication adherence should be assessed as a component of the encounter. The encounter may be a targeted medication review (TMR) or a comprehensive medication review (CMR) depending on the needs of the patient. Assessing for medication contraindications in pregnancy or breastfeeding, potential gaps in drug therapy, and adequate control of chronic medical conditions may improve maternal and fetal outcomes.
Obesity screening	Screening for obesity should be conducted annually starting as young as 6 years of age. Obese individuals should be referred for interventions to help with weight management. Over 30% of adult women in the U.S. are obese. Obesity increases the risk for many chronic medical conditions, neural tube defects, and preterm delivery.
Pregnancy spacing and need for contraception	Women planning to conceive or those who have given birth within the previous 18 months should be educated on the benefits of spacing pregnancies at least 18 months apart. Less than 18 months between pregnancies is a risk factor for preterm birth.
Progesterone administration to reduce recurrent preterm birth	Women with a history of preterm birth may require 17 alpha-hydroxyprogesterone caproate (17P) therapy. Patients who may not have a family member or friend available to administer the weekly injection may receive care at a pharmacy. Several states allow pharmacists to administer injectable medications, which may include 17P for the prevention of preterm birth.
Skin cancer counseling	All women, especially adolescent and young adult women, should be educated annually on sun safety and the importance of minimizing exposure to ultraviolet radiation to prevent skin cancer. Individuals with fair skin, light hair and eye color, or freckles and those who sunburn easily are at greatest risk. Skin cancer is the most common cancer in the U.S. Exposure to ultraviolet radiation increases skin cancer risk.
STI prevention counseling	Adolescents and sexually active women should be assessed for increased risk of contracting a STI. Those at risk should be referred for testing. All women should be educated on how to minimize the risk of transmission and the importance of treatment. Women should also be encouraged to inform any sexual partners, so they get treated to prevent further spread of the infection. STIs can lead to pelvic inflammatory disease, infertility, and cancer. During pregnancy, STIs may cause perinatal infections, disabilities, or death.
Substance use screening and counseling	Adults and adolescents should be screened annually for illicit drug use and substance abuse. Individuals with substance use disorders should be counseled on the risks associated with use and be referred for treatment whenever possible. Substance use disorders are among the top 10 preventable risk factors for death and disability.

Preventive Service	Description and Rationale
Tobacco screening and counseling	Adults and adolescents should be assessed for tobacco use at least annually. Individuals who use tobacco should be offered tobacco cessation counseling and treatment. Tobacco is the leading preventable cause of disease, disability and death in the U.S. Use in pregnancy increases the risk of birth defects, perinatal complications, and neonatal and pediatric complications.
Vitamin D supplementation	Women at high risk of vitamin D deficiency may benefit from supplementation. High risk women are those with limited sun exposure (live in cold climates or northern latitudes), vegetarians, and some ethnic minorities (darker skin). Routine supplementation is not recommended; however, women who are unable to tolerate a prenatal vitamin may need a vitamin D supplement to ensure intake of 400 – 600 international units per day. A serum 25-hydroxyvitamin D is recommended to identify women needing supplementation. Vitamin D deficiency has been associated with skeletal disorders, congenital rickets, and fractures in the newborn.

WPSI. "Recommendations for Well-Woman Care – A Well-Woman Chart Clinical Summary Tables." *ACOG* 2018. Accessed 22 January 2020. https://www.womenspreventivehealth.org/wp-content/uploads/ClinicalSummaryTables.pdf

DiPietro Mager NA and Bright DR. "Delivering Preconception Medication Therapy Management Services in the Community Pharmacy." Community Pharmacy Foundation. 2015 June 30. Accessed 23 January 2020. https://www.communitypharmacyfoundation.org/resources/grant_docs/CPFGrantDoc_62211.pdf

ACOG. "Vitamin D: Screening and Supplementation During Pregnancy." Committee Opinion No. 495. July 2011 (Reaffirmed 2019). Accessed 27 January 2020. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Vitamin-D-Screening-and-Supplementation-During-Pregnancy?IsMobileSet=false

U.S. Preventive Services Task Force. "Published Recommendations." March 2020. Accessed 9 March 2020. https://www.uspreventiveservicestaskforce.org/BrowseRec/Index

Appendix B. Maternal Health Services Flowchart