



October 2017

NEWBORN HEALTH

Federal Action Needed to Address Neonatal Abstinence Syndrome

Why GAO Did This Study

As the opioid crisis has increased in recent years, so has the number of pregnant women who use opioids, which can result in NAS. A recent peer-reviewed study found that cases of NAS have grown nearly five-fold between 2000 and 2012 and that most infants with NAS are covered under Medicaid.

The Comprehensive Addiction and Recovery Act of 2016 includes a provision for GAO to examine NAS in the United States and related treatment services covered under Medicaid. This report 1) describes the hospital and non-hospital settings for treating infants with NAS and how Medicaid pays for services, 2) describes recommended practices and challenges for addressing NAS, and 3) examines HHS's strategy for addressing NAS.

GAO reviewed HHS documentation and interviewed HHS officials. GAO also conducted site visits to four states—Kentucky, Vermont, West Virginia, and Wisconsin—selected based on several factors, including incidence rates of NAS and geographic variation. GAO interviewed stakeholders from 32 organizations, including health care providers and state officials in the selected states.

What GAO Recommends

HHS should expeditiously develop a plan for implementing the recommendations included in its strategy related to addressing NAS. HHS concurred that it should expeditiously address NAS, but noted implementation of the strategy is contingent on funding.

View [GAO-18-32](#). For more information, contact Katherine M. Iritani at (202) 512-7114 or iritanik@gao.gov.

NEWBORN HEALTH

Federal Action Needed to Address Neonatal Abstinence Syndrome

What GAO Found

The prenatal use of opioids or other drugs can produce a withdrawal condition in newborns known as neonatal abstinence syndrome (NAS). Health care providers, state officials, and other stakeholders told GAO that most infants with NAS are treated in the hospital—such as in a neonatal intensive care unit—though some may be referred to a non-hospital setting—such as a neonatal withdrawal center with nursery rooms—to complete their treatment. The table below provides more information on settings for treating infants with NAS and on how Medicaid pays for services in these settings.

Setting of care	Examples of setting	Reimbursement method
Hospital	<ul style="list-style-type: none"> Neonatal intensive care unit Well newborn nursery 	Fixed payment for a group of hospital services
Non-hospital	<ul style="list-style-type: none"> Outpatient clinic Neonatal withdrawal center 	Fee-for-service or per-diem rate

Source: GAO analysis of interviews with stakeholders. | GAO-18-32

According to stakeholders GAO interviewed and literature reviewed, there are several recommended practices and challenges associated with addressing NAS. The most frequently recommended practices included prioritizing non-pharmacologic treatment to infants—treatment that does not involve medications—such as allowing the mother to reside with the infant during treatment; educating mothers and health care providers on treatment of NAS, among other things; and using a protocol in the hospital or non-hospital setting for screening and treating infants with NAS. The most frequently cited challenges included the maternal use of multiple drugs—or polysubstance use—as it can exacerbate NAS symptoms; stigma faced by pregnant women who use opioids; hospital staff burden and limited physical capacity to care for infants with NAS; limited coordination of care for mothers and infants with NAS; and gaps in research and data on NAS, such as research on the long-term effects of the condition.

In May 2017, the Department of Health and Human Services (HHS) published a strategy document that makes key recommendations to address NAS. The Strategy recommends, for example, that health care providers receive continuing education on managing and treating infants with NAS and promote non-pharmacologic treatment. According to HHS officials, these recommendations will inform planning and policy across the department. However, HHS has yet to determine how and when the recommendations will be implemented, including establishing priorities; the roles and responsibilities of other federal, state, and public stakeholders; implementation timeframes; and methods for assessing progress. HHS officials told GAO that they expect to develop an implementation plan sometime in 2017 but had no timeline for doing so. Without a plan that clearly specifies how HHS will implement the Strategy and assess its progress, the department increases the risk that its recommendations for addressing NAS will not be implemented.

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Abbreviations

CARA	Comprehensive Addiction and Recovery Act of 2016
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DRG	diagnosis-related group
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
ICD	International Classification of Disease
NAS	neonatal abstinence syndrome
NICU	neonatal intensive care unit
SAMHSA	Substance Abuse and Mental Health Services Administration

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October 4, 2017

Congressional Addressees

Opioid misuse, including the use of heroin and misuse of opioids prescribed for pain management, has been recognized by the federal government, states, researchers, and others as a growing crisis in the United States. As opioid misuse has increased in recent years, so has the number of pregnant women who use opioids. The prenatal use of opioids by pregnant women—including opioid misuse, use of opioids prescribed for pain management, and use of certain medications given to treat opioid addiction—can produce a withdrawal condition in newborn infants known as neonatal abstinence syndrome (NAS).¹ NAS symptoms range from excessive crying and irritability to difficulties with breathing and feeding. NAS is a rapidly increasing public health problem, with the incidence of NAS in the United States growing nearly five-fold between 2000 and 2012.² Specifically, cases of NAS increased from a rate of 1.2 per 1,000 hospital births per year in 2000 to 5.8 per 1,000 hospital births per year in 2012, reaching a total of 21,732 infants diagnosed with NAS.³ A 2015 study noted that by 2012 one infant was born about every 25 minutes with NAS.⁴

While experts consider NAS to be an expected and treatable result of prenatal opioid exposure, infants with NAS require specialized care that

¹See Mark L. Hudak and Rosemarie C. Tan, American Academy of Pediatrics, “Neonatal Drug Withdrawal,” *Pediatrics*, vol. 129, no.2 (2012). Though other drugs may cause NAS, opioids are considered the primary cause. When it is possible to determine that the withdrawal symptoms are unique to opioids, the more precise term “neonatal opioid withdrawal syndrome” is used. However, because opioid use often does not occur in isolation from other risk factors or other substance use—such as alcohol, barbiturates, and selective serotonin reuptake inhibitors—it can be difficult to identify neonatal opioid withdrawal syndrome. For purposes of this report, we refer to these withdrawal symptoms as neonatal abstinence syndrome, or NAS.

²Stephen W. Patrick et al., “Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome: United States 2009-2012,” *Perinatology*, vol. 35 (2015).

³See Stephen W. Patrick et al., “Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009,” *JAMA*, vol. 307, no.18 (2012) and Patrick et al., “Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome: United States 2009-2012.”

⁴Patrick et al., “Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome,” 652.

typically results in longer and more complicated and costly hospital stays. More than eighty percent of the NAS cases identified in the 2015 study were paid for by Medicaid, the federal-state program that finances health care coverage for low-income and medically needy populations, including children and aged or disabled adults.⁵

Due to the growing opioid epidemic and its deleterious effects, including the effects on infants, Congress has held hearings and passed legislation aimed at addressing various aspects of this epidemic. For example, the Protecting Our Infants Act of 2015 directed the Department of Health and Human Services (HHS) to conduct a study and develop recommendations for preventing and treating prenatal opioid use disorders, including NAS. This law also required HHS to review its planning and coordination related to NAS and to develop a strategy to address gaps in research and gaps, overlap, and duplication among federal programs to address NAS.⁶ We have previously reported that HHS has nine agencies involved with addressing NAS and has a council dedicated to coordinating activities across the department to address NAS.⁷

The Comprehensive Addiction and Recovery Act of 2016 (CARA) included a provision for GAO to examine NAS in the United States and the treatment services for the condition covered under Medicaid in hospital settings as well as any non-hospital settings.⁸ The act required us to report within a year after passage, and to meet this mandated date,

⁵Patrick et al., “Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome,” 653-654.

⁶Pub. L. No. 114-91, §§ 2, 3, 129 Stat. 723, 724-725 (2015). In May 2017, HHS published the *Protecting Our Infants Act: Report to Congress*, which—among other things—includes a review of planning and coordination activities relating to NAS; recommendations for identifying, preventing, and treating NAS; and a strategy for addressing gaps, overlap, and duplication among federal programs to address NAS. See Substance Abuse and Mental Health Services Administration (SAMHSA), “Protecting Our Infants Act: Report to Congress,” May 2017.

⁷The nine agencies we identified were one staff office—the Office of the Assistant Secretary for Health—and eight operating divisions: the Administration for Children and Families, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and SAMHSA. See GAO, *Prenatal Drug Use and Newborn Health: Federal Efforts Need Better Planning and Coordination*, [GAO-15-203](#) (Washington, D.C., February 10, 2015).

⁸Pub. L. No. 114-198, § 504, 130 Stat. 695, 731 (2016).

we briefed your staff on our preliminary findings in July 2017. This report includes information shared during that briefing and

1. describes the hospital settings for treating infants with NAS and how Medicaid pays for services in these hospital settings;
2. describes the non-hospital settings for treating infants with NAS and how Medicaid pays for services in these non-hospital settings;
3. describes the recommended practices and challenges for addressing NAS; and
4. examines HHS's strategy for addressing NAS.

To address our first three audit objectives describing care settings for treating infants with NAS, Medicaid payment for NAS treatment, and the recommended practices and challenges for addressing NAS, we did the following:

- We selected 32 stakeholders based on their relevant experience to cover a range of perspectives on NAS. This included stakeholders from site visits we conducted in four states—Kentucky, Vermont, West Virginia, and Wisconsin. We selected these states because they met the following criteria: (1) high incidence rate of NAS as of 2013; (2) variation in United States geographic regions with high rates of NAS as of 2012; (3) more than 40 percent of births in the state were financed by Medicaid in 2016; and (4) the state has a perinatal quality collaborative—a state or multi-state network of teams working to improve health outcomes for mothers and infants—with work related to NAS.⁹ The stakeholders we selected within these states consisted of four state agencies, including Medicaid officials; officials from the perinatal collaborative that work on NAS in each state; officials from one residential treatment facility in each state that provides prenatal and postpartum care to mothers; and hospital providers, including physicians or nurses, from eight hospitals (two hospitals in each state).¹⁰ We also selected 12 additional stakeholders outside of these four states, including health care providers or administrators in four

⁹See Jean Y. Ko et al., "Incidence of Neonatal Abstinence Syndrome – 28 states, 1999-2013," CDC MMWR, vol. 65 (2016); Stephen W. Patrick et al., "Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome," 650-651; and Kaiser Family Foundation State Health Facts: Births Financed by Medicaid, downloaded on October 31, 2016.

¹⁰We selected hospitals and residential treatment facilities based on recommendations from state perinatal collaboratives.

non-hospital settings across the United States; officials from five medical specialty societies, such as the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists; and three experts, such as the authors of studies we identified.

We interviewed each of these 32 stakeholders and requested information from stakeholders about treating infants with NAS, including the utilization of available hospital and non-hospital care settings and associated costs of treatment services. For example, we requested protocols for screening and treating infants with NAS from hospital and non-hospital care settings. We reviewed available protocols provided by hospitals and a non-hospital care setting. We also reviewed available information reported by state officials, hospital and non-hospital providers, and state perinatal collaboratives on the utilization of hospital and non-hospital care settings, the facility's cost of treating NAS in hospital and non-hospital settings, length of stay for treating infants with NAS, or the amount of Medicaid payments for treating infants with NAS. We discussed the information provided by stakeholders and examined the information for obvious errors. The information obtained from these stakeholders is not generalizable to other states or other hospital and non-hospital settings. In addition, in some cases, stakeholders collected information differently, including information on Medicaid payments; as a result, the information reported by stakeholders is not directly comparable.

- We conducted a literature review to identify relevant peer-reviewed articles published between January 2013 and December 2016.¹¹ As a result, we identified and reviewed 40 relevant studies. We examined the methodologies for each of these studies and determined that the studies were sufficiently reliable for our audit objectives.
- We interviewed officials from HHS, including those from the Centers for Medicare & Medicaid Services (CMS) and HHS's Behavioral Health Coordinating Council—which includes officials from the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration, among others—concerning NAS treatment services, settings of care,

¹¹We selected this timeframe to ensure that we captured literature that best reflects the current state of treatment efforts and the most recent data available on NAS.

Medicaid payment, and recommended practices and challenges related to addressing NAS.¹²

- We conducted a web-based survey administered to Child Welfare Directors in fifty states and the District of Columbia and included in the survey questions about whether Child Welfare Directors had received federal or state guidance related to NAS. All 51 respondents completed the survey for a response rate of 100 percent.

To examine our last audit objective on HHS's strategy related to addressing NAS, we interviewed agency officials and reviewed documents on the department's efforts to develop a strategy. Specifically, we interviewed relevant officials from CMS and HHS's Behavioral Health Coordinating Council concerning their efforts to develop a strategy related to addressing NAS. In reviewing relevant HHS documents, we focused on HHS's *Protecting Our Infants Act Report to Congress*, which includes a strategy to address identified gaps, challenges, and recommendations related to NAS and prenatal opioid use. In addition, we reviewed the relevant standards for internal control in the federal government and the relevant criteria from GAO's body of work on effectively managing performance under the Government Performance and Results Act (GPRA) of 1993 and the GPRA Modernization Act of 2010.¹³ See appendix I for further details of our methodology related to these objectives.

We conducted this performance audit from September 2016 to October 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for

¹²The Behavioral Health Coordinating Council is a coordinating body within HHS with the goals to share information and identify and facilitate collaborative, action-oriented approaches to address HHS's behavioral health agenda without duplication of effort across the department.

¹³Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. See GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 2014). In past reports, we have identified best practices in planning. For example, see GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1996), GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004) and GAO, *Health Care Quality: HHS Should Set Priorities and Comprehensively Plan Its Efforts to Better Align Health Quality Measures*, [GAO-17-5](#) (Washington, D.C.: October 13, 2016).

our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

NAS and Prenatal Opioid Use

NAS is a withdrawal condition within infants that can result from the prenatal use of opioids by pregnant women. Prenatal opioid use occurs when a woman, during the course of her pregnancy, uses an opioid-based medication or substance. Prenatal opioid use can take various forms, including (1) the use of prescriptions for pain management, such as fentanyl and oxycodone; (2) medication-assisted treatment for opioid addiction, such as methadone and buprenorphine; (3) prescription drug misuse or use disorder (such as using an opioid without a prescription, using a different dosage than prescribed, or continuing to use an opioid when it is no longer needed for pain); and (4) illicit opioid use, such as heroin use. These types of prenatal opioid use are not mutually exclusive. A 2014 study found that almost 22 percent of pregnant Medicaid beneficiaries filled a prescription for an opioid during their pregnancy.¹⁴ Medication-assisted treatment—an approach that combines the use of certain medications and behavioral therapy—is generally considered by HHS and medical specialty societies to be the standard of care for treating pregnant women with opioid use disorders, depending on the individual and her circumstances.¹⁵ SAMHSA and several medical

¹⁴Rishi J. Desai et al., “Increase in Prescription Opioid Use During Pregnancy Among Medicaid-Enrolled Women,” *Obstetrics and Gynecology*, vol. 123, no. 5 (2014).

¹⁵In August 2017, the American College of Obstetricians and Gynecologists issued updated guidance noting that medication-assisted treatment continues to be the recommended therapy for pregnant women with opioid use disorders; however, the society recognizes that medically supervised withdrawal can also be considered under the care of a physician experienced in perinatal addiction treatment and with informed consent if a woman does not accept medication assisted treatment. The guidance notes that more research is needed to assess safety, efficacy, and long-term outcomes of medically supervised withdrawal. See Committee on Obstetric Practice and the American Society of Addiction Medicine, “Committee Opinion: Opioid Abuse and Opioid Use Disorder in Pregnancy,” no. 711 (August 2017, replaces committee opinion number 524).

specialty societies, including the American College of Obstetricians and Gynecologists and the American Society of Addiction Medicine, have noted that providing medication-assisted treatment during pregnancy prevents complications associated with illicit opioid use, encourages prenatal care, and reduces the risk of obstetric complications.¹⁶ Further, women may use multiple substances in addition to opioids during pregnancy—known as maternal polysubstance use—such as tobacco, alcohol, or anti-depressants, among others.¹⁷

Experts consider NAS to be an expected and treatable result of women’s prenatal opioid use. Symptoms of NAS usually develop within 72 hours of birth, but may develop anytime in the first 2 weeks of life, including after hospital discharge.¹⁸ These symptoms in infants typically include symptoms of opioid withdrawal, such as

- irritability,
- high-pitched and excessive crying,
- stiffness,
- sweating,
- vomiting,

GAO reported in 2015 that the gaps in efforts to address prenatal opioid use and NAS most commonly cited by federal agency officials and experts were related to the treatment of prenatal opioid use and NAS. Agency officials and experts said that there has not been adequate research comparing different types of treatment approaches and that research is needed on how best to treat a pregnant woman with an opioid use disorder so that the treatment is most effective for the woman while offering minimal risk to the fetus. See [GAO-15-203](#). For more information on factors that can affect access to medication-assisted treatment, see GAO, *Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, [GAO-16-833](#) (Washington, D.C.: Sept. 2016).

¹⁶For more information see SAMHSA, “Methadone Treatment for Pregnant Women.” HHS Publication No. (SMA) 14-4124 (Revised 2014) and Committee on Obstetric Practice and the American Society of Addiction Medicine, “Committee Opinion: Opioid Abuse and Opioid Use Disorder in Pregnancy.”

¹⁷See Stephen W. Patrick et al., “Prescription Opioid Epidemic and Infant Outcomes,” *Pediatrics*, vol. 135, no. 5 (2015) and Kendra Grim et al., “Management of Neonatal Abstinence Syndrome from Opioids,” *Clinics in Perinatology*, vol. 40 (2013).

¹⁸The onset of opioid withdrawal, including methadone withdrawal, frequently occurs during the first 12 to 72 hours, but may be delayed for weeks. Because NAS symptoms sometimes take days to appear, the mother and infant may be discharged from the hospital before the infant begins to show withdrawal symptoms.

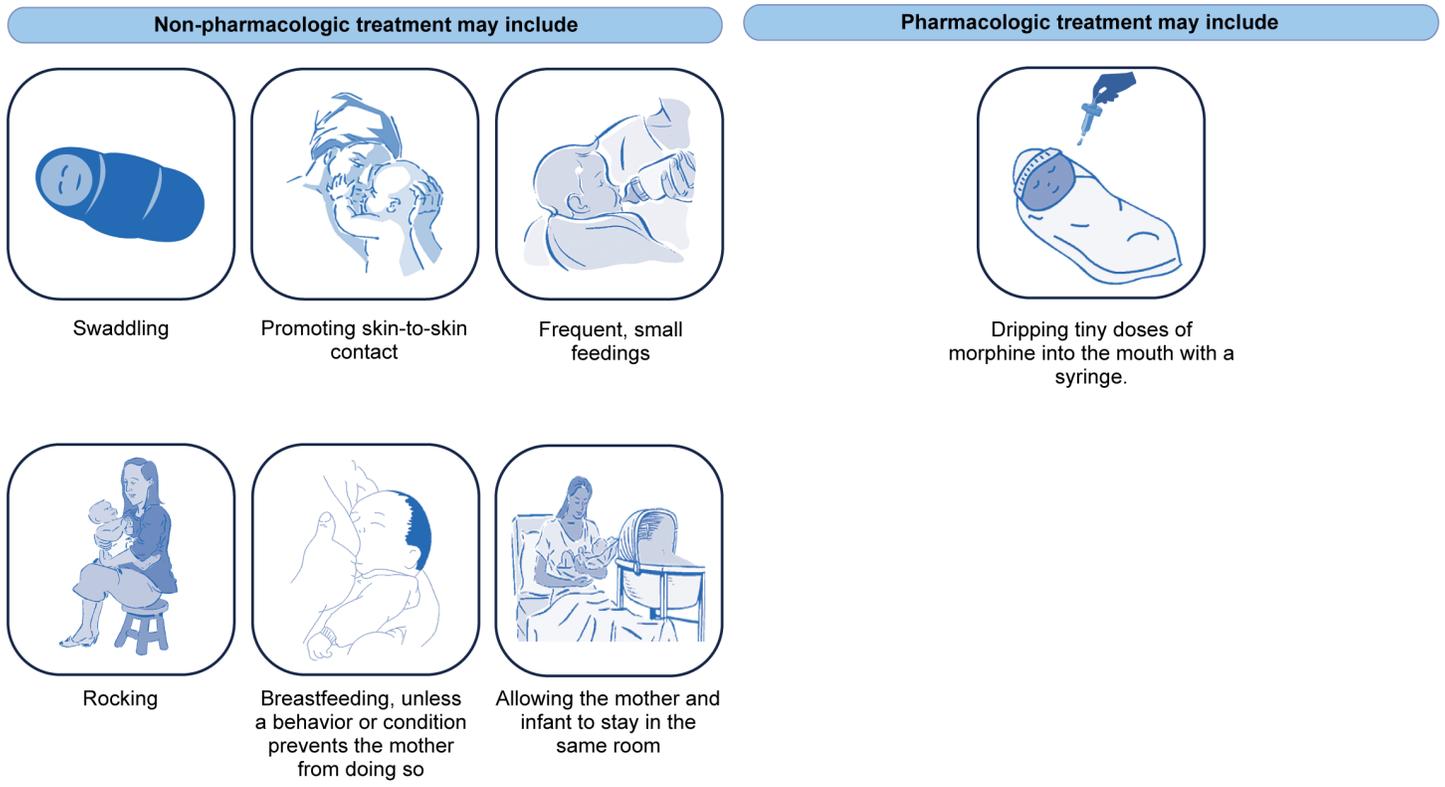
-
- diarrhea,
 - poor feeding,
 - seizures, and
 - respiratory distress.¹⁹

There is currently no national standard of care for screening or treating NAS. There have been a few scoring tools developed to screen the infant to determine the appropriate course of treatment. Health care providers predominantly diagnose NAS using the Finnegan Neonatal Abstinence Scoring Tool, which calculates a score based on a variety of central nervous, metabolic, respiratory, and gastro-intestinal symptoms that might be observed.²⁰ The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists recommend that infants with NAS should not be initially treated with medication, known as pharmacologic treatment. Instead, these organizations recommend starting with non-pharmacologic treatment, which includes placing the infant in a dark and quiet environment, swaddling, breastfeeding, rooming-in with the mother, and providing high-calorie nutrition, among other things. For example, rooming-in—allowing the mother to reside with the infant during the infant’s treatment—may have benefits, such as helping to develop a bond between the mother and infant and to reduce the severity of the infant’s NAS symptoms. Pharmacologic treatment, such as using methadone or morphine, may be necessary only for the relief of moderate to severe signs of NAS. See figure 1 for more information on non-pharmacologic and pharmacologic treatment.

¹⁹NAS is also associated with premature birth and lower birth weight and can interfere with the mother-infant bonding process.

²⁰Other available scoring tools used to screen infants for NAS include the Lipsitz Neonatal Drug-Withdrawal Scoring System, the Neonatal Narcotic Withdrawal Index, Neonatal Withdrawal Inventory, and the modified Finnegan scale. Each scoring tool assesses individual NAS symptoms to determine the severity of NAS for purposes of guiding treatment. The tools differ in the items assessed and the score threshold that determines how the infant is treated. For example, infants scoring an 8 or greater on the Finnegan Neonatal Abstinence Scoring Tool are recommended to receive pharmacologic treatment. In contrast, infants who receive a score of four on the Lipsitz scoring system are recommended to receive pharmacologic treatment. For more information about these and other scoring tools, see Lauren M. Jansson et al., “The Opioid Exposed Newborn: Assessment and Pharmacologic Management,” *Journal of Opioid Management*, vol. 5, no. 1 (2009).

Figure 1: Non-Pharmacologic and Pharmacologic Treatment for Infants with Neonatal Abstinence Syndrome



Source: GAO analysis of literature and information from the American Academy of Pediatrics. | GAO-18-32

Federal Resources on NAS and Prenatal Opioid Use

HHS has published several guidance and educational resources related to NAS and prenatal opioid use. These documents serve as tools to help stakeholders, including state entities and health care providers, who work with this population. For example, SAMHSA published a clinical report for health care providers in 2016 that provides recommendations to help them when making decisions regarding the evaluation, care, and treatment of women with opioid use disorders and infants with NAS.²¹ As of July 2017, SAMHSA is in the process of producing a clinical guide based on this report and expects to publish an updated report later this year. In another example, SAMHSA published a guidance document in 2016 that aims to support the efforts of states, tribes, and local

²¹SAMHSA, "Advancing the Care of Pregnant and Parenting Women With Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance," Rockville, MD: Substance Abuse and Mental Health Services Administration, 2016.

communities in addressing the needs of pregnant women with opioid use disorders and their infants.²² Among other things, the document includes strategies and guidance to promote care coordination among stakeholders, including child welfare agencies and medical professionals, when treating infants with NAS. (See app. II for a list of federal educational resources related to NAS and prenatal opioid use published by HHS.)

Medicaid Program Overview

As we previously noted, more than 80 percent of NAS cases are paid for by Medicaid, which is a federal-state health care program that finances health care coverage for low-income and medically needy populations, including children and aged or disabled adults. States administer their Medicaid programs within broad federal requirements and according to a state plan approved by CMS, the federal agency within HHS that oversees Medicaid. The Medicaid program allows states to design and implement their programs within certain federal parameters, resulting in more than 50 distinct state-based programs.²³ For example, states generally determine the type and scope of services to cover, set payment rates that different health care providers will receive for various covered services, and pay these providers for claims submitted for services rendered. In addition, states vary in the extent to which they enroll beneficiaries in managed care versus delivering care through the more traditional fee-for-service model. Under a managed care delivery model, states typically contract with managed care plans to provide a specific set of Medicaid-covered services to beneficiaries and pay them a set amount per beneficiary—referred to as capitation payments—to provide those services.²⁴ Under fee-for-service, Medicaid pays health care providers a fee for each service provided to a Medicaid beneficiary. Medicaid’s Early and Periodic Screening, Diagnostic, and Treatment benefit, which states

²²SAMHSA, *A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders*. HHS Publications No. (SMA) 16-4978. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2016.

²³Medicaid programs are administered by the 50 states, the District of Columbia, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the Virgin Islands.

²⁴Capitation payment is a payment the state makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the state plan. The state makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment. 42 C.F.R. § 438.2.

are required to provide, covers comprehensive health screenings, preventive health services, and all medically necessary treatment and services—for Medicaid eligible-children under the age of 21—to correct or ameliorate health conditions discovered through screenings.²⁵

Most Infants with NAS Complete Treatment in Various Hospital Settings, and in Selected States Medicaid Pays for Services Using Bundled Payments

Hospital Settings for Treating Infants with NAS

According to the literature we reviewed, most infants with NAS in the United States are treated in a hospital setting, often in the neonatal intensive care unit (NICU), which has a relatively high daily cost of care.²⁶ Stakeholders we interviewed told us that these infants may also be treated in other hospital settings. According to state and perinatal collaborative officials in the four selected states we reviewed, infants diagnosed with NAS begin—and most complete—treatment for the condition in various hospital settings which provide different levels of care: a well newborn nursery (level I), special care nursery (level II), or

²⁵The medically necessary treatment and services must be covered for an individual child regardless of whether the service is covered under the state's Medicaid plan. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r).

²⁶For example, see V. N. Tolia, et al., "Increasing Incidence of the Neonatal Abstinence Syndrome in U.S. Neonatal ICUs," *The New England Journal of Medicine*, vol. 372, no. 22 (2015) and Walter K. Kraft et al., "Neonatal abstinence syndrome: Pharmacologic strategies for the mother and infant," *Seminars in Perinatology*, 40 (2016).

Literature also suggests that NICUs have a high daily cost of care and that the NICU setting makes it difficult to provide many of the non-pharmacologic treatment practices, such as rooming-in. See also Alison V. Holmes et al., "Rooming-In to Treat Neonatal Abstinence Syndrome: Improved Family-Centered Care at Lower Cost," *Pediatrics*, vol. 137, no.6, e1-e9 (2016).

NICU (level III or IV).²⁷ For example, according to these officials, most infants with NAS in Vermont are treated in well newborn nurseries, while most infants with NAS in Kentucky and Wisconsin are treated in NICUs. West Virginia perinatal collaborative officials told us that about a third of infants with NAS are treated in well newborn nurseries, while two-thirds receive treatment in either a special care nursery or NICU. According to perinatal collaborative officials and hospital providers in the four selected states, the severity of the infant's NAS symptoms or the hospital's capability to treat NAS can determine whether the infant receives care in a nursery or NICU.

Health care providers in the four selected states described the general clinical approach for treating infants with NAS. According to these providers, they generally start with non-pharmacologic treatment—for example, swaddling or placing the infant in a quiet, dark room. Health care providers may continue to monitor and assess the severity of the infant's NAS symptoms using one of the available scoring tools for NAS. If the infant's symptoms meet or exceed a certain threshold, these providers may initiate pharmacologic treatment by administering morphine or methadone, for example.

Some perinatal collaborative officials that we interviewed in the four selected states told us that not all hospitals may have the capability to provide pharmacologic treatment. For example, these officials told us that level I hospitals—hospitals with only well newborn nurseries—in Kentucky and Wisconsin may not provide pharmacologic treatment to infants with NAS because these hospitals may not have the staff expertise to administer the needed medication and monitor the infants who receive it. Instead, these hospitals may transfer infants with NAS who require pharmacologic treatment to hospitals with higher levels of care, such as those with a NICU. Table 1 provides information on the eight selected hospitals in our review that provide NAS services.

²⁷The American Academy of Pediatrics defines four levels of neonatal care within a hospital—well newborn nursery (level I), special care nursery (level II), NICU (level III), and regional NICU (level IV). Well newborn nurseries can care for low-risk healthy infants. Special care nurseries can care for stable or moderately ill infants with problems that are expected to resolve rapidly. NICUs can care for more complex and critically ill infants.

Table 1: Selected Hospitals That Treat Infants with Neonatal Abstinence Syndrome (NAS) in Four States, 2016

Hospital (state)	Hospital setting commonly used to treat infants with NAS ^a	Does hospital provide pharmacologic treatment to infants with NAS, if needed?
Hospital 1 (KY)	Level III neonatal intensive care unit (NICU)	Yes
Hospital 2 (KY)	Level III NICU	Yes
Hospital 3 (VT)	Level I well newborn nursery	Yes
Hospital 4 (VT)	Level III NICU	Yes
Hospital 5 (WV)	Level I well newborn nursery	Yes
Hospital 6 (WV)	Level II special care nursery	Yes
Hospital 7 (WI)	Level I well newborn nursery	No ^b
Hospital 8 (WI)	Level II special care nursery	Yes

Source: GAO review of information from and interviews with officials from selected hospitals. | GAO-18-32

Notes: According to health care providers, they generally start with non-pharmacologic treatment—for example, swaddling or placing the infant in a quiet, dark room. These providers may continue to monitor and assess the severity of the infant's NAS symptoms using one of the available scoring tools for NAS. If the infant's symptoms meet or exceed a certain threshold, these providers may initiate pharmacologic treatment by administering morphine or methadone, for example.

^aThe American Academy of Pediatrics defines four levels of neonatal care within a hospital—well newborn nursery (level I), special care nursery (level II), NICU (level III), and regional NICU (level IV). Well newborn nurseries can care for low-risk healthy infants. Special care nurseries can care for stable or moderately ill infants with problems that are expected to resolve rapidly. NICUs can care for more complex and critically ill infants. Within each hospital, there may be multiple settings used to provide NAS treatment services.

^bInfants with NAS are provided non-pharmacologic treatment—such as swaddling and keeping the infant in a quiet, dark room—and infants who require pharmacologic treatment are transferred to another hospital to receive care in a NICU, according to hospital providers.

According to a 2015 study we reviewed, nationwide, infants with NAS who require pharmacologic treatment generally have longer average hospital stays (23 days) compared with infants with NAS who do not require such medication (17 days).²⁸ Health care providers from our selected hospitals also indicated a similar trend—the average length of hospital stay in calendar year 2016 for infants with NAS who received pharmacologic treatment ranged from 7 to 30 days, while the stays for infants who did not require such medication ranged from 3 to 7 days.

²⁸The average length of stay for infants with NAS—depending on the treatment required—compares to an average of 2.1 days for all other hospital births. Patrick et al., “Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome: United States 2009-2012,” 653.

Medicaid Payments for NAS Treatment Services Provided in Hospital Settings

Medicaid generally pays for NAS treatment services in our four selected states using a diagnosis-related group (DRG) based payment system, in which hospitals receive a fixed amount for a bundle of services.²⁹ In general, the DRG-based system used in Medicaid pays for the medical services necessary for treating infants with NAS, such as medication, bed space, and nursing staff, according to CMS officials. CMS officials said that the DRG-based system generally does not pay for professional services, such as physician visits; instead, these services are typically paid under a fee-for-service payment schedule, in which states or contracted managed care plans pay health care providers directly for their services.

Officials in our selected states said information on total Medicaid payments for hospital-based NAS services was not readily available. Several DRGs are typically used to bill Medicaid for services provided to infants. However, these codes alone cannot provide an accurate estimate of Medicaid payments for NAS treatment services because the codes are not used exclusively for NAS. For example, according to some health care providers we interviewed, two DRG codes that may be used to bill Medicaid and other payers for NAS treatment services are 791 (prematurity with major problems) and 793 (full term neonate with major problems). However, these codes could be used to bill for over 2,000 diagnoses—for example, pneumonia or measles. One state official said that while they could provide us with information on Medicaid payments for these infants, they could not parse out the costs by diagnosis codes, such as those related to NAS. Thus, estimates of total Medicaid payments based only on DRG codes likely overstate the amount paid for NAS hospital-based services.

Officials from two of the four selected states told us that their state has a public health surveillance system that tracks the incidence of infants diagnosed with NAS; however, the surveillance systems do not capture

²⁹This payment system is based on DRG codes, which CMS classifies based on a number of factors, such as the patient's age, diagnosis codes, and the presence of complications or multiple conditions. According to CMS officials, states set the DRG base payment rates, and managed care plans can further negotiate the DRG payment with health care providers. Health care providers from seven of our eight selected hospitals told us their state Medicaid program paid for NAS treatment services in calendar year 2016 using a DRG-based payment system. Health care providers from one hospital did not have knowledge on how their hospital bills Medicaid for these services.

financial information, including Medicaid payments for NAS.³⁰ At our request, one of the states cross-referenced their surveillance and Medicaid data and estimated that in 2016, their state Medicaid program spent over \$22 million to treat 1,565 infants with NAS.

While selected states generally could not provide information on total Medicaid payments for infants with NAS, some hospitals in our selected states were able to generate this information at our request using diagnosis codes that they identified as related to NAS from hospital claims data. Six of our selected eight hospitals reported that in calendar year 2016, the average Medicaid payment for treating infants with NAS ranged from about \$1,500 to about \$20,200 per infant per stay. The wide range in Medicaid payment averages may be because the averages included both infants who did and did not require pharmacologic treatment and because these hospitals treated infants in various settings, such as a nursery or a NICU. The literature we reviewed also had limited information on Medicaid payments for NAS treatment services provided in hospitals. A recent study reported that from 2009 through 2012—the most recent data available at the time of the study—Medicaid payments to hospitals for NAS treatment services increased from about \$564 million to \$1.2 billion nationwide.³¹

³⁰The two NAS surveillance systems rely on self-reported data submitted by hospital providers. One state requires these providers to indicate whether an infant is diagnosed with NAS, while the other state requires these providers to identify infants with NAS using International Classification of Diseases (ICD) diagnosis codes. Although one state requires these providers to identify the infant's insurance payer, such as the state Medicaid program, it does not require information on total Medicaid payment. ICD codes are the standard code set used in the U.S. to document patient medical diagnoses. ICD-10 (tenth revision) codes have been in effect since October 1, 2015.

³¹Infants with NAS in this study were identified using the ICD-9 code 779.5 (drug withdrawal syndrome in a newborn). This estimate was determined through analysis of aggregate hospital charges by payer. The study noted that hospital charges do not equal hospital costs and do not include professional fees. Patrick et al., "Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome," 651.

Some Infants with NAS May Complete Treatment in Non-Hospital Settings Available in Certain States, and in These States Medicaid Pays for a Subset of Services

Non-Hospital Settings for Treating Infants with NAS

While most infants with NAS typically complete treatment in a hospital setting, stakeholders told us that some of these infants may be transferred to a non-hospital setting to complete pharmacologic treatment and continue non-pharmacologic treatment. HHS officials told us that there is not a comprehensive list of facilities that may treat infants with NAS outside of the hospital. Based on information from the stakeholders we interviewed and the literature we reviewed, we identified two types of non-hospital settings available in certain states that treat infants with NAS: (1) outpatient clinics and programs and (2) neonatal withdrawal centers. For the purposes of this report, we defined neonatal withdrawal centers as facilities that can treat infants who are prenatally exposed to drugs, including infants with NAS, within the facility.

Outpatient clinics and programs to treat NAS

Through stakeholder interviews and the literature we reviewed, we identified examples of outpatient clinics and programs in certain states where infants with NAS can continue pharmacologic treatment after their discharge from the hospital. For example, some stakeholders we interviewed told us about a Neonatal Medical Follow-Up Clinic in Vermont used to follow-up with infants with NAS who have been discharged from the hospital and are being weaned off methadone on an outpatient basis. Hospital providers train the infant's family on how to administer the infant's medication at home and provide a referral to the clinic. After hospital discharge, the infant and family have follow-up visits in the clinic every 1 to 2 weeks, during which the family discusses with health care

providers the weaning schedule and demonstrate how they administer the infant's medication.³² Health care providers told us that they also encourage the family to continue providing non-pharmacologic treatment to the infant. After weaning is complete, the infant continues to follow-up at the clinic every 1 to 2 months until the infant reaches 12 to 18 months of age.

Literature we reviewed indicated that other outpatient treatment clinics or programs such as the one in Vermont have been established or considered in other states. Specifically, four studies we reviewed described instances in which infants began their treatment in the hospital but completed their treatment through a dedicated outpatient program in Florida, Ohio, and Pennsylvania.³³ Each study noted that the inpatient-to-outpatient approach can result in a shorter hospital length of stay. For example, one 2015 study found that infants who began treatment in a hospital and completed their treatment in an outpatient setting stayed in the hospital an average of 11 days, compared to infants who completed treatment in the hospital, where the stays averaged about 25 days.³⁴ However, the studies also noted that the inpatient-to-outpatient approach resulted in a longer overall treatment duration across the two settings.

Neonatal withdrawal centers to treat NAS

Some stakeholders we interviewed, including health care providers, described examples of neonatal withdrawal centers in two states, where infants with NAS can continue pharmacologic treatment after their

³²According to health care providers, to ensure that a mother is administering the medication correctly to her infant, the mother must bring the medication to the follow-up visits so that these providers can measure the amount of medication left over.

³³See CH Backes et al., "Neonatal Abstinence Syndrome: Transitioning Methadone-Treated Infants from an Inpatient to an Outpatient Setting," *Journal of Perinatology*, vol. 32, no.6 (2012); Kim T. Chau et al., "Outpatient Management of Neonatal Abstinence Syndrome: A Quality Improvement Project," *The Joint Commission Journal on Quality and Patient Safety*, vol. 42, no. 11 (2016); Katherine E. Gregory, "Caring for the Infant with Neonatal Abstinence Syndrome in a Community-Based Setting," *The Journal of Perinatal & Neonatal Nursing* (2014); and Jerry Lee et al., "Neonatal Abstinence Syndrome: Influence of a Combined Inpatient/Outpatient Methadone Treatment Regimen on the Average Length of Stay of a Medicaid NICU Population," *Population Health Management*, vol. 18, no.5 (2015).

³⁴The study examined data between 2007 and 2013 from one managed care plan in Pennsylvania. See Lee et al., "Combined Inpatient/Outpatient Methadone Treatment," 393.

discharge from the hospital. Health care providers in these facilities told us that in Washington and West Virginia, some infants with NAS who began treatment in a hospital may be referred to these facilities, where they reside until they complete treatment and are discharged from the facility. These providers explained that in these facilities, the infants are placed in nursery rooms, where health care providers can monitor them and administer and adjust their medication as needed. In addition, nursing staff or other caregivers are responsible for providing continuous non-pharmacologic treatment, and mothers are encouraged to visit and continue this care. For example, health care providers told us that in Washington, two to three infants may share a nursery room where trained caregivers provide them with non-pharmacologic treatment. In West Virginia, health care providers said infants are typically placed in individual nursery rooms where nurses provide them with non-pharmacologic treatment. The rooms in the West Virginia facility are also equipped with a rocking chair to encourage mothers to visit and provide this care as well. Health care providers told us that the facility currently offers one nursery room equipped with a bed to help prepare mothers on what to expect after discharge; they also said that they encourage mothers to spend the night prior to the infant's discharge from the facility. (See text box below).

Treating infants with neonatal abstinence syndrome (NAS) in a neonatal withdrawal center

One health care provider from a neonatal withdrawal center told us that the practice of rooming-in helps to facilitate the bond between the mother and infant. He also said that rooming-in allows health care providers to model care for the mothers and for mothers to learn how to care for their infants with NAS.

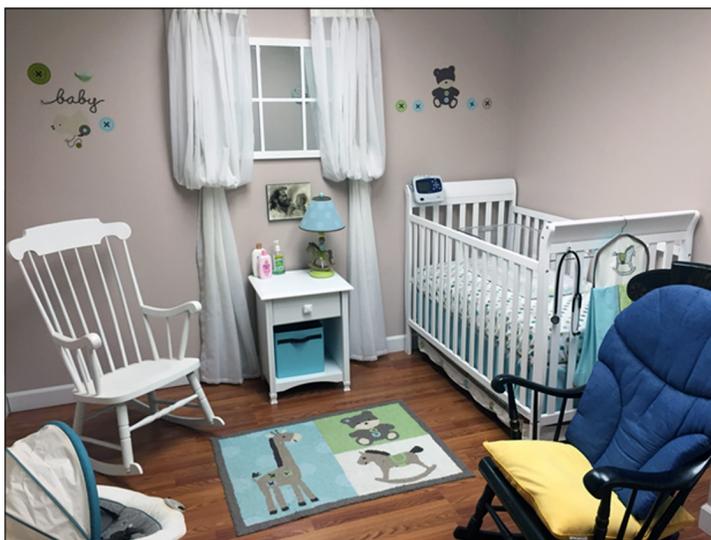
Health care providers told us that the facility currently offers one nursery room equipped with a bed to help prepare mothers on what to expect after discharge and that they encourage mothers to spend the night prior to the infant's discharge from the facility. One health care provider told us that one mother, after staying overnight with her infant, realized that she was not prepared to take care of her infant and consequently gave up custody of the infant. Because of rooming-in, health care providers were able to ensure that the infant was safe because the mother came to this realization at the facility, rather than alone at home.

Although the lack of physical space at the facility currently makes it difficult to accommodate rooming-in for the entire course of the infant's treatment, these providers noted the importance of this practice and that they are committed to parental involvement when treating infants with NAS at their facility.

Source: GAO analysis of interviews with stakeholders and review of literature. | GAO-18-32

Figure 2 depicts nursery rooms in the neonatal withdrawal center in West Virginia. Efforts are also underway to open a neonatal withdrawal center in Arizona and Ohio, according to stakeholders we interviewed.

Figure 2: Examples of Nursery Rooms with a Rocking Chair or Bed in a West Virginia Neonatal Withdrawal Center



Source: Courtesy of Lily's Place, West Virginia. | GAO-18-32

Stakeholders we interviewed and the literature we reviewed suggest some limitations as well as benefits of treating infants with NAS in non-hospital settings, including factors to consider in these settings.

- Health care providers from one of the hospitals we visited in Vermont told us that their hospital is the only one in the state that allows infants with NAS to complete pharmacologic treatment through the Vermont outpatient clinic because they have established the necessary infrastructure to ensure families' compliance and safe practices at home. These providers said that they worked with one local pharmacy to ensure proper dispensing of the medication. Additionally, these providers measured the amount of medication left over at each follow-up visit with the families.
- Some state and perinatal collaborative officials told us that neonatal withdrawal centers may not be the best environment to treat infants with NAS because these settings may limit a mother's access to her infant, since she may not always be allowed to reside with the infant. Such limits, according to officials, do not facilitate bonding between mother and infant.
- Another state perinatal collaborative official, as well as health care providers and staff, told us that neonatal withdrawal centers may be better for treating infants with NAS because the environment is quieter and less stimulating than hospital settings, such as NICUs.³⁵
- Several studies we reviewed also emphasized that the inpatient-to-outpatient approach requires ongoing coordination, communication, and commitment from multidisciplinary providers, as well as the families. These studies highlighted instances in which these approaches reduced the length of the infants' stay in a hospital, though the studies emphasized that more work needs to be done to determine whether these are the optimal approaches for infants with NAS, as well as the potential long-term benefits of such approaches.

³⁵According to the American Academy of Pediatrics, excess environmental stimuli can make the infants' withdrawal more difficult. See Mark L. Hudak and Rosemarie C. Tan, American Academy of Pediatrics. "Neonatal Drug Withdrawal," *Pediatrics*, vol. 129, no.2 (2012).

Medicaid Payments for NAS Treatment Services Provided in Non-Hospital Settings

Medicaid pays for NAS treatment services provided in the non-hospital settings we identified in certain states, according to CMS officials and other stakeholders we spoke with, but generally pays for these services separately, in contrast with the single bundled payment paid to hospitals.³⁶ State officials and health care providers in the non-hospital settings we examined described various ways in which Medicaid covered services they provided to treat infants with NAS. For example:

- **Outpatient follow-up clinic in Vermont.** State officials and staff at this facility told us that the Vermont Medicaid program pays for an infant's outpatient physician visits using a fee-for-service payment schedule. They added that the Vermont Medicaid program also pays for the infant's medication used in pharmacologic treatment and explained that the pharmacy that dispenses the medication bills Medicaid for these services.
- **Neonatal withdrawal center in Washington.** Health care providers at this facility told us that the Washington Medicaid program or their contracted managed care plans pay for physician visits using a fee-for-service payment schedule, noting that the facility decided to stop billing Medicaid for medical supplies because of the low reimbursement.³⁷ Additionally, these providers suggested that because the facility does not meet the Medicaid standards required for receiving payment for hospital inpatient, nursing, or other covered facility services, the facility is ineligible to receive Medicaid payment for the costs of room and board. These providers said that they receive funding for the cost of these services through state

³⁶In addition, Medicaid only pays for the cost of room and board in certain types of facilities, including hospitals, nursing facilities, and psychiatric residential treatment facilities that meet Medicaid standards for such payment. See, e.g., 42 C.F.R. §§ 440.10, 440.150, 440.155.

³⁷According to a state agency report, the facility previously received Medicaid payment in 2012 for NAS-related services including physician visits, medication, gloves, and syringes. See Children's Administration, Division of Program and Practice Improvement, Washington State Department of Social & Health Services, *Report to the Legislature: Pediatric Interim Care Center Performance-Based Contracts* (Olympia, WA: December 1, 2012), accessed September 25, 2017, https://app.leg.wa.gov/ReportsToTheLegislature/Home/GetPDF?fileName=Pediatric%20Interim%20Care%202012-1-12_0e865170-67d7-4235-8992-68729e324c93.pdf. However, health care providers told us that Medicaid reduced its payment for these medical supplies and as a result, these providers did not bill Medicaid for these supplies in 2016. We did not interview Washington state officials about this facility.

appropriations, foster care payments, city contracts, grants, and private donations.³⁸

- **Neonatal withdrawal center in West Virginia.** State officials and health care providers at this facility told us that West Virginia pays for NAS services through two mechanisms, depending on whether the infant is in foster care.³⁹ Specifically, if the infant is in foster care, the facility receives a bundled payment from the state Medicaid program and the Bureau of Children and Families.⁴⁰ However, if the infant is not in foster care, the state Medicaid program pays for physician visits using a fee-for-service schedule. Additionally, the facility can receive payment under a per diem rate that is negotiated with state Medicaid managed care plans.⁴¹ The health care providers said that they also receive funding through grants and private donations to help cover the costs of NAS services.

Stakeholders we interviewed and literature we reviewed suggest that the costs of treating infants with NAS in non-hospital settings were lower than treating them in hospital settings. However, supporting data and research of the costs in different settings are anecdotal or otherwise limited. For example:

- Health care providers from the neonatal withdrawal center in Washington told us that their facility could treat infants at a lower average cost per day than could hospitals—at about \$700 per infant per day compared to an average cost of about \$1,500-2,500 per infant per day in a hospital. These providers said that this cost savings is in part due to their limited staffing of nurses and their ability to leverage

³⁸According to health care providers, this facility is licensed by the state as a group care facility and received \$668,000 in the state appropriations for fiscal year 2016. These providers told us that they received a foster care payment of about \$18 per day for each infant in state custody in 2016.

³⁹The West Virginia Department of Health and Human Resources administers a foster care program, in which it can accept custody of dependent children. Parents may also voluntarily request placement of their child into foster care on a short-term basis.

⁴⁰The facility is eligible to receive this type of bundled payment because it is licensed by the state as a residential child care facility. Facility staff told us that the state Medicaid program pays about \$56 per day per infant while the Bureau of Children and Families pays about \$313 per day per infant. The payment helps to cover some of the facility's cost for medical care and room and board.

⁴¹Medicaid managed care plans have the flexibility to cover services not included in the state Medicaid plan, but if they do so, the plans may bear the financial risk of providing any additional services.

specially trained caregivers to provide infants with non-pharmacologic treatment and hands-on care, such as feeding and bathing. These providers also said they use volunteers to help with household duties, such as laundry and replenishing supplies.

- A health care provider from the neonatal withdrawal center in West Virginia conducted a study that found that the average daily charges per infant were about \$400 in their facility, compared to about \$2,600 in a special care nursery and \$4,000 in a NICU.⁴²
- Two studies we reviewed found that inpatient-to-outpatient treatment approaches reduced hospital costs for NAS treatment; however, these studies were not generalizable and did not account for the duration of treatment across the two settings. Specifically, one study found that an inpatient-to-outpatient treatment approach reduced hospital length of stay by 55 percent—estimated to save hospitals \$396 million annually—compared with treatment provided solely in a hospital.⁴³ The second study found that infants who received care for NAS through an inpatient-to-outpatient treatment approach had an average length of stay of 13 days and cost about \$14,000, while an inpatient-only approach had an average length of stay of 25 days and cost about \$28,000.⁴⁴

⁴²S. Loudin et al., “A management strategy that reduces NICU admissions and decreases charges from the front line of the neonatal abstinence syndrome epidemic,” *Journal of Perinatology* (July 6, 2017). Facility staff told us that the average daily cost per infant was about \$600.

⁴³The study examined data between 2007 and 2013 from one managed care plan in Pennsylvania. See Lee et al., “Combined Inpatient/Outpatient Methadone Treatment.”

⁴⁴The study examined data between January 2007 and January 2009 from a non-generalizable sample of infants at the Ohio State University Medical Center. See CH Backes et al., “Neonatal Abstinence Syndrome: Transitioning Methadone-Treated Infants from an Inpatient to an Outpatient Setting.”

Recommended Practices for Addressing NAS Include Prioritizing Non-Pharmacologic Treatment, While Challenges Include Maternal Use of Multiple Substances

Recommended Practices for Addressing NAS Include Prioritizing Non-Pharmacologic Treatment, Educating Mothers, and Addressing Stigma

The 32 stakeholders we interviewed and the literature we reviewed identified several recommended practices for addressing NAS—that is, treating women with opioid use disorders during pregnancy or treating infants diagnosed with NAS after birth. The most frequently recommended practices were (1) prioritizing non-pharmacologic treatment, such as allowing the mother to reside with the infant during treatment, to facilitate the mother-infant bond; (2) educating mothers on prenatal care, treatment for NAS, and available resources for after an infant’s discharge; (3) educating health care providers on the stigma faced by women who use opioids during pregnancy and on how to screen for and treat NAS; and (4) using a protocol in a hospital or non-hospital setting for screening and treating infants with NAS.⁴⁵ These recommended practices are described in more detail below.

Prioritizing non-pharmacologic treatment for NAS to facilitate the mother-infant bond. Most stakeholders we interviewed and several of the literature articles we reviewed noted that non-pharmacologic treatment for NAS, such as allowing a mother to stay in the room with the infant in the hospital or other treatment location, should be prioritized prior to initiating pharmacologic treatment. The stakeholders and literature

⁴⁵We counted the number of times stakeholders we interviewed cited a practice to determine the most commonly identified recommended practices. We included a recommended practice if at least ten of the 32 stakeholders we interviewed identified it. Many of these practices are similar to those we have identified in prior work on NAS. See [GAO-15-203](#).

Volunteer programs to provide non-pharmacologic treatment for neonatal abstinence syndrome (NAS)

Some stakeholders told us that some hospitals have established volunteer cuddler programs that train volunteers to help provide some of these non-pharmacologic treatments—namely, swaddling, feeding, soothing, and cuddling infants. However, health care providers at some facilities noted that volunteers are not necessarily available during late shifts.

Source: GAO analysis of interviews with stakeholders. | GAO-18-32

indicated that non-pharmacologic treatment may (1) facilitate the mother-infant bond, (2) reduce the severity of NAS symptoms, (3) reduce the need for pharmacologic treatment, and (4) reduce the length of an infant's hospital stay. For example, two of the articles we reviewed noted that rooming-in has been shown to help decrease the need for pharmacologic treatment, the number of admissions to the NICU, and the length of an infant's hospital stay.⁴⁶ Additionally, 17 of the stakeholders we interviewed and nine articles we reviewed recommended that mothers be allowed to breastfeed while their infants are treated for NAS, as it helps to build a bond between the mother and infant. Most of these articles also noted that breastfeeding has been shown to reduce the severity of NAS.⁴⁷

Educating mothers on prenatal care, treatment for NAS, and resources for after an infant's hospital discharge. Most stakeholders we interviewed and several of the literature articles we reviewed recommended providing comprehensive, ongoing education to mothers on prenatal care and treatment for NAS and on the resources that are available after an infant's discharge. (See text box below). The stakeholders and literature indicated that this education may (1) facilitate a non-combative relationship between the mother and health care providers; (2) help to reassure and support the mother, who may feel responsible for the infant's suffering, in addition to facilitating treatment of NAS; and (3) help the mother understand her infant's behavior and develop greater confidence in her parenting skills.⁴⁸ For example, one article noted that an infant's withdrawal behavior, such as fisting, back arching, and jaw clenching, may be misinterpreted by the mother as

⁴⁶See Holmes et al., "Rooming-In to Treat Neonatal Abstinence Syndrome: Improved Family-Centered Care at Lower Cost," and Mary Beth Sutter et al., "Neonatal Opioid Withdrawal Syndrome," *Obstetrics and Gynecology Clinics of North America*, vol. 41, issue 2 (2014).

⁴⁷For example, see Deborah W. Busch, "Clinical Management of the Breast-Feeding Mother-Infant Dyad in Recovery from Opioid Dependence," *Journal of Addictions Nursing*, vol. 27, no. 2 (2016) and Cheryl Cirillo et al., "Does Breast Milk Affect Neonatal Abstinence Syndrome Severity, the Need for Pharmacologic Therapy, and Length of Stay for Infants of Mothers on Opioid Maintenance Therapy During Pregnancy?," *Advances in Neonatal Care*, vol. 16, no.5 (2016).

⁴⁸Tammy Casper and Megan Arbour, "Evidence-Based Nurse-Driven Interventions for the Care of Newborns with Neonatal Abstinence Syndrome," *Advances in Neonatal Care*, vol. 14, no. 6 (2014).

dislike of touch, and that educating mothers on these behaviors can help alleviate feelings of guilt.⁴⁹

Education for mothers on prenatal care, treatment for neonatal abstinence syndrome (NAS), and resources for after an infant’s hospital discharge

- Explaining to the mother during the prenatal period what she can expect when the infant is born to help ensure she understands the effects of and treatment for NAS;
- Informing the mother about non-pharmacologic treatment techniques that can help reduce the severity of the infant’s NAS symptoms;
- Modeling good parenting skills, such as demonstrating how to comfort an infant who may be crying inconsolably for hours because of withdrawal; and
- Informing the mother about contraception for preventing future pregnancies.

Source: GAO analysis of interviews with stakeholders and literature. | GAO-18-32

Educating health care providers on the stigma faced by women who use opioids during pregnancy, and how to screen for and treat NAS. Most stakeholders we interviewed and several of the literature articles we reviewed recommended educating health care providers, including providers who are not addiction specialists, on both the stigma faced by women who use opioids during pregnancy as well as on how to screen for and treat infants with NAS. The stakeholders and literature indicated that this education may: (1) improve care so that mothers with opioid use disorders feel more comfortable seeking and obtaining prenatal care, (2) help health care providers know how to recognize NAS symptoms to help ensure infants receive appropriate treatment, and (3) allow for more consistency among these providers in NAS screening and treatment. For example, 26 stakeholders told us that educating health care providers about stigma is important because provider attitudes affect how and if pregnant women obtain prenatal care and treatment for their opioid use disorders, which can affect the severity of NAS. Additionally, several articles we reviewed noted the importance of educating and training clinicians on how to administer the screening tools used to identify infants

⁴⁹Grim et al., “Management of Neonatal Abstinence Syndrome from Opioids.” (2013).

with NAS, which helps ensure infants are identified and receive optimal care.⁵⁰

Using a protocol for screening and treating infants with NAS. While there is no single national standard of care for screening and treating NAS, most stakeholders we interviewed and several of the literature articles we reviewed recommended that hospital and non-hospital settings use a protocol to screen for and treat infants with NAS.⁵¹ The stakeholders and literature indicated that having a protocol can help: (1) identify infants at risk for NAS, (2) ensure that care is provided consistently, and (3) reduce the length of stay for infants receiving pharmacologic treatment.⁵² For example, the stakeholders we interviewed explained that a standard protocol also helps health care providers understand the tools used to assess the severity of NAS; know the types of medication used in treatment, including amounts and duration; and learn how to wean the infant off these medications. Similarly, one article we reviewed noted that infants who were treated at facilities that adopted standard treatment protocols experienced shorter durations of pharmacologic treatment compared with infants who were treated at facilities that did not use a standard protocol.⁵³

⁵⁰For example, see Lisa Clark and Annie Rohan, "Identifying and Assessing the Substance-Exposed Infant," *MCN in Advance* (2015); Walter K. Kraft et al., "Neonatal Abstinence Syndrome: Pharmacologic Strategies for the Mother and Infant" (2016); and Katherine M. Newnam, "The Right Tool at the Right Time: Examining the Evidence Surrounding Measurement of Neonatal Abstinence Syndrome," *Advances in Neonatal Care*, vol. 14, no.3 (2014).

⁵¹For example, the American Academy of Pediatrics recommends that every facility in the United States adopt a protocol for screening and treating NAS. See Hudak and Tan, American Academy of Pediatrics. "Neonatal Drug Withdrawal."

⁵²Additionally, officials we interviewed from all of the eight hospital and four non-hospital settings told us they had implemented or planned to implement a protocol for treating infants with NAS. However, health care providers at one hospital in West Virginia told us that while most children's hospitals likely had established protocols for screening and treating infants with NAS, some newborn nurseries not within children's hospitals may not have a protocol for screening and treating NAS. As a result, health care providers said, these facilities may not have a standard practice of keeping the infants long enough at the facility to identify withdrawal symptoms if the infants do not begin withdrawing until after discharge.

⁵³Eric S. Hall et al., "Implementation of a Neonatal Abstinence Syndrome Weaning Protocol: A Multicenter Cohort Study," *Pediatrics*, vol. 136, no.4 (2015).

Challenges Faced by Health Care Providers in Addressing NAS Include Maternal Use of Multiple Substances and Stigma Faced by Women Who Use Opioids

Stakeholders we interviewed and literature we reviewed identified several challenges health care providers face in their efforts to address NAS.⁵⁴ The most frequently cited challenges included (1) the use of multiple substances by pregnant women, which can exacerbate NAS; (2) the stigma faced by women who use opioids during pregnancy, which may affect whether they seek prenatal care to address NAS, among other things; (3) hospital staff burden and limited physical capacity to care for infants with NAS; (4) limited coordination of care for mothers and infants with NAS; and (5) gaps in research and data on NAS. These challenges are described in more detail below.

The use of multiple substances by pregnant women, which can exacerbate NAS. Most stakeholders we interviewed and some of the literature we reviewed noted that the use of multiple substances by pregnant women, including opioids—referred to as maternal polysubstance use—can be a challenge, and some stated that the use of these substances can exacerbate NAS symptoms. According to the stakeholders, the substances can include methamphetamines, nicotine, alcohol, cocaine, marijuana, benzodiazepines, and Gabapentin.⁵⁵ The stakeholders and literature indicated that maternal polysubstance use can lead to multiple conditions in the infant—such as prematurity or Hepatitis C—that can exacerbate NAS symptoms and prolong the length of an infant’s hospital stay. For example, one expert noted that many women with opioid use disorders are also heavy cigarette smokers, and the nicotine typically exacerbates NAS withdrawal symptoms. Additionally, officials from a hospital and non-hospital setting we visited told us that they had developed a separate protocol for treating infants exposed to multiple substances that includes the use of several medications to address the more severe NAS withdrawal symptoms.

⁵⁴We counted the number of times stakeholders we interviewed cited a challenge to determine the most commonly identified challenges. We included a challenge if at least ten of the 32 stakeholders we interviewed identified it. Many of these challenges are similar to those we have identified in prior work on NAS. See [GAO-15-203](#).

⁵⁵Gabapentin is an anti-epileptic medication used clinically to address convulsions. Health care providers at several of the facilities in West Virginia that we spoke with told us that it has been used recreationally to boost the effects of illicit opioids while at the same time making the symptoms of NAS substantially worse and more difficult to treat. However, health care providers at one of the facilities told us that it is difficult to test the infant for in utero exposure to this substance.

Stigma faced by women who use opioids which may affect whether they seek prenatal care to mitigate the severity of NAS, among other things. Most stakeholders we interviewed and several of the literature articles we reviewed noted that the stigma faced by pregnant women with opioid use disorders is a challenge in addressing NAS. The stakeholders and literature indicated that stigma may: (1) prevent pregnant women from seeking substance use treatment or prenatal care; (2) prevent them from disclosing their drug use to health care providers during pregnancy; or (3) cause the women to fear punitive effects, such as losing custody of their children, being detained, or losing their jobs. For example, officials from one perinatal quality collaborative told us that these women may fail to seek care because of stigma, which can ultimately make it more difficult for health care providers to build relationships with these women and identify infants at risk for NAS.

Hospital staff burden and limited physical capacity to care for infants with NAS. According to most stakeholders we interviewed and some literature we reviewed, staff burden and a limited physical capacity at facilities can pose challenges for addressing NAS. The stakeholders and literature indicated that there is increased burden on staff to care for these infants because they require frequent, personal attention. For example, the stakeholders explained that a hospital may have to increase the number of nurses on duty in order to provide the care the infants need. Health care providers at one hospital said that nurses still struggle to care for infants with NAS, even with additional staff, because these infants are overstimulated, cry, and do not eat or sleep well. As a result, they require much time and one-on-one attention—including cuddling—from nurses. With respect to physical capacity, some stakeholders told us that limited physical capacity can make it difficult to (1) find space in the facility where the infants can be protected from high levels of stimulation and (2) facilitate the mother-infant bond. For example, some stakeholders told us that hospitals may not have a dedicated space for rooming-in, making it more difficult to facilitate bonding between mothers and infants.

Limited coordination of care for mothers and infants with NAS. Most stakeholders we interviewed explained that the lack of coordination among health care providers and others for the mother and infant with NAS during the prenatal period, after the infant is born, and following the infant's discharge can be a challenge. This coordination includes organizing patient care activities and sharing information among health care providers, social workers, and all other participants concerned with the mother and infant's care. The stakeholders indicated that this lack of coordination can make it difficult for families to get the resources or

support they need. (See text box below). For example, some stakeholders told us that women may miss health care visits because of a lack of access to enabling services such as transportation or child care.⁵⁶

Limited coordination of care for mothers and infants with neonatal abstinence syndrome (NAS)

One expert told us that there is a disproportionate number of infants with NAS born in rural areas. Infants in these areas may be discharged from the hospital without many follow-up services, such as transportation and care coordination.

Source: GAO interview with expert. | GAO-18-32

Gaps in research and data on NAS. Some stakeholders we interviewed noted that gaps in research and data on NAS make it challenging to conduct research on the affected population and fully understand the magnitude of the problem. The stakeholders indicated that there are gaps in adequate research and data on (1) the different types of treatment approaches for NAS; (2) the extent and effects of maternal polysubstance use among pregnant women; (3) the long-term effects of prenatal drug exposure, including the effects seen in childhood and adolescence; and (4) the efforts to ensure more consistent provider diagnosis and screening, such as through an improved screening tool. For example, the stakeholders told us that gaps in research and data may contribute to a lack of a national standard of care for screening and treating infants with NAS. According to some stakeholders, this may result in missed opportunities for identifying and treating infants with NAS. Some stakeholders also told us that because of gaps in research on the long-term effects of prenatal drug exposure, there is limited information on the types of services that infants with NAS may need in early childhood. Additionally, some stakeholders noted they found that because NAS was not consistently diagnosed and coded in medical records using diagnosis codes, the condition may be under-reported, and researchers may be limited in their ability to track these infants.

⁵⁶We also surveyed Child Welfare Directors from 50 states and the District of Columbia about their knowledge of existing guidance, such as SAMHSA's *A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorder*—a guidance document that provides strategies to stakeholders, such as child welfare agencies, related to care coordination for this population. Officials from 42 of the 49 states that responded indicated that they had not received any federal guidance or did not know whether any such resources were available.

HHS’s Strategy Includes Recommendations Related to Addressing NAS but Lacks Priorities, Timeframes, and Responsibilities for Implementing the Recommendations

In May 2017, HHS published the *Protecting Our Infants Act: Report to Congress*, which—among other things—presents a strategy that identifies key recommendations related to addressing NAS.⁵⁷ Specifically, HHS’s strategy—known as the *Protecting Our Infants Act: Final Strategy*—made 39 recommendations related to the prevention, treatment, and related services for NAS and prenatal opioid use. Of the 39 recommendations HHS made in its report, we found that 28 of them directly relate to the recommended practices or challenges that we describe above. For example, the Strategy recommends the following:

- promoting non-pharmacologic treatment, such as rooming-in;
- providing continuing medical education to health care providers for managing and treating infants with NAS, such as on NAS treatment protocols;
- conducting research on the long-term effects of prenatal drug exposure so that appropriate services can be developed for infants with NAS; and
- establishing clear definitions of NAS and standardizing the use of diagnosis codes to collect more meaningful and actionable data on NAS.

According to the Strategy, the recommendations will be used to inform planning and policy across HHS. However, HHS does not include any information in the Strategy on how the department and other stakeholders will implement the recommendations. Specifically, HHS does not include in its Strategy the following:

- the explicit priorities among the numerous recommendations and associated efforts the department has initiated related to NAS;
- timeframes for partial or full implementation of these recommendations;

⁵⁷HHS’s report also (1) provides background on prenatal opioid exposure and NAS; (2) summarizes HHS activities related to prenatal opioid exposure and NAS, including a summary of published educational resources; and (3) presents clinical evidence and recommendations for preventing and treating NAS. See SAMHSA, “Protecting Our Infants Act: Report to Congress,” May 2017. This report, including the strategy, was mandated in the Protecting Our Infants Act of 2015. Pub. L. No. 114-91, §§ 2, 3, 129 Stat. 723, 724-725 (2015).

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- clear roles and responsibilities for the recommendations, such as the extent to which HHS will need to rely on the medical community and federal and public stakeholders for implementation; and
 - the methods that will be used to assess the department's progress in implementing any of these recommendations.

HHS officials told us that they expect to develop a separate plan to guide implementation of the recommendations and that efforts to develop this plan were likely to begin in July 2017. However, as of September 2017, HHS could not provide any documentation that it had started to develop this implementation plan or establish a timeline for completing the plan; nor was HHS able to provide any information on what the plan may include. Having such a plan in place is important to ensure priorities are known and responsibilities are clear so that agencies and stakeholders can take appropriate action. Federal internal control standards call for agencies to have defined objectives clearly as part of their objective-setting process and to assign roles and responsibilities for achieving these objectives. Objectives defined in specific and measurable terms allow for the assessment of performance toward achieving objectives.⁵⁸ Furthermore, leading principles on sound planning we have identified in our prior work call for developing robust plans to achieve agency goals.⁵⁹ Until HHS finalizes an implementation plan that includes specific priorities, timeframes, responsibilities, and methods for evaluating progress, it is at risk of not being able to provide reasonable assurance that it can successfully implement these recommendations in a timely manner and assess the effectiveness of its efforts.

Conclusions

The rising opioid crisis has caused a significant increase in the number of infants born and diagnosed with NAS, a condition that affects infants and their families, hospitals, and other health care providers who are treating them. The increase in infants born with NAS also increases medical and other treatment costs experienced by the federal government and states. HHS recently published a strategy with key recommendations that have the potential to address some of the challenges related to treating NAS. However, HHS lacks a sound plan for implementing these

⁵⁸See [GAO-14-704G](#).

⁵⁹Specifically, sound plans include such components as what the plan is trying to achieve and how it will achieve these results, as well as priorities, milestones, and performance measures to monitor and gauge the results. For example, see [GAO/GGD-96-118](#), [GAO-04-408T](#), and [GAO-17-5](#).

recommendations. The absence of such planning raises questions about whether and when HHS will be able to implement these recommendations in a timely manner and be able to assess its progress.

Recommendation for Executive Action

The Secretary of HHS should expeditiously develop a plan—that includes priorities, timeframes, clear roles and responsibilities, and methods for assessing progress—to effectively implement the NAS-related recommendations identified in the *Protecting Our Infants Act: Final Strategy*. (Recommendation 1)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review, and HHS provided written comments, which are reprinted in appendix III. HHS also provided technical comments, which we incorporated as appropriate. In its written comments, HHS concurred with our recommendation to expeditiously take steps to address NAS and re-stated that its Strategy will be used to inform planning and policy across HHS. Specifically, HHS said that as part of its broader initiative to address the opioid crisis, the department will develop and implement a plan—that will include priorities, timeframes, roles and responsibilities, and methods for assessing progress—to address as appropriate and possible, the NAS-related recommendations in its Strategy. HHS also stated that full implementation would be contingent on funding, though it provided no information on how much funding was needed or how the funding would be used. Developing a plan to guide implementation can help the department determine what resources, if any, are needed to implement the recommendations in its Strategy.

We are sending copies of this report to the appropriate congressional addressees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at iritanik@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

A handwritten signature in black ink that reads "Katherine Iritani". The signature is written in a cursive style with a large, prominent initial "K".

Katherine M. Iritani
Director, Health Care

List of Addressees

The Honorable Orrin G. Hatch
Chairman

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Lamar Alexander
Chairman

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Greg Walden
Chairman

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sherrod Brown
United States Senate

The Honorable Shelley Moore Capito
United States Senate

The Honorable Cheri Bustos
House of Representatives

The Honorable Evan H. Jenkins
House of Representatives

Appendix I: Detailed Scope and Methodology

To address our first three audit objectives to describe care settings for treating infants with neonatal abstinence syndrome (NAS), Medicaid payment for NAS treatment, and the recommended practices and challenges for addressing NAS, we selected 32 stakeholders based on their relevant experience to cover a range of perspectives on NAS. Specifically, these stakeholders included those from site visits we conducted to four states—Kentucky, Vermont, West Virginia, and Wisconsin. We selected these states because they met the following criteria:

1. the state had one of the top 10 highest incidence rates of NAS, according to data from the Centers for Disease Control and Prevention (CDC) for 2013, the most recent year of publicly available data;¹
2. the state provided variation in United States geographic regions with high rates of NAS, as of 2012;²
3. more than 40 percent of births in the state were financed by Medicaid, according to a 2016 Kaiser Family Foundation Medicaid Budget Survey;³ and
4. the state has a perinatal quality collaborative—a state or multi-state network of teams working to improve health outcomes for mothers and infants—with work related to NAS, which we identified through the American College of Obstetricians and Gynecologists.

As part of these site visits, we interviewed (1) officials from each of the four states, including Medicaid officials, Maternal and Child Health Directors, and Women’s Services Coordinators; (2) representatives from the four state perinatal collaboratives; (3) health care providers (including

¹See Jean Y. Ko et al., “Incidence of Neonatal Abstinence Syndrome – 28 states, 1999-2013,” CDC MMWR, vol. 65 (2016).

²NAS rates by geographic region are based on a study using data from the Kids’ Inpatient Database and from the Nationwide Inpatient Sample, both of which are compiled by the Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization project. See Stephen W. Patrick et al., “Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome,” 650-651.

³States were asked to report the share of all births in the state that were financed by Medicaid in the most recent 12 month period for which data were available. States reported data from 2010-2016, which varied by calendar year, state fiscal year, and federal fiscal year. See Kaiser Family Foundation State Health Facts: Births Financed by Medicaid, downloaded on October 31, 2016. See <http://kff.org/medicaid/state-indicator/births-financed-by-medicaid/>.

physicians or nurses) from eight hospitals of varying levels of care (two hospitals in each state), which were selected based on recommendations from the state perinatal collaboratives because of the hospitals' experience treating NAS; and (4) officials from a residential treatment facility in each of the four states that provide prenatal and postpartum care to mothers, which were also selected based on recommendations from the state perinatal collaboratives regarding the facilities' experience with pregnant women with opioid use disorders and their infants with NAS.

In addition to our site visits, we selected 12 additional stakeholders that included health care providers or administrators in non-hospital settings across the United States; officials from medical specialty societies; and experts. Specifically, we spoke with (1) health care providers (including physicians or nurses) or administrators from four non-hospital settings in Arizona, Ohio, Washington, and West Virginia, which were selected based on recommendations from stakeholders we interviewed and on the availability of such settings and their experience treating NAS; (2) health care providers from five medical specialty societies, including the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Society of Addiction Medicine, MedNAX (a network of physicians that specialize in neonatal care, including NAS treatment), and the National Association of Neonatal Nurses; and (3) three experts, including the authors of published literature we reviewed.⁴

We interviewed each of these 32 stakeholders and requested information from stakeholders about treating infants with NAS, including the utilization of available hospital and non-hospital care settings and associated costs of treatment services. For example, we requested protocols for screening and treating infants with NAS from hospital and non-hospital care settings. We reviewed available protocols provided by hospitals and a non-hospital care setting. We also reviewed available information reported by state officials, hospital and non-hospital providers, and state perinatal collaboratives on the utilization of hospital and non-hospital care settings, the facilities' cost of treating NAS in hospital and non-hospital settings, the lengths of stay for treating infants with NAS, or the amount of Medicaid payments for treating infants with NAS. We discussed the information provided by stakeholders and examined the information for obvious errors. The information obtained from these stakeholders is not

⁴Efforts are underway to open the non-hospital settings in Arizona and Ohio.

generalizable to other states or other hospital and non-hospital settings. In addition, in some cases, stakeholders used different methods to collect the information they reported, including information on Medicaid payments; as a result, the information reported by stakeholders is not directly comparable.

Additionally, we interviewed officials from HHS, including those from the Centers for Medicare & Medicaid Services (CMS) and HHS's Behavioral Health Coordinating Council—which includes officials from the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration, among others—concerning NAS treatment services, settings of care, Medicaid payment, and recommended practices and challenges related to addressing NAS.⁵

We also conducted a comprehensive literature review to identify relevant studies on NAS published in peer-reviewed journals from January 2013 to December 2016.⁶ We searched more than 40 databases for research published in relevant peer-reviewed journals, including BIOSIS Previews[®], Embase[®], Gale Group Health Periodicals Database, MEDLINE[®], and New England Journal of Medicine. Key search terms included “neonatal abstinence syndrome,” “neonatal opioid withdrawal syndrome,” and “newborn infants.” After excluding duplicates, we identified and reviewed 325 abstracts. For those abstracts we found relevant, we obtained and reviewed the full study and selected 40 that were relevant to (1) hospital and non-hospital settings and related treatment services for infants with NAS; (2) the costs associated with treating infants with NAS, including Medicaid payments for services in these care settings; or (3) recommended practices and challenges for addressing NAS. We examined the methodologies for each of these studies and interviewed some of their authors. We determined that the studies were sufficiently reliable for our audit objectives. For a complete list of the studies we reviewed, see below.

⁵The Behavioral Health Coordinating Council is a coordinating body within HHS with the goals to share information and identify and facilitate collaborative, action-oriented approaches to address HHS's behavioral health agenda without duplication of effort across the department.

⁶We selected this timeframe to ensure that we captured literature that best reflects the current state of NAS treatment efforts and the most recent data available.

To examine our last audit objective on HHS’s strategy related to addressing NAS, we interviewed agency officials and reviewed agency documents on the agency’s efforts to develop a strategy. Specifically, we interviewed relevant officials from CMS and HHS’s Behavioral Health Coordinating Council concerning their efforts to develop a strategy related to addressing NAS. In reviewing relevant HHS documents, we focused on HHS’s *Protecting Our Infants Act Report to Congress*, which includes a strategy to address identified gaps, challenges, and recommendations related to NAS and prenatal opioid use. In addition, we reviewed the relevant standards for internal control in the federal government and the relevant criteria from GAO’s body of work on effectively managing performance under the Government Performance and Results Act (GPRA) of 1993 and the GPRA Modernization Act of 2010.⁷

Studies GAO Reviewed

Allocco, E., M. Melker, F. Rojas-Miguez, C. Bradley, K. A. Hahn, and E. M. Wachman. “Comparison of Neonatal Abstinence Syndrome Manifestations in Preterm Versus Term Opioid-Exposed Infants.” *Advances in Neonatal Care*, vol. 16, no.5 (2016).

Artigas, V. “Management of Neonatal Abstinence Syndrome in the Newborn Nursery.” *Nursing for Women’s Health*, vol. 18, issue 6 (Dec. 2014/Jan. 2015).

Asti, L., J. S. Magers, E. Keels, J. Wispe, and R. E. McLead. “A Quality Improvement Project to Reduce Length of Stay for Neonatal Abstinence Syndrome.” *Pediatrics*, vol. 135, no. 6 (2015).

Busch, D. W. “Clinical management of the Breast-Feeding Mother-Infant Dyad in Recovery from Opioid Dependence.” *Journal of Addictions Nursing*, vol. 27, no. 2 (2016).

⁷Internal control is a process effected by an entity’s oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. See GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 2014). In past reports, we have identified best practices in planning. For example, see GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1996), GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004) and GAO, *Health Care Quality: HHS Should Set Priorities and Comprehensively Plan Its Efforts to Better Align Health Quality Measures*, [GAO-17-5](#) (Washington: D.C.: October 13, 2016).

Casper, T. and M. Arbour. "Evidence-Based Nurse-Driven Interventions for the Care of Newborns with Neonatal Abstinence Syndrome." *Advances in Neonatal Care*, vol. 14, no. 6 (2014).

Chau, K. T., J. Nguyen, B. Miladinovic, C. M. Lilly, T. L. Ashmeade, and M. Balakrishnan. "Outpatient Management of Neonatal Abstinence Syndrome: A Quality Improvement Project." *The Joint Commission Journal on Quality and Patient Safety*, vol. 42, no. 11 (2016).

Cirillo, C. and K. Francis. "Does Breast Milk Affect Neonatal Abstinence Syndrome Severity, the Need for Pharmacologic Therapy, and Length of Stay for Infants of Mothers on Opioid Maintenance Therapy During Pregnancy?" *Advances in Neonatal Care*, vol. 16, no.5 (2016).

Clark, L. and A. Rohan. "Identifying and Assessing the Substance-Exposed Infant." *MCN in Advance* (2015).

Demirci, J. R., D. L. Bogen, and Y. Klionsky. "Breastfeeding and Methadone Therapy: The Maternal Experience." *Substance Abuse*, vol. 36, no. 2 (2015).

Edwards, L. and L. F. Brown. "Nonpharmacologic Management of Neonatal Abstinence Syndrome: An Integrative Review." *Neonatal Network*, vol. 35, no. 5 (2016).

Gregory, K. E. "Caring for the Infant with neonatal Abstinence Syndrome in a Community-Based Setting." *The Journal of Perinatal & Neonatal Nursing*, (2014).

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Hahn, J., A. Lengerich, R. Byrd, R. Stoltz, J. Hench, S. Byrd, and C. Ford. "Neonatal Abstinence Syndrome: The Experience of Infant Massage." *Creative Nursing*, vol. 22, issue 1 (2016).

Hall, E. S., S. L. Wexelblatt, M. Crowley, J. L. Grow, L. R. Jasin, M. A. Klebanoff, R. E. McClead, J. Meinen-Derr, V. K. Mohan, H. Stein, and M. C. Walsh. "A Multicenter Cohort Study of Treatments and Hospital Outcomes in Neonatal Abstinence Syndrome." *Pediatrics*, vol. 134, no. 2 (2014).

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Holmes, A. V., E. C. Atwood, B. Whalen, J. Beliveau, J. D. Jarvis, J. C. Matulis, and S. L. Ralston. "Rooming-In to Treat Neonatal Abstinence Syndrome: Improved Family-Centered Care at Lower Cost." *Pediatrics*, vol. 137, no. 6 (2016).

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Kraft, W.K., M. W. Stover, and J. M. Davis. "Neonatal Abstinence Syndrome: Pharmacologic Strategies for the Mother and Infant." *Seminars in Perinatology*, vol. 40, issue 3 (2016).

Krans, E. E., G. Cochran, and D. L. Bogen. "Caring for Opioid Dependent Pregnant Women: Prenatal and Postpartum Care Considerations." *Clinical Obstetrics and Gynecology*, vol. 58, no. 2 (2015).

Lee, J., S. Hulman, M. Musci Jr., and E. Stang. "Neonatal Abstinence Syndrome: Influence of a Combined Inpatient/Outpatient Methadone Treatment Regimen on the Average Length of Stay of a Medicaid NICU Population." *Population Health Management*, vol. 18, no.5 (2015).

MacMullen, N. J., L. A. Dulski, and P. Blobaum. "Evidence-Based Interventions for Neonatal Abstinence Syndrome." *Pediatric Nursing*, vol. 40, no. 4 (2014).

Maguire, D. J., "Mothers on Methadone: Care in the NICU." *Neonatal Network*, vol. 32, no. 6 (2013).

Marcellus, L. "Supporting Women with Substance Use Issues: Trauma-Informed Care as a Foundation for Practice in the NICU." *Neonatal Network*, vol. 33, no.6 (2014).

McKeever, A. E., S. Spaeth-Brayton, and S. Sheerin. "The Role of Nurses in Comprehensive Care Management of Pregnant Women with Drug Addiction." *Nursing for Women's Health*, vol. 18, no.4 (2014).

Meyer, M. and J. Phillips. "Caring for Pregnant Opioid Abusers in Vermont: A Potential Model for Non-Urban Areas." *Preventive Medicine*, vol. 80 (2015).

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Appendix II: Department of Health and Human Services' Resources Related to Neonatal Abstinence Syndrome and Prenatal Opioid Use

The Department of Health and Human Services (HHS) has published several guidance and educational resources related to neonatal abstinence syndrome and prenatal opioid use. According to HHS, these documents serve as tools to help stakeholders, including state entities and health care providers, and policymakers. Examples of these resources are listed below.

Centers for Disease Control and Prevention (CDC), *Pregnancy and Opioid Medications Factsheet*, accessed June 8, 2017, https://www.cdc.gov/drugoverdose/pdf/pregnancy_opioid_pain_factsheet-a.pdf.

CDC Public Health Grand Rounds, *Primary Prevention and Public Strategies to Prevent Neonatal Abstinence Syndrome* (Atlanta, GA: CDC, last updated August 18, 2016), accessed July 19, 2017, <https://www.cdc.gov/cdcgrandrounds/archives/2016/August2016.htm>.

CDC, *Treating for Two: Safer Medication Use in Pregnancy Initiative* (Atlanta, GA: CDC, last updated May 5, 2016), accessed June 8, 2017, <https://www.cdc.gov/pregnancy/meds/treatingfortwo>.

Department of Health and Human Services, *Opioids: The Prescription Drug & Heroin Overdose Epidemic* (Washington, D.C., last reviewed March 24, 2016), accessed June 8, 2017, <https://www.hhs.gov/opioids/index.html>.

Department of Health and Human Services, National Center for Substance Abuse and Child Welfare, *Resources & Topics on Neonatal Abstinence Syndrome*, accessed June 8, 2017, <https://www.ncsacw.samhsa.gov/resources/opioid-use-disorders-and-medication-assisted-treatment/neonatal-abstinence-syndrome.aspx>.

Jean Y. Ko. et al., "CDC Grand Rounds: Public Health Strategies to Prevent Neonatal Abstinence Syndrome," *Morbidity and Mortality Weekly Report* (Centers for Disease Control and Prevention, March 10, 2017), accessed June 8, 2017, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6609a2.htm>.

National Institute on Drug Abuse, *Principles of Substance Abuse Prevention for Early Childhood: A Research Based Guide* (last updated March 2016), accessed June 8, 2017, <https://www.drugabuse.gov/publications/principles-substance-abuse-prev>

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Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 26 2017

Katherine Iritani
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Iritani:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome*" (GAO-18-32).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: NEWBORN HEALTH: FEDERAL ACTION NEEDED TO ADDRESS NEONATAL ABSTINENCE SYNDROME (GAO-18-32)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation

The Secretary of HHS should expeditiously develop a plan- that includes priorities, timeframes, clear roles and responsibilities, and methods to assess progress – to effectively implement the NAS-related recommendations identified in the *Protecting Our Infants Act: Final Strategy*.

HHS Response

HHS concurs with GAO that it is appropriate for HHS expeditiously to take steps to address the issue of neonatal abstinence syndrome. However, as that document itself noted, the *Protecting Our Infants Act: Final Strategy* is intended to be used to inform planning and policy across HHS and that full implementation would be contingent upon funding.

As part of its broader HHS-wide initiative to address the opioids crisis, HHS will develop and implement a plan – including priorities, timeframes, roles and responsibilities, and methods to assess progress – to address the issue of neonatal abstinence syndrome, including, as appropriate and possible, the NAS-related recommendations identified in the *Protecting Our Infants Act: Final Strategy*.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contacts

Katherine M. Iritani, (202) 512-7114 or iritanik@gao.gov

Acknowledgments

In addition to the contact named above, Rashmi Agarwal, Assistant Director; Amy Leone, Analyst-in-Charge; Melissa Duong; Krister Friday; Jacquelyn Hamilton; Giao N. Nguyen; and Laurie Pachter made key contributions to this report.

Related GAO Products

Drug Control Policy: Information on Status of Federal Efforts and Key Issues for Preventing Illicit Drug Use. [GAO-17-766T](#). Washington, D.C.: July 26, 2017.

Medicaid Expansion: Behavioral Health Treatment Use in Selected States in 2014. [GAO-17-529](#). Washington, D.C.: July 21, 2017.

VA Health Care: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements. [GAO-17-242](#). Washington, D.C.: February 15, 2017.

Highlights of a Forum: Preventing Illicit Drug Use. [GAO-17-146SP](#). Washington, D.C.: November 14, 2016.

Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access. [GAO-16-833](#). Washington, D.C.: September 27, 2016.

Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations. [GAO-16-737T](#). Washington, D.C.: June 22, 2016.

Office of National Drug Control Policy: Progress toward Some National Drug Control Strategy Goals, but None Have Been Fully Achieved. [GAO-16-660T](#). Washington, D.C.: May 17, 2016.

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Mental Health: Better Documentation Needed to Oversee Substance Abuse and Mental Health Services Administration Grantees. [GAO-15-405](#). Washington, D.C.: May 12, 2015.

Prenatal Drug Use and Newborn Health: Federal Efforts Need Better Planning and Coordination. [GAO-15-203](#). Washington, D.C.: February 10, 2015.

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