DEPARTMENT OF HEALTH & HUMAN SERVICES

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CMCS Informational Bulletin

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Subject: Neonatal Abstinence Syndrome: A Critical Role for Medicaid in the Care of Infants

This Informational Bulletin provides states with considerations when designing approaches to treatment of infants with Neonatal Abstinence Syndrome (NAS), including Medicaid coverage options and limitations. It contains a summary of some current studies on such treatment, which suggest possible strategies states may want to consider in building effective coverage programs. It further discusses ways in which Medicaid can support the mothers, fathers, and caregivers of the infants in providing care that can improve health outcomes for their infants with NAS.

Background

Neonatal Abstinence Syndrome (NAS) is a constellation of symptoms in newborn infants exposed to any of a variety of substances in utero, including opioids. Clinically significant neonatal withdrawal most commonly results from exposure to opioids, but symptoms of neonatal withdrawal have also been noted in infants exposed to antidepressants, anxiolytics, and other non-opioids. NAS is not characterized as an addiction or substance use disorder; rather it is a medical condition resulting in a physiologic response to the infant's exposure to cessation of the opioid or other substance the mother was using.

NAS is a significant and rapidly growing public health concern. It is directly related to the opioid crisis facing this country. The incidence of NAS in the United States increased nearly five-fold between 2000 and 2012⁴ 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 in

¹ Wiles JF, Isemann B, Ward LP, Vinks AA, Akinbi H. "Current Management of Neonatal Abstinence Syndrome Secondary to Intrauterine Opioid Exposure." J Pediatr 2014 165:440-6 DOI:10.1016/jpeds 2014.05.010.

² Kocherlakota P, "Neonatal Abstinence Syndrome." Pediatrics 2014:134e:e547 (2014) DOI:10.15242/peds.2013-3524

³ Kocherlakota P, "Neonatal Abstinence Syndrome." Pediatrics 2014

⁴ Patrick SW, Davis MM, Lehman CU, Cooper WO "Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome: United States 2009-2012." J Perinato, 2015 35, 667, http://dx.doi.org/10.1038/jp.2015.63

that year.⁵ This translates to a rate of one infant born with NAS approximately every 25 minutes in 2012.⁶ More than eighty percent of infants treated for NAS have their care paid for by Medicaid.⁷

NAS is a complex condition and symptoms vary from infant to infant, based on a number of factors, including but not limited to the longevity and history of substance use by the mother and the quantity and type of opioid and/or other substances used.⁸ The clinical signs of NAS include high pitched and excessive crying, irritability, poor sleep, sweating, poor feeding, respiratory distress, seizures, tremors and other signs.⁹ Experts consider NAS to be an expected and treatable result of women's prenatal opioid or other substance use, although long term ramifications for the infants are still unknown.¹⁰ Symptoms of NAS usually develop within 72 hours of birth, but may develop anytime in the first week of life, including after hospital discharge.¹¹

Conceptually, every infant with *in utero* opioid and/or other substance exposure falls along the continuum of withdrawal symptoms, ranging from mild and at times clinically insignificant signs, to much more severe signs. The diagnosis of NAS is made by observing these clinical signs of neonatal withdrawal that the newborn exhibits in the days to weeks after birth. ¹²

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⁵ Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM, "Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009," JAMA, 2012, 307(18):1934-40. doi: 10.1001/jama.2012.3951 and also Patrick SW, Davis, MM, Lehman CU, Cooper WP "Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome: United States 2009-2012."

⁶ Patrick SW, et al. "Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome," (2015) 652

⁷ Patrick SW, et al. "Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome, (2015)" 653-654.

⁸ Hudak M. L., Tan, R. C., American Academy of Pediatrics (AAP), Committee on Drugs, & AAP Committee on Fetus and Newborn. (2012). "Neonatal Drug Withdrawal" Pediatrics, 2012, 129, e540-560, doi: 10.1542/peds.2011-3212 ⁹ Hudak and Tan, et al. "Neonatal Drug Withdrawal, 2012; and see also Hamdan, Ashraf, "Neonatal Abstinence Syndrome" published in Medscape, Updated: Dec 20, 2017 https://emedicine.medscape.com/article/978763-overview

¹⁰ Maguire DJ, Tylor S, Armstrong K, Shaffer-Hudkins E, Germain AM, Brooks SS, Cline GJ, Clark, L. "Long-term Outcomes of Infants with Neonatal Abstinence Syndrome" Neonatal. Netw. 2016; 35(5): 277-286

¹¹ Hudak and Tan, et al. "Neonatal Drug Withdrawal AAP Guidance, 2012

¹² Kraft WK, Stover MW, Davis JM. "Neonatal Abstinence Syndrome: Pharmacologic Strategies for the Mother and Infant," Seminars in perinatology. 2016;40(3):203-212. doi:10.1053/j.semperi.2015.12.007

NAS Diagnosis and Treatment

Diagnosis

While standards of care are evolving for screening and treating NAS, the use of assessment and screening tools is acknowledged as critical ¹³. There is no one specific NAS screening guideline that is uniformly endorsed or adopted. Health care providers predominantly diagnose NAS using validated scoring tools, such as 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 in the infant. ¹⁴ Medical literature highlights the importance of hospitals and nurseries adopting standard protocols and training staff in the correct use of the chosen assessment tool, as well as providing training in the evaluation and treatment of the presenting NAS symptoms. ¹⁵

Treatment

The American Academy of Pediatrics recommends that infants with NAS should not be initially treated with medication. Pharmacologic treatment, such as the use of liquid methadone, morphine, or other pharmacological interventions, may be necessary only for the treatment of more severe signs of NAS. Instead, recommendations highlight initially attempting the use of non-pharmacologic treatment, which includes placing the infant in a dark and quiet environment, swaddling, rocking, breastfeeding, and providing high-calorie nutrition in frequent small feedings, among other techniques. Not all opioid-exposed infants develop NAS and it is important to tailor treatment to the individual needs of the infant. Some infants develop very mild signs of drug withdrawal that can be effectively treated with non-pharmacological intervention, including rooming in with their mother and breastfeeding when it is appropriate. When utilized appropriately, such non-pharmacological interventions have resulted in a reduction in length of stay, length of treatment, and percentage of infants requiring pharmacotherapy. Pharmacotherapy.

¹³ Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

¹⁴ Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018. P79

¹⁵ Hudak and Tan, et al. "Neonatal Drug Withdrawal, 2012

¹⁶ Hudak and Tan, et al. "Neonatal Drug Withdrawal, 2012

MacMillan KDL, Rendon CP, Verma K, Riblet N, Washer DB, Volpe Holmes A. Association of Rooming-in With Outcomes for Neonatal Abstinence Syndrome: A Systematic Review and Meta-analysis. *JAMA pediatrics*. 2018
Jannson LM. ABM clinical protocol #21: Guidelines for breastfeeding and the drug-dependent woman.
Breastfeed Med. 2009;4(4):225-228

¹⁹ MacMillan KDL, Rendon CP, Verma K, Riblet N, Washer DB, Volpe Holmes A. Association of Rooming-in With Outcomes for Neonatal Abstinence Syndrome: A Systematic Review and Meta-analysis. *JAMA pediatrics*. 2018; and

Mothers as Part of Treatment

Several studies currently highlight the importance of the involvement of mothers and their interaction with the newborns during treatment whenever possible. The importance of mothers residing (or "rooming in") with the infant (or spending as much time as possible in direct contact with the infant) during the NAS treatment period and breastfeeding when possible is becoming more recognized as the standard of care. Skin-to-skin contact and breastfeeding have been shown to be of direct benefit to the infant in the treatment of the symptoms of infants with NAS. Multiple Specialty Societies support breastfeeding among opioid-dependent women if the women are enrolled in substance abuse treatment and no contraindications to breastfeeding are observed, such as ongoing drug use or HIV infection. Studies continue to show the importance of keeping the mother and infant together as part of the infant's treatment for NAS.

One prominent option for accomplishing these goals involves creating an environment that allows mothers to "room-in" with the infants. A recent study found that infants who "roomed-in" with their mothers were 63 percent less likely to receive drugs like morphine or methadone for withdrawal symptoms. They also tended to leave the hospital about ten days sooner than infants who did not room in with mothers.²³

Supporting the mother, father, and other caregivers alongside the infants additionally provides a direct benefit to the infant, by encouraging the infant's mother, father, and/or other future caregivers to learn and practice specialized strategies to comfort an infant with NAS. This hands-on specialized training and supervised practice of methods of caring for infants with NAS provides a direct benefit to the infant during all phases of treatment.

Continuity of Care and Case Management as Part of Treatment

Further, in order to provide the infant with the best chances for a continued healthy trajectory, coordination and planned transitions from each treatment stage, including case management and ongoing services for the infant and mother should be addressed.

Holmes AV, Atwood EC, Whalen B, et al. Rooming-In to Treat Neonatal Abstinence Syndrome: Improved Family-Centered Care at Lower Cost. *Pediatrics*. 2016;137(6)

²⁰ Bagley SM, Wachman EM, Holland E, Brogly SB. "Review of the assessment and management of neonatal abstinence syndrome." Addict Sci Clin Pract. 2014 9(1):19. doi: 10.1186/1940-0640-9-19

²¹ Hamdan, Ashraf, "Neonatal Abstinence Syndrome" updated 2017

²² Abrahams, R.R., Kelly, S.A., Payne, S., Theissen, P.N., Mackintosh, J. & Janssen, P.A. (2007) "Rooming-in Compared with Standard Care for newborns of mothers using Methadone or Heroin." Canadian Family Physician, 53(10), 1722-1730

²³ MacMillan KD, Rendon CP, Verma K, Riblet M. Washer DB. Holmes AV, "Association of Rooming-in With Outcomes for Neonatal Abstinence Syndrome: A Systematic Review and Meta-analysis.", JAMA JAMA Pediatr, doi:10.1001/jamapediatrics.2017.5195 https://jamanetwork.com/journals/jamapediatrics/fullarticle/2672042

As part of NAS treatment and planning, mothers may require an assessment of their own SUD and/or mental health treatment needs. This is an opportunity to identify timely and appropriate treatment options for the mother or caregiver to benefit not only that individual, but the continued wellbeing of the infant.

Case management pre-delivery, during treatment, and post-discharge, can be a lynchpin for providing and maintaining effective care and treatment of infants with NAS. Case management services assist the infant and caregiver in gaining access to needed medical, social, educational and other services. Case management services are critical for infants with NAS and their caregivers since they both are experiencing continuous changes in their health, environment, and recovery status. In order to sustain the infant and caregiver as they navigate these changes, case management can assist them in identifying and gaining access to supports that help surmount the challenges and engage in behaviors that support healthy outcomes.

Medicaid Coverage for NAS Treatment

General Medicaid Requirements

In terms of coverage of services under the state plan, among other applicable standards, coverage must meet three foundational requirements: freedom of choice of providers; comparability of services; and statewideness of coverage. Freedom of choice of providers means that beneficiaries must be able to receive services from any qualified provider who agrees to furnish services to them (including agreement to accept Medicaid payment and abide by applicable program standards). Comparability of services means that states must offer services in the same amount, duration and scope to all members of a categorically needy eligibility group. For example, if a beneficiary who is a child under age 21 does not have a NAS diagnosis, but has comparable needs as a child who has been diagnosed with NAS, services to address that child's needs must be covered in the same amount, duration and scope as for a child who has been diagnosed with NAS. Finally, NAS treatment services under the state plan must be available statewide, and not restricted to certain geographic locations in the state.²⁴ The Medicaid Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit provides comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid. In accordance with section 1905(r) of the Act, states are required to make available all medically necessary services that are included under the benefits in section 1905(a) of the Act in order to correct or ameliorate the child's physical and mental health conditions. EPSDT services must be provided by qualified providers, and must be made available to children with a medical need for the services.

Coverage for Infants, Excluding Payment for Room and Board

²⁴ A state seeking to provide NAS coverage without satisfying the free choice of provider, comparability, and statewideness requirements would need to seek approval for a waiver of these requirements, or expenditure authority for costs not otherwise matchable, under an applicable Medicaid authority such as section 1115, section 1915(b), or section 1915(c) of the Act.

As the number of infants born with NAS continues to rise, states are exploring NAS treatment settings outside of hospital inpatient settings. These settings may be used to treat infants with less severe NAS or to care for infants who are not medically ready to return home, but who are stable enough to transfer to a lower level of care and can be safely discharged from the hospital. While these treatment settings may be residential in nature and provide 24 hour care, they may not meet the Medicaid standards for facility-based inpatient settings, thus preventing reimbursement for room and board. The Medicaid covered services delivered in these settings, however, may be appropriately covered and paid under section 1905(a) of the Act as described in the State plan.

For infants with NAS, specific services may include assessments, development of care plans, swaddling, feeding, and specialized care of the infants. These services may be covered under a variety of Medicaid state plan benefits provided they meet the requirements for the benefit under which the services are provided. Potential benefit categories include, but are not necessarily limited to, physicians' services; services provided by other licensed practitioners; physical and occupational therapies; speech, hearing and language disorder services; respiratory care services; diagnostic and rehabilitative services; prescription drugs; non-emergency transportation to medical care; and case management.

States may design payment methodologies for individual services, or may consider creating a bundled rate for services provided to infants in settings, like a pediatric residential center specializing in NAS treatment services. As an example, CMS approved a West Virginia state plan amendment (WV-17-0004) on February 8, 2018 that pays an all-inclusive rate for neonatal abstinence treatment professional services, as well as ancillary costs directly related to the provision of these services, but does not include room and board costs. A state could reimburse providers for medically necessary Medicaid state plan services provided to infants with NAS who are residing in a neonatal residential center or at home. The residential setting could act as a point of coordination for billing and payment for covered Medicaid services furnished to the infants by qualified providers who may be employees of or under contract with the neonatal residential center. However, such payments may not include costs associated with room and board unless the neonatal residential center meets the definition of any inpatient facility type for which expenditures for room and board may be made under the state plan (as discussed below).

Coverage for Infants, Including Payment for Room and Board

Infants with NAS have traditionally been treated in hospital inpatient settings, often with lengthy stays. Under current Medicaid law, medical assistance payment for room and board is only available with respect to four facility types that provide Medicaid-covered, institutionally-based benefits: nursing facilities, inpatient hospitals, psychiatric facilities for individuals under age 21, institutions for mental disease for individuals age 65 or older that otherwise would qualify as an inpatient setting, and intermediate care facilities for individuals with intellectual disabilities. These types of facilities must meet certain federal standards and conditions of participation requirements prescribed by the Secretary. Facilities that meet the Medicaid requirements, including conditions of participation, could receive a Medicaid payment that includes room and

board costs. As an example, an inpatient hospital or a nursing facility for individuals under 21 that meets the Medicaid requirements and includes a pediatric center treating infants with NAS may receive such payments.

Coverage for Medicaid Eligible Mothers of Infants with NAS

If the mother is Medicaid-eligible in her own right, she may receive any medically necessary services covered in her state, which may include counseling and medication-assisted treatment (MAT) to treat her substance use disorder (SUD) under the rehabilitative services benefit, as well as other medically necessary Medicaid services. Women with SUD are more likely to relapse after delivery. 25 During this extraordinarily stressful time, it is important to assist the mother with a review of her potential Medicaid coverage, and offer meaningful, effective, and ongoing SUD treatment services and support to mothers, fathers, and other caregivers. Discontinuation of pharmacotherapy for SUD should generally be avoided in the immediate postpartum period.²⁶

Many states are moving toward covering a full continuum of care for SUD treatment. These services may be provided to a mother on an outpatient basis or in a residential setting. However, services provided in a residential setting for the mother, such as treatment for SUD may be subject to the Institution for Mental Diseases (IMD) coverage exclusion.

An IMD is a hospital, nursing facility or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases (i.e., mental illness and/or SUDs), including medical attention, nursing care and related services. The IMD exclusion prevents Medicaid coverage for individuals aged 19-64 who are residents of an IMD, for any services, either inside or outside the IMD.²⁷ CMS recently established a new Section 1115 Demonstration policy designed to facilitate partnerships with states to ensure Medicaid beneficiaries have access to evidence-based treatment along a full continuum of care that may include certain SUD treatment in facilities that qualify as IMDs.²⁸

Like all post-partum mothers, mothers of infants with NAS are at risk for maternal depression, a well-documented serious and widespread condition that not only affects the mother, but may have a lasting, detrimental impact on the child's health. State Medicaid agencies may cover maternal depression screening as part of a well-child visit.²⁹ For mothers who are also Medicaid

²⁵ Helmbrecht, GD. & Thiagarajah, S (2008). "Management of addiction disorders in pregnancy" Journal of Addiction Medicine, 2(1), 1-16

²⁶ Jones, HE, Deppen, K., Hudak, ML, Leffert, L., McClelland, C., Sahin, L., Creanga, A. A. (2014b). Clinical care for opioid-using pregnant and postpartum women: The role of obstetric providers. American Journal of Obstetrics and Gynecology, 210(4), 302-310. doi:10.1016/j.ajog.2013.10.010

²⁷ State Medicaid Manual 4390 A2; at https://www.cms.gov/Regulations-and-Guidance/guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html

²⁸ https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf SMD # 17-003 RE: Strategies to Address the Opioid Epidemic

²⁹ https://www.medicaid.gov/federal-policy-guidance/downloads/cib051116.pdf

eligible, Medicaid can play a significant role not only in screening, but also in maternal depression treatment.

Coverage for Non-Medicaid Eligible Mothers of Infants with NAS

Medicaid-covered services are only available to Medicaid-eligible individuals. CMS has previously stated, however, that non-Medicaid-eligible mothers may receive some benefit from certain services that are directed at treating and promoting the health of the child to reduce or treat the effects of the mother's condition on the child. NAS treatment services such as counseling the mother in how to care for and interact with her infant with NAS, and providing training to the mother about special protocols on how to care for and breastfeed an infant with NAS, may be covered if the infant is present and the therapeutic interventions are for the direct benefit of the infant. For NAS treatment services to be for the direct benefit of the infant, the services must actively involve the infant, be directly related to the individualized needs of the infant and be delivered to the infant and mother together. Finally, the services must be coverable under a benefit in section 1905(a) of the Act (e.g., medical or remedial services provided by a physician or other licensed practitioner). If each of the foregoing conditions is met, services that involve a non-Medicaid eligible mother may be claimed as a direct service to the infant pursuant to the EPSDT benefit.

Coverage of Case Management Services

Targeted Case Management is an available service under Medicaid state plan benefits.³¹ Effective case management includes: assessing the need for medical, educational, social and/or other services; development of a specific individualized care plan in conjunction with the mother and/or caregiver; referral and related activities to help the individual obtain needed services; and monitoring and follow up activities to ensure that changes in the needs or status of the infant are reflected in the care plan and that the plan is effectively implemented and adequately addresses the needs of the individual. Case management assistance to caregivers in accessing transportation, appropriate child care, and other services post discharge may be critical in meeting continuing health care needs.

Coverage of Services at Home

After the infant is discharged home, there may be a need for follow-up or additional services to ensure the infant's continued health and development. The Maternal, Infant, and Early Childhood Home Visiting (MIEDHV) Program funds states, territories, and tribal entities to develop and implement evidence-based home visiting services for at-risk pregnant women and

Maternal Depression Screening and Treatment: A Critical Role for Medicaid in the Care of Mothers and Children https://www.medicaid.gov/federal-policy-guidance/downloads/cib051116.pdf

Maternal Depression Screening and Treatment: A Critical Role for Medicaid in the Care of Mothers and Children ³¹ 42 CFR 440.169:

parents with young children up to kindergarten entry. ³² The majority of home visiting programs deliver services such as screening, case management, family support, counseling, and skills training. ³³ Some programs serve expecting mothers, while others serve families after the birth of a child. Each state has its own system in place to determine MIECHV eligibility. ³⁴ Once enrolled in the program, home visitors screen all enrolled children using standardized developmental screening tools. Home visitors will help ensure that children and families, on a voluntary basis, obtain the services they need, as the coordination of services to families is a MIECHV Program priority.

As noted above, Medicaid coverage for services would depend on whether 1) the infant and/or other caregiver are Medicaid-eligible; and 2) the proposed services are coverable through existing Medicaid coverage authorities. Examples of Medicaid state plan benefits that include services that may be furnished as part of a home visiting program are: case management, physical therapy, occupational therapy, speech-language and audiology services, preventive services, rehabilitative services, and home health services. States may also wish to consider other Medicaid authorities to furnish services within a home visiting program such as managed care authorities, home and community-based services waiver programs, and section 1115 demonstration programs. Also as noted above, if a state sought to cover services to a non-Medicaid-eligible mother and claim the service as a direct service for the infant, the services must actively involve the infant, be directly related to the needs of the infant, and such treatment must be delivered to the infant and mother (or caregiver) together. For further information, states can refer to the Joint Informational Bulletin on Coverage of Maternal, Infant, and Early Childhood Home Visiting Services.³⁵

Continued Monitoring of Child Development and Provision of Necessary Services

Of additional importance to these infants is a continued assessment to review the infant's attainment of normal developmental milestones. The current data on in utero opioid and other substance exposed infants is limited, although more concrete information will no doubt be emerging as more of these infants are studied through their formative years. While research continues, close follow up during home visits and well child visits are important ways to determine whether additional assessments or services may be necessary to ensure the infant's continued health and optimal development.

³² Social Security Act, title V, §511(a);

³³ https://mchb.hrsa.gov/maternal-child-health-initiatives/home-visiting-overview

³⁴ Under Social Security Act, Title V, § 511(k)(2), "[t]he term "eligible family" means— (A) a woman who is pregnant, and the father of the child if the father is available; or (B) a parent or primary caregiver of a child, including grandparents or other relatives of the child, and foster parents, who are serving as the child's primary caregiver from birth to kindergarten entry, and including a noncustodial parent who has an ongoing relationship with, and at times provides physical care for, the child."

³⁵ Coverage of Maternal, Infant, and Early Childhood Home Visiting Services, CMS/HRSA Joint Informational Bulletin at https://www.medicaid.gov/federal-policy-guidance/downloads/cib-03-02-16.pdf

Conclusion

The significant increase in the number of infants born with NAS presents challenges for treatment of both infants and their mothers. Appropriate treatment using the best evidence-based practices can help these infants withdraw from opioids and other substances and lead healthier lives. NAS treatment may occur not only in hospitals, but subsequently in other settings. In addition to Medicaid covered treatment for infants, it is important for states to involve mothers and other caregivers in the infant's care, as appropriate. The use of interventions like swaddling, quiet environments, little stimulation, skin-to-skin contact, and other environmental approaches are critical first line care for these infants. States may also seek to cover initial or ongoing SUD treatment services for Medicaid eligible mothers and/or fathers concurrently with NAS treatment services directed at the infant. Services that begin at this critical time, and continue to follow and support the infant and caregiver when the infant returns home, provide the highest likelihood for optimal health status and positive outcomes for infants born with NAS. Medicaid services can play a critical role in helping ensure access to treatment for these vulnerable infants and their families.

States interested in learning more on this topic and/or requesting technical assistance may contact Kirsten Jensen, Director, Division of Benefits and Coverage at Kirsten.Jensen2@cms.hhs.gov.