



Treatment of Pregnant Women With Opioid Use Disorders



Introduction

This guidance publication is intended to support the efforts of states, tribes, and local communities in addressing the needs of pregnant women with opioid use disorders and their infants and families.¹ National data show that from 2000 to 2009 the use of opioids during pregnancy increased from 1.19 to 5.63 per 1,000 hospital births (Patrick, Schumacher, Benneyworth, Krans, McAllister, & Davis, 2012). Because of the high rate of opioid use and misuse among all women, including pregnant women, medical, social service, and judicial agencies are having to confront this concern more often and, in some communities, at alarming rates.

Opioids are drugs that reduce the intensity of pain signals. The term “opiates” refers only to natural opium derivatives, and the term “opioids” refers to drugs that activate opioid receptors, including opiates, heroin, and synthetic opioids (e.g., certain prescription painkillers, such as oxycodone) (CSAT, 2004).

Data from SAMHSA’s National Survey on Drug Use and Health show that between 2007 and 2014, the numbers of past-year heroin initiates, heroin users, and people with heroin dependence increased significantly (SAMHSA, 2015). The pattern of initiating heroin use has changed over the past decade. Approximately three-quarters of persons who use heroin report prior non-medical use of prescription opioids, as well as current abuse or dependence on additional substances such as stimulants, alcohol, and marijuana. Conversely a small percentage, approximately four percent, of persons with non-medical use of prescription drugs initiate heroin use. However given the

10.3 million persons who reported non-medical use of prescription drugs in 2014, this small percentage of conversion to heroin generates several hundred thousand new heroin users (Compton, Jones & Baldwin, 2016).

When pregnant women use opioids, their infants may be affected. Neonatal abstinence syndrome (NAS) is the common term used to represent the pattern of clinical findings typically associated with opioid withdrawal in newborns (Hudak & Tan, 2012). However, the U.S. Food and Drug Administration (FDA) now uses the term “neonatal opioid withdrawal syndrome” on warning labels when referring to the maternal use of opioids during pregnancy.² Most newborns of mothers who used opioids during pregnancy develop symptoms of NAS, a postnatal drug withdrawal syndrome, primarily caused by maternal opioid use (Patrick et al., 2012). The range and severity of the symptoms experienced by the infant depends on a variety of factors, including the type of opioid the infant was exposed to and whether the infant was exposed to multiple substances. Treatment of NAS includes non-pharmacological and pharmacological methods.

Abrupt discontinuation of opioid use during pregnancy can result in premature labor, fetal distress, and miscarriage. Medical withdrawal from opioids should be conducted under the supervision of physicians experienced in perinatal addiction (Kaltenbach, Berghella, & Finnegan, 1998). However, pregnant women who stop using opioids and subsequently relapse are at greater risk of overdose death. There is also an increased risk of harm to the fetus. Because NAS is treatable, medication-assisted treatment (MAT) is typically recommended instead of withdrawal or abstinence (Jones, O’Grady, Malfi, & Tuten, 2008).

¹ According to the U.S. National Library of Medicine, the term “infant” is used to describe a child from newborn to 1 year (<http://www.nlm.nih.gov/medlineplus/ency/article/002004.htm>), and the term “newborn” (neonate) is used to describe an infant who is 4 weeks old or younger (<http://www.nlm.nih.gov/medlineplus/ency/article/002271.htm>). For the purpose of this document, these definitions are applied.

² “What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?” Statement of Douglas C. Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives on May 1, 2015. <http://www.fda.gov/newsevents/testimony/ucm446076.htm>

The use of MAT during pregnancy is a recommended best practice for the care of pregnant women with opioid use disorders³ (American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, & American Society of Addiction Medicine, 2012). MAT is the use of medications in combination with counseling and behavioral therapies to provide a whole-patient approach to the treatment of substance use disorders (SAMHSA, 2014a). Research shows that a combination of medication and behavioral therapies is most successful for substance use disorder treatment. MAT is clinically driven and focuses on individualized patient care.

Medications used to treat opioid use disorders include methadone and buprenorphine. Both of these medications stop and prevent opioid withdrawal and reduce opioid cravings, allowing the person to focus on other aspects of recovery.

Like any medication given during pregnancy, the use of MAT in pregnant women has both risks and benefits to the mother and fetus. Therefore, MAT needs careful consideration by the pregnant women themselves as well as coordination by the providers and agencies that have influence and authority over this population of pregnant women and their infants.

To inform this guidance document, the National Center on Substance Abuse and Child Welfare (NCSACW), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration on Children and Families (ACF) formed a national panel of experts (listed in *Appendix 6: Additional Acknowledgments*). This panel identified the practice and policy considerations that each partner agency or organization needs to consider when working with, and on behalf of, pregnant women with opioid use disorders and their children. These experts met several times over six months in 2014.

Panel members agreed that building knowledge, skills, and expertise within the healthcare (including obstetrics, pediatrics, substance abuse treatment, and mental health), child welfare, and judicial systems and tribal communities will enable these entities to better deliver coordinated services to this population of pregnant women and their families. This guidance document is designed to assist these systems in improving their collaborative practice and to provide information about additional resources that will strengthen their capacity to provide coordinated, best-practice care and services.

The overarching message of this guide is that a coordinated, multi-system approach best serves the needs of pregnant women with opioid use disorders and their infants. Collaborative planning and implementation of services that reflect best practices for treating opioid use disorders during pregnancy are yielding promising results in communities across the country. Advance planning for the treatment of pregnant women with opioid use disorders that addresses safe care for mothers and their newborns can help prevent unexpected crises at the time of delivery. This guidance document provides background information on the treatment of pregnant women with opioid use disorders, summarizes key aspects of guidelines that have been adopted by professional organizations across many of the disciplines, presents a comprehensive framework to organize these efforts in communities, and provides a collaborative practice guide for community planning to improve outcomes for these families. A set of appendices provides details on implementing the recommendations in the guide as well as a summary of lessons from one community's experience over the past decade.

³The fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* ([DSM-5] American Psychiatric Association, 2013) uses the term "opioid use disorder" to include abuse of or dependence on opioids. Previous editions of the DSM differentiated between the two categories. The DSM-5 combines abuse and dependence into a single disorder, measured on a continuum from mild to severe.

Background

Opioid medications used to relieve pain are beneficial to many people but are often overprescribed.⁴ The overuse and misuse of these medications in the United States over the past decade has contributed to thousands of overdose deaths. According to the Centers for Disease Control and Prevention (CDC), from 1999 to 2010, yearly prescription opioid overdose deaths among women increased from 1,287 to 6,631 (CDC, 2013). These numbers represent a 400 percent increase over 10 years (see *Scope of the Problem* on page 5 for additional information). The use of heroin has also increased greatly over the last decade. Between 2007 and 2014, the numbers of past-year heroin initiates, heroin users, and people with heroin dependence has increased significantly (SAMHSA, 2015).

The use of MAT, in combination with counseling and behavioral therapies, and access to a range of supportive services, such as housing and employment services, assists the mother in achieving a more stable life (Newman & Kagen, 1973; Finnegan, 1991; CSAT, 2005). In turn, it also stabilizes the intrauterine environment and avoids subjecting the fetus to repeated episodes of withdrawal, which places the fetus at higher risk for morbidity and mortality (Kaltenbach & Finnegan, 1998; Jones et al., 2005; CSAT, 2005). According to the National Institute on Drug Abuse (NIDA):

“Methadone maintenance therapy (MMT) enhances an opioid-dependent woman’s chances for a trouble-free pregnancy and a healthy baby. Compared with continued opioid [use], MMT lowers her risk of developing infectious diseases, including hepatitis and HIV; of experiencing

pregnancy complications, including spontaneous abortion and miscarriages; and of having a child with challenges including low birth weight and neurobehavioral problems.

Along with these benefits, MMT may also produce a serious adverse effect. Like most drugs, methadone enters fetal circulation via the placenta. The fetus becomes dependent on the medication during gestation and typically experiences withdrawal when it separates from the placental circulation at birth. The symptoms of withdrawal, known as neonatal abstinence syndrome (NAS) include hypersensitivity and hyperirritability, tremors, vomiting, respiratory difficulties, poor sleep, and low-grade fevers. Newborns with NAS often require hospitalization and treatment, during which they receive medication (often morphine) in tapering doses to relieve their symptoms while their bodies adapt to becoming opioid-free.” (Whitten, 2012).

Methadone has been accepted as a treatment for opioid use disorders during pregnancy since the late 1970s (Kaltenbach & Finnegan, 1998; Kandall et al., 1999; CSAT, 2005). In 1998, a National Institutes of Health consensus panel recommended methadone maintenance as the standard of care for pregnant women with opioid use disorders (National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, 1998). However, the use of buprenorphine for the management of opioid use disorders is becoming more widely used, with the emergence of data from randomized clinical

⁴The Office of Disease Prevention and Health Promotion has developed Pathways to Safer Opioid Use, a training resource that uses the principles of health literacy and a multimodal, team-based approach to promote the appropriate, safe, and effective use of opioids to manage chronic pain. <http://www.health.gov/hcq/training.asp#pathways>

trials that demonstrate its safety and efficacy (Jones et al., 2005; Fischer et al., 2006; Jones et al., 2010). Between 2005 and 2008, A National Institute on Drug Abuse (NIDA)-supported clinical trial, the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study, examined the use of both methadone and buprenorphine maintenance therapy during pregnancy. Both medications are widely used to help individuals with opioid use disorders achieve stability and decrease illicit opioid use. The study also found that infants exposed to buprenorphine required shorter treatment duration and less medication to treat the symptoms of NAS and experienced shorter hospital stays when compared to infants exposed to methadone. No significant difference was found with respect to any serious maternal or neonatal adverse events (e.g., abnormal fetal health, neurological symptoms; Jones et al., 2010).

Methadone and buprenorphine are classified as Pregnancy Category C⁵ drugs by the FDA, meaning that adequate, well-controlled studies of how these drugs affect pregnant women are lacking. However, prescribing methadone or buprenorphine during pregnancy is not considered “off-label.” Choosing to proceed with methadone or buprenorphine treatment during pregnancy is an individual decision that women should make with their health care providers.

Another medication used to treat opioid use disorders is naltrexone. Naltrexone functions as a pure opioid blocker; however, withdrawal can be induced if naltrexone is administered to an individual who is engaged in current opioid use. Thus, induction to naltrexone requires detoxification and an opioid-free period, which may lead to relapse vulnerability, re-establishment of physical dependence, increased risk behaviors, treatment dropout, and possible opioid overdose and death. There is insufficient research to support the use of naltrexone during pregnancy. When

considering naltrexone use during pregnancy, the potential risk to the fetus should be given due consideration. Before research is conducted to determine the safety of naltrexone use during pregnancy, the benefits and risks must be carefully weighed (Jones, Chisolm, Jansson, & Terplan, 2013). Additional information on the use of methadone, buprenorphine, and naltrexone appears in *Appendix 4: Key Features of Medications Approved for Treating Opioid Use Disorders*. As more women using MAT during pregnancy give birth to newborns, the field is gaining knowledge about the typical withdrawal course that newborns experience, based on the types and doses of medications mothers are given to treat opioid use disorders as well as other aspects of their prenatal obstetrical care.

Some distinctions among women who use opioids during pregnancy are paramount to understand because of care coordination for both mothers and infants. Although women who use opioids during pregnancy test positive for opioid use at the birth of their newborn, the supports and system responses should differ depending on whether or not the mother’s opioid use is medically managed. Generally, women who use opioids during pregnancy and/or at delivery can be categorized within one of the following groups:

- Are receiving pain management with medications under the care of a physician.
- Are under the care of a physician and undergoing treatment for an opioid use disorder with medications, such as methadone or buprenorphine.
- Are misusing or abusing opioid pain medications with or without a prescription (e.g., obtaining pills illegally for a non-medical use, “doctor shopping,” obtaining a prescription illegally).
- Are using or abusing illicit opioids, particularly heroin.

⁵ In December 2014, the FDA published the Requirements for Pregnancy and Lactation Labeling Rule. The nomenclature is not used in the final rule, which requires the removal of the Pregnancy Categories A, B, C, D, and X from all human prescription drug and biological product labeling. Labeling is based on descriptive subsections for pregnancy exposure and risk, lactation, and effects to reproductive potential for females and males. Retrieved from <http://www.gpo.gov/fdsys/pkg/FR-2014-12-04/pdf/2014-28241.pdf> (accessed August 19, 2015).

Women with opioid use disorders often face a host of complex and entwined issues. Although they may come from all socioeconomic backgrounds, their lives are complicated by psychosocial and environmental factors. Often, there is a history of sexual abuse and/or interpersonal violence, inadequate social supports, unpredictable parenting models, poor nutrition, unstable housing, and co-occurring psychiatric conditions. Pregnant women with opioid use disorders are likely to use multiple substances during pregnancy, including tobacco and alcohol. Fetal Alcohol Spectrum Disorders (FASD) is a term used to describe the range of conditions, including physical, mental, and behavioral conditions as well as learning disabilities, that can be experienced by an individual prenatally exposed to alcohol.⁶ Infants prenatally exposed to multiple substances are at risk for developing a wide spectrum of physical, emotional, and developmental problems. Exposure to multiple substances can affect an infant's withdrawal symptoms. Other factors that can affect the infant's withdrawal symptoms include the type of opioid that the mother used, whether the mother's opioid use disorder was medically managed, and whether she received routine prenatal care. The hospital environment itself, such as the methodology used to treat the infant's withdrawal symptoms is also an important factor that can reduce or exacerbate the infant's withdrawal (see the section on *Neonatal Abstinence Syndrome* for additional information).

Scope of the Problem

Opioid Use Trends

Rates of prescription opioid pain medication use vary across regions of the country and among subpopulations. From 2000 through 2013, the rate of overdose deaths related to heroin increased across all regions—11-fold in

Growing concerns about the substantial increase in the number of pregnant women and newborns who test positive for opiates, coupled with the overwhelmingly inaccurate and alarmist reporting by the popular media regarding this issue, prompted more than 50 leading national and international researchers and experts to release an open letter to the media and policy makers in March 2013. In an effort to counter misinformation about pregnant women and prescription opioid use, these experts noted the following:

Newborn babies are NOT born “addicted” and referring to newborns with NAS as “addicted” is inaccurate, incorrect, and highly stigmatizing.

Portraying NAS babies as “victims” results in the vilification of their mothers, who are then viewed as perpetrators, and further perpetuates the criminalization of addiction.

Using pejorative labels such as “oxy babies,” “oxy tots,” “victims,” “tiny addict,” or “born addicted” places these children at substantial risk of stigma and discrimination and can lead to inappropriate child welfare interventions.

NAS is treatable and has not been associated with long-term adverse consequences.

Mischaracterizing MAT as harmful and unethical contradicts the efficacy of MAT and discourages the appropriate and federally recommended treatment for opioid use disorder.

— International Drug Policy Consortium, 2013

⁶ Resources for FASD include (1) the CDC website (<http://www.cdc.gov/ncbddd/fasd/facts.html>) and (2) the FASD Center for Excellence (<http://fasdcenter.samhsa.gov>).

the Midwest, more than 4-fold in the Northeast, more than 3-fold in the South, and doubled in the West (Hedegaard, Chen, & Warner, 2015). As the opioid crises emerged, by 2008 the states with the highest rates of opioid-related morbidity and mortality were concentrated in the Appalachian region (e.g., Kentucky, West Virginia, and Ohio) (Behavioral Health Coordinating Committee [BHCC], 2013). States vary a great deal in rates of: (1) non-medical use of opioid pain medications, (2) prescriptions for opioid pain medications, and (3) drug overdose deaths (Centers for Disease Control and Prevention, 2013). States with lower rates of non-medical use of and prescriptions for opioid pain medications also had lower rates of drug overdose deaths (Centers for Disease Control and Prevention, 2011).

Opioid use and related consequences also vary by several key demographics. For example, the Medicaid patient population is more likely to receive prescriptions for opioid pain medications and to have opioids prescribed at higher doses and for longer periods of time than the non-Medicaid patient population. Opioid medication overdose deaths are also more common among Medicaid-eligible populations (BHCC, 2013).

The overall rate of first time heroin use increased among all women, from 0.06 percent in 2002–2004 to 0.10 percent in 2009–2011, estimated to be an increase from 43,000 women to 77,000 women (SAMHSA, 2013). Among women, the number of overdose deaths due to the use of prescription opioid pain medications has increased significantly since 2007, surpassing deaths from motor vehicle-related injuries. Overdose deaths due to opioid medication increased among women more than 5-fold between 1999 and 2010, totaling 47,935 during that period (CDC, 2013).

From 1992 to 2012, treatment admissions for pregnant women among all female admissions remained stable at four percent. However, the proportion of pregnant women entering treatment who reported any prescription opioid misuse increased substantially from two percent in 1992 to 28 percent in 2012, an increase from 351 to 6,087 women. The

proportion of pregnant women who entered treatment and reported prescription opioids as their primary substance increased from one percent in 1992 to 19 percent in 2012, an increase from 124 to 4,268 women (Martin, Longinaker, & Terplan, 2014).

Neonatal Abstinence Syndrome

Among infants, the incidence of NAS increased from 1.20 per 1,000 hospital births in 2000 to 3.39 in 2009 (Patrick et al., 2012) and 5.80 in 2012 (Patrick, Davis, Lehmann & Cooper, 2015). In a study of 299 neonatal intensive care units (NICU) across the country, the rate of NICU admissions for infants with NAS increased from 7 cases per 1,000 admissions in 2004 to 27 cases per 1,000 admissions in 2013 (Tolia, Patrick, Bennett, Murthy, Sousa, Smith, Clark & Spitzer, 2015). The study by Patrick et al. (2012) did not distinguish between NAS that resulted from illicit opioids, prescription opioid pain medications, or MAT. Between 2006 and 2012, the rate of infant and maternal hospitalizations related to substance use increased substantially, from 5.1 to 8.7 per 1,000 infant hospitalizations and from 13.4 to 17.9 per 1,000 maternal hospitalizations, resulting in a total cost of \$944 million in 2012 (Fingar, Stocks, Weiss & Owens, 2015). In 2012, among the neonatal stays with a substance-related condition, approximately 60% were related to neonatal drug withdrawal or NAS. Among maternal stays related to substance abuse, almost one-fourth involved opioids (Finger et al., 2015).

As previously discussed, NAS is the term used to represent the pattern of effects that are associated with opioid withdrawal in newborns (Hudak & Tan, 2012). NAS symptoms are affected by a variety of factors, including the type of opioid the infant was exposed to, the point in gestation when the mother used the opioid, genetic factors, and exposure to multiple substances (Wachman, Hayes, Brown, Paul, Harvey-Wilkes, Terrin, Huggins, Aranda, & Davis, 2013). To assess the severity of the infant's symptoms, a scoring system,

such as the Finnegan Neonatal Abstinence Scoring System or the Lipsitz Neonatal Drug-Withdrawal Scoring System is used. The results of the scoring system are used in conjunction with an assessment of other factors, including the infant's gestational age, overall health, medical history, exposure to other substances, and tolerance or response to medications, to determine the course of treatment (Jansson, Velez, & Harrow, 2009).

Non-pharmacological treatment is the standard of care for the infant with NAS and should start at birth and continue throughout the infant's hospitalization and beyond (Velez & Jansson, 2008). Non-pharmacological treatment seeks to soothe the infant's symptoms, while also encouraging the mother-infant bond. Some of the symptoms associated with NAS can be challenging and disruptive to the attachment between the mother and infant, particularly for women who have substance use disorders and may have difficulty responding to an infant's cues. Non-pharmacological methods include rooming together post-delivery and modification of the environment to support attachment and provide a soothing environment for the infant. Environmental modifications include swaddling the infant and reducing his or her exposure to light and excessive noise.

Pharmacological treatment is primarily intended to relieve NAS symptoms and its associated complications, such as fever, weight loss, and seizures. Pharmacological treatment typically entails using a neonatal morphine solution or methadone (Hudak & Tan, 2012). Supports are necessary to address the challenges and risk factors that mothers and infants may face following discharge from the hospital. As previously described, women with opioid use disorders often face complex psychosocial, environmental, and cultural factors that can impact treatment, recovery, and parenting. Post-discharge supportive services can include identifying family or others for social support

Treatment considerations for newborns with prenatal substance exposure are available in a 2012 clinical report from the American Academy of Pediatrics. The Academy recommends that staff with training in identifying signs of withdrawal monitor these infants and initiate therapy when indicated.

“Each nursery that cares for infants with neonatal withdrawal should develop a protocol that defines indications and procedures for screening for maternal substance abuse. In addition, each nursery should develop and adhere to a standardized plan for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal.”

—Hudak & Tan, 2012

and participating in ongoing support groups, counseling, housing services, and follow-up services for the infant. See *Appendix 5: Children and Recovery Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study*, for information on post-discharge supportive services.

The advent of new medications used in treating opioid use disorders during pregnancy calls for additional studies on the long-term impact of prenatal exposure to opioids to better understand the best course of treatment for affected children (Wahlsten & Sarman, 2013; Hamilton, McGlone, MacKinnon, Russell, Bradnam, & Mactier, 2010; Farid, Dunlop, Tait, & Hulse, 2008).

Guidelines for Supporting Collaborative Policy and Practice

This guidance is intended to support the development of collaborative, interagency policies and practices that can assist communities to develop approaches that support the health, safety, well-being, and recovery of pregnant women with opioid use disorders and their infants. These approaches begin with prevention strategies designed to help all women of childbearing age, as well as their health care providers, to understand both the implications of opioid use during pregnancy and the interventions in the prenatal period that extend through—and ideally beyond—the postpartum time frame. This guidance highlights key decision points and recommended strategies based on the research literature as well as evidence from innovative strategies being implemented around the country.

Any response to the many barriers facing the families of pregnant women with opioid use disorders must be grounded in solutions within the community that reflect best practices (e.g., evidence-based practices) as well as perspectives, resources, and policies that address the needs of the community. A number of communities across the United States have developed collaborative initiatives to make systems and processes work more effectively for women with opioid use disorders and their infants. Although these approaches vary, they share a focus on coordinating the goals and efforts of an array of partners. In particular, efforts focus on effective screening and linkages to treatment in the prenatal period, as well as

efficient communication between hospitals and community partners. One of these well-developed initiatives is described in the case study in *Appendix 5: Children and Recovery Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study*.

Existing Guidelines

Research shows that a combination of medication and behavioral therapies is the most successful way to treat opioid use disorders and increases the likelihood of cessation of opioid abuse (CSAT, 2005). Similarly, the literature summarizing the most current research offers best-practice guidance for developing efficacious practices and policies for women with opioid use disorders and their infants.

Recommendations have been published in the last several years by national and international organizations, such as the American College of Obstetricians and Gynecologists (ACOG), World Health Organization (WHO), US HHS, SAMHSA, American Society of Addiction Medicine (ASAM), Legal Action Center, and American Academy of Pediatrics. Although this publication is not intended to provide an exhaustive literature review, some of the key recommendations from these organizations are cited throughout, and select highlights are presented in the section that follows. Links to these publications are provided in *Appendix 3: Training Needs and Resources*.

American College of Obstetricians and Gynecologists and American Society of Addiction Medicine

The following excerpt from the 2012 ACOG and ASAM Committee Opinion on Opioid Abuse, Dependence, and Addiction in Pregnancy summarizes the current knowledge of the risks and benefits of MAT for opioid use during the prenatal and postpartum period.

Opioid use in pregnancy is not uncommon, and the use of illicit opioids during pregnancy is associated with an increased risk of adverse outcomes. The current standard of care for pregnant women with opioid use disorders is referral for opioid-assisted therapy with methadone, but . . . evidence suggests that buprenorphine also should be considered. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use.⁷ Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. During the intrapartum and postpartum period, special considerations are needed for women who are opioid dependent to ensure appropriate pain management, to prevent postpartum relapse and a risk of overdose, and to ensure adequate contraception to prevent unintended pregnancies. Patient stabilization with opioid-assisted therapy is compatible with breastfeeding. Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioid agonists. All infants born to women who use opioids during pregnancy should be monitored for neonatal abstinence syndrome and be treated if indicated.

World Health Organization

The WHO's *Guidelines for the identification and management of substance use and substance use disorders in pregnancy* (2014) provide technical guidance primarily for health care professionals who work with women and their infants from conception to birth as well as during the postnatal period. The publication also offers guidelines on identifying and managing alcohol and other substance use in pregnant women,

with the goal of ensuring healthy outcomes for both pregnant women and their infants. While developing the recommendations, WHO established the following overarching principles to provide guidance in planning, implementing, and evaluating the most relevant recommendations, based on regional contexts and available resources.

PRIORITIZING PREVENTION. Preventing, reducing and ceasing the use of alcohol, tobacco and illicit drugs before and during pregnancy and in the postpartum period for breastfeeding mothers are essential for optimizing the health and well-being of women and their children. Ensure that women who are receiving opioid treatment for a medical condition understand the risks of prenatal exposure and have access to highly effective birth control methods.

ENSURING ACCESS TO PREVENTION AND TREATMENT SERVICES. All pregnant women and their families affected by substance use disorders should have access to affordable prevention and treatment services and interventions delivered with special attention to confidentiality, legal and human rights; women should not be excluded from accessing health care because of their substance use. Treatment, especially residential programs, for postpartum women should incorporate consideration for the infant and siblings.

RESPECTING PATIENT AUTONOMY. The autonomy of pregnant and breastfeeding women should always be respected; each woman with a substance use disorder needs to be fully informed

⁷The optimal methadone dosage for pregnant women generally increases throughout pregnancy, and this increase does not necessarily increase fetal exposure to methadone. See John Drozdick, III, et al., *Methadone Trough Levels in Pregnancy*, 187 *American Journal of Obstetrics and Gynecology*, 1184 (2002); John J. McCarthy, *Addiction Treatment Forum, Methadone Dosing During Pregnancy: Does Anyone Have a Clue?* (Oct. 2012).

about the risks and benefits, for herself and for her fetus or infant, of available treatment options, when making decisions about her health care and the care of her infant.

PROVIDING COMPREHENSIVE CARE. Services for pregnant and breastfeeding women with substance use disorders should have a level of comprehensiveness that matches the complexity and multifaceted nature of substance use disorders and their antecedents in this population.

SAFEGUARDING AGAINST DISCRIMINATION AND STIGMATIZATION. Interventions should be provided to pregnant and breastfeeding women in ways that prevent stigmatization, discrimination, criminalization, and marginalization of women seeking treatment to benefit themselves and their infants. Prevention and treatment should promote and facilitate family, community and social support as well as social inclusion by fostering strong links with available childcare, economic supports, education, housing, and relevant services.

In addition to these principles, WHO makes specific practice recommendations. One recommendation suggests that pregnant women should be advised to continue or begin opioid maintenance therapy with methadone or buprenorphine.

American Society of Addiction Medicine

ASAM's National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use (2015) provides information on evidence-based treatment of opioid use disorder, including guidelines for the treatment of pregnant women. The publication discusses recommendations on assessment and diagnosis, treatment, and the use of psychosocial treatment in conjunction with medications. ASAM's recommendations for the treatment of opioid use disorders in pregnant women include:

ASSESSMENT OF OPIOID USE DISORDER IN PREGNANT WOMEN. A comprehensive assessment, including medical examination and psychosocial assessment is recommended in evaluating opioid use disorder in pregnant women. The clinician should ask questions in a direct and nonjudgmental manner to elicit a detailed and accurate history.

OPIOID AGONIST TREATMENT IN PREGNANCY.

Decisions to use opioid agonist medications in pregnant women with opioid use disorder revolve around balancing the risks and benefits to maternal and infant health. Opioid agonist treatment is thought to have minimal long-term impacts on children relative to harms resulting from maternal use of heroin and prescription opioids. Therefore, women with opioid use disorder who are not in treatment should be encouraged to start opioid agonist treatment with methadone or buprenorphine monotherapy (without naloxone) as early in the pregnancy as possible. Pregnancy in women with opioid use disorder should be co-managed by an obstetrician and an addiction specialist physician.

OPIOID AGONISTS VERSUS WITHDRAWAL MANAGEMENT.

Pregnant women who are physically dependent on opioids should receive treatment using agonist medications rather than withdrawal management or abstinence as these approaches may pose a risk to the fetus. Furthermore, withdrawal management has been found to be inferior in effectiveness over pharmacotherapy with opioid agonists and increases the risk of relapse without fetal or maternal benefit.

INDUCTION AND DOSING OF OPIOID

AGONISTS. Treatment with methadone should be initiated as early as possible during pregnancy.

BREASTFEEDING. Mothers receiving methadone and buprenorphine monoprodukt for the treatment of opioid use disorders should be encouraged to breastfeed.

In addition to these aforementioned organizations, state and local jurisdictions have developed guidelines for hospitals, child welfare agencies, treatment providers, and other care providers regarding MAT, NAS treatment, and responses to pregnant women with opioid dependency. These guidelines may help ensure a more consistent approach among communities within a given state or region. Addressing disparities in treatment related to resource shortages and geographic and financial barriers to accessing health care and other services is another vital consideration in meeting the needs of pregnant women with opioid use disorders.

One example of a regional approach that incorporates best practice guidelines is the CHARM Collaborative in Burlington, Vermont—a multidisciplinary group of agencies serving women with opioid use disorders and their families during pregnancy and through infancy. The CHARM Collaborative focuses on meeting the needs of pregnant and postpartum women who have a history of opioid use and their infants. This group emerged in the late 1990s in response to the increasing need for MAT resources for pregnant women with opioid use disorders. Today, the CHARM Collaborative includes 11 organizations that collectively provide this population of women with coordinated comprehensive care from child welfare, medical (including obstetrics and pediatrics) and substance abuse treatment professionals across Vermont. Their efforts have ensured that the vast majority of pregnant women are identified and provided treatment during the prenatal period. They jointly develop plans for the infant and family's safety and

well-being prior to the baby's birth. Additional information on the approach and practices of the CHARM Collaborative is provided in *Appendix 5: Children and Recovery Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study.*

Need for Collaboration Among Multiple Agencies

Professionals in the child welfare, judicial, medical (including obstetrics, pediatrics, substance abuse treatment, and mental health), and addiction treatment systems generally share significant concerns about pregnant women who misuse opioids and newborns with NAS and other problems related to in utero drug or alcohol exposure. However, this is often where the consensus ends. At times, the responses of various systems to the needs of these families diverge, resulting in apparent conflicts among treatment practices, medical recommendations, and the policies and oversight provided by courts and child welfare services.

The types of agencies and professionals that provide treatment and other services to pregnant women with opioid use disorders and their infants can vary widely from one community to another. A considerable range and mix of approaches, settings, programs, and professionals can be involved, and health and social service systems typically operate and intersect in ways that are unique to each community. This mixture of participating systems and relationships among them affects service coordination. For example, several different professionals and specialty providers within the medical care system (i.e., an obstetrician, neonatologist, pediatrician, and addiction specialist) might provide care to a woman and her infant during the prenatal and postpartum periods. Within the substance abuse treatment system, treatment is delivered in a variety of settings (e.g., residential facilities, outpatient clinics, and offices of physicians who provide MAT), using a combination of therapeutic approaches (e.g., medications, individual and group counseling, and self-help groups). In the child welfare system, services are delivered along a continuum, based on risk

and safety factors that range from supports to children remaining in the custody of their parents (often referred to as in-home services) to out-of-home care (e.g., foster or kinship care).

Different systems and provider communities also have different policies, priorities, and perspectives. For example, hospitals—even those in the same state or county—often have inconsistent protocols for screening infants for prenatal substance exposure and sometimes have seemingly inconsistent practices for contacting child welfare agencies if substance use is detected or NAS is diagnosed. Even when hospitals have clear policies in place, adherence to these policies depends largely on the relationships between hospital staff and child welfare workers. Adherence to policies also varies by medical team members' perceptions

“Medication-Assisted Treatment (MAT) is an evidence-based practice that combines pharmacological interventions with substance abuse counseling and social support. Although not for everyone, it is an essential part of the comprehensive array of services available to people struggling with addiction to alcohol or other drugs.

A paradox in our field is that although we recognize addiction as a chronic, relapsing disease, some substance abuse counselors and administrators have been reluctant to embrace new technologies for its treatment. At the same time, most physicians and other health care professionals receive little or no training in the treatment of addiction. As a result, adoption of MAT has been slow in some areas.”

**— Mark G. Stringer, Director
Missouri Department of Health,
Division of Behavioral Health**

of whether a positive toxicology screen for the newborn is likely to trigger legal consequences for the mother, which may be perceived to not be in the best interest of the mother and infant (National Abandoned Infants Assistance Resource Center, 2012).

The fact that many non-medical professionals can potentially affect treatment decisions for pregnant women with opioid use disorders further exacerbates the care of women and their infants. These professionals may include judges (if the woman is involved in the criminal justice system) or residential substance abuse treatment providers that do not offer MAT. If a woman is already involved in the child welfare system as a result of a case related to her older children, child welfare social workers and judicial representatives related to this separate case also influence decisions regarding her care, and these decisions might not be consistent with her treatment plan or best practice recommendations. If a woman is receiving MAT in an opioid treatment program (OTP) or buprenorphine from her doctor, she is likely to experience conflict if she also participates in a substance abuse treatment program or a mutual aid support group that does not embrace the use of MAT. It is essential to recognize that each mutual aid support group is autonomous and self-directed; and group members may have their own views on the use of MAT. Despite this potential conflict, each professional and the organizations or systems that they represent are responding to the directives issued from their respective fields of practice. If no such directives exist, they must rely on their best professional judgment when making critical decisions that affect women and their infants and that have the potential to impact entire families.

Every professional involved needs to understand the different contexts of opioid use by a pregnant woman to accurately assess her distinct needs and those of her family members in order to implement the most appropriate and comprehensive plan of care. In addition to being familiar with effective and evidence-based addiction treatment, treatment counselors, social workers, health care

providers, and legal system professionals need to be aware of the primary risk and protective factors that promote or inhibit resiliency in women and their children. These factors have a direct impact on the types and intensities of support and supervision that a woman requires throughout pregnancy as well as during the critical first year of parenting a newborn.

For example, child welfare agencies have the complicated dual role of supporting families while monitoring them to prevent child maltreatment. These agencies have risk and safety assessment policies and practices that are intended to identify immediate safety concerns

for children, while evaluating the risk and protective factors of each family. When making decisions about whether to intervene and how to do so in the most supportive manner, staff must take into account the distinctions related to a woman's history, motivation, and pattern of opioid use (and other drug use).

The Child Abuse and Prevention Treatment Act (CAPTA) Reauthorization Act of 2010 require states to have policies and procedures for hospitals to notify child protective services (CPS) of all children born who are affected by illegal substance use or withdrawal symptoms resulting from prenatal drug exposure or

The privacy provisions in the U.S. Code of Federal Regulations (C.F.R.), Title 42, Part 2, describe the limited circumstances in which information about a patient's treatment for a substance use disorder may be disclosed with and without the patient's consent. The regulations are available at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=b7e8d29be4a2b815c404988e29c06a3e&rqn=div5&view=text&node=42:1.0.1.1.2&idno=42>

42 C.F.R. 2 applies to all clinicians who use a controlled substance (i.e., methadone and buprenorphine) for detoxification or maintenance treatment of a substance use disorder. Such physicians must register with the federal Drug Enforcement Agency (DEA), and their DEA license, along with representations concerning their status as opioid treatment providers, makes them subject to the regulations.

With limited exceptions, 42 C.F.R. 2 requires patient consent for disclosures of protected health information, even for the purposes of treatment, payment, or health care operations. Consent for disclosure must be in writing.

42 C.F.R. 2 does not apply to information on substance use treatment maintained in connection with the Veterans' Administration or the Armed Forces (42 CFR § 2.12 (c)).

Most substance-abuse treatment programs are also subject to the Health Insurance Portability and Accountability Act of 1996 Privacy Rule. In 2004, SAMHSA issued a guidance document that summarizes the differences between the two rules and implementation solutions, which is available at <http://www.samhsa.gov/sites/default/files/part2-hipaa-comparison2004.pdf>

Frequently asked questions (FAQs) about substance abuse confidentiality regulations are available on the SAMHSA website. The FAQs include information on exceptions to 42 C.F.R. 2 (e.g. medical emergencies) and guidance on which entities or individuals are subject to the regulations. <http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs>

indications of FASD (CAPTA, 2010). CAPTA requires CPS agencies to develop a plan of safe care for every such infant referred to their agency and address the health and substance use disorder treatment needs of the infant. The 2016 Title V, *Section 503, "Infant Plan of Safe Care"* of S. 524, "Comprehensive Addiction and Recovery Act of 2016" requires the plan of safe care to also address the treatment needs of affected family or caregivers and requires states to develop a monitoring system to determine whether and how the local entities are providing referrals to and delivery of appropriate services for the infant and affected family or caregiver. The Comprehensive Addiction and Recovery Act of 2016 was signed into law on July 22, 2016. CAPTA also requires that all children who are younger than three years who are substantiated victims of child maltreatment are referred to early intervention agencies that provide developmental disabilities services (Office on Child Abuse and Neglect, 2003). However, state, tribal, and local agency policies determine how newborns with prenatal substance exposure are identified, whether notice to CPS constitutes a report alleging child abuse or neglect, and the level and type of proof needed to warrant further investigation (Young et al., 2009). For these reasons, CPS agencies handle referrals of infants with prenatal substance exposure in ways that vary greatly by state and community. A February 2015 analysis by the Guttmacher Institute showed that four states require health care professionals to test newborns for prenatal drug exposure when drug use is suspected, while 15 states require providers to report women to CPS for suspected drug use during pregnancy (Guttmacher Institute, 2015). Different CPS agencies also make very different decisions regarding whether an infant remains in the custody of the mother. These decisions determine how infants are evaluated for early intervention service needs and whether they receive these services when needed. These inconsistencies in policy and practice result in differing approaches across communities to identify pregnant women in need of treatment and different responses for the infant's care and safety considerations.

In addition to these practice and policy concerns, there are often knowledge gaps about the risk and safety of a newborn who tests positive for opioids. For example, professionals need to understand distinctions in risk and safety between infants exposed to opioids as a result of the mother's opioid use or misuse versus infants exposed to opioids as a result of the mother's treatment for opioid dependency with medications under a doctor's care. In addition, in the well-meaning effort to maintain child safety, child welfare agencies may establish uninformed requirements on minimal dosing of MAT medications or withdrawal from MAT for women as a condition for keeping custody of their newborns⁸ and may use a positive toxicology result for methadone or buprenorphine at birth as a presumptive cause for child removal.

These decisions often have negative and sometimes irrevocable consequences for families, including interference with the critical mother–infant attachment process. In addition, many Family Treatment Drug Courts (FTDCs) around the country treat a woman's use of MAT as a criterion for excluding her from participating in or graduating from the program until she is no longer taking medications. The National Association of Drug Court Professionals (NADCP) resolved that drug courts should not impose blanket prohibitions against the use of MAT for their participants and further suggests that drug courts attain reliable expert consultation on the appropriate use of MAT for their participants, including partnering with substance abuse treatment programs (NADCP, 2013). In addition, recognizing that MAT may be an essential part of a comprehensive treatment plan, SAMHSA Treatment Drug Court grantees were encouraged, beginning in 2015, to use a percentage of the annual grant award to pay for FDA-approved medications.

State laws vary regarding legislation on the use of substances during pregnancy. The variance includes whether there is criminal prosecution or if substance use is considered maltreatment and grounds for termination of parental rights under civil statutes. The 2013 National Drug Control Strategy states that criminal justice professionals should include the use of MAT

⁸ Minimal dosing may in fact *increase* the likelihood of relapse as well as *increase* risks to both the mother and infant. Important health issues are associated with proper dosing. (Kaltenbach et al., 1998)

as appropriate treatment for an opioid use disorder for those individuals involved in the judicial system (Office of National Drug Control Policy, 2013). The previously described analysis by the Guttmacher Institute showed that one state allows assault charges to be filed against pregnant women who use certain substances and that 18 states consider evidence of substance use during pregnancy (often only evidence of use and not a diagnosis of dependency or addiction or findings of harm) to indicate child abuse and provide grounds for termination of parental rights (Guttmacher

Institute, 2015). On the other hand, some states have begun to implement Safe Harbor legislation to facilitate access to treatment for pregnant women. Safe Harbor laws provide a provision in a law or agreement that protects against liability or penalty as long as set conditions have been met. Two states have implemented or introduced Safe Harbor laws in which pregnant women who seek treatment for opioid and other substance use disorders, in the absence of other risk or safety factors, will not have to fear risking loss of custody of their infant or termination of parental rights.

As amended in 2010, the Child Abuse Prevention and Treatment Act (CAPTA) requires states to include the following in their state plans.

An assurance in the form of a certification by the Governor of the State that the State has in effect and is enforcing a State law, or has in effect and is operating a statewide program relating to child abuse and neglect that includes:

A) policies and procedures (including appropriate referrals to child protection service systems and for other appropriate services) to address the needs of infants born with and identified as being affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, or a Fetal Alcohol Spectrum Disorder, including a requirement that health care providers involved in the delivery or care of such infants notify the child protective services system of the occurrence of such condition in such infants, except that such notification shall not be construed to: (I) establish a definition under Federal law of what constitutes child abuse or neglect; or (II) require prosecution for any illegal action;

B) the development of a plan of safe care for the infant born and identified as being affected by illegal substance abuse or withdrawal symptoms, or a Fetal Alcohol

Spectrum Disorder.

The CAPTA Reauthorization Act of 2010 is available at: <http://www.gpo.gov/fdsys/pkg/BILLS-111s3817enr/pdf/BILLS-111s3817enr.pdf>

— Section 106(b)(2)(B)(ii-iii) of the Child Abuse Prevention and Treatment Act [42 U.S.C. 5106a(b)(2)(B)(ii-iii)]

Title V, Section 503, “Infant Plan of Safe Care,” of S. 524, “Comprehensive Addiction and Recovery Act of 2016” was signed into law on July 22, 2016. The bill amends CAPTA to address the health and substance use disorder treatment needs of the infant and affected family or caregiver; and to ensure the development and implementation by the State of monitoring systems regarding the implementation of plans to determine whether and in what manner local entities are providing, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver.

The 2016 changes also provide monitoring and oversight changes for HHS.

The Comprehensive Addiction and Recovery Act of 2016 is available at: <https://www.congress.gov/bill/114th-congress/senate-bill/524>

The various configurations and approaches in each discipline can exacerbate the challenges in coordinating services among providers, agencies, and organizations. The many differences that exist need to be reconciled to facilitate a coordinated cross-disciplinary approach. The purpose of this document is to assist communities in assessing their current practice and to develop practice and policy improvements to better meet the needs of these families.

Comprehensive Framework for Intervention

As discussed in the previous section, many professionals may be involved in decisions related to the treatment, care, and supervision of pregnant women with opioid use disorders. These decision makers might include health care providers, substance abuse treatment providers, child welfare workers, and judicial system representatives (e.g., judges, parents' lawyers, and children's lawyers or advocates). Each of these professionals and the systems they represent are responding to directives that stem from a combination of federal regulations, state legislation, ethics, and system-specific guidelines.

Ideally, these directives are aligned to ensure the best possible outcomes for both mothers and infants. Unfortunately, however, this is not usually the case, particularly when state laws or agency policies are silent on or conflict with best practices, or are driven by misinformation. When directives are unclear, conflicting, or missing, workers must rely on their professional judgment to determine the best approach and course of action.

Without proper training and knowledge about best practices, professionals might

not serve the best interests of mothers, children, and families. To surmount this risk, professionals must establish mechanisms for working together across systems, agencies, and providers to develop a coordinated and cohesive approach. Such an approach has the highest likelihood of achieving successful outcomes related to maternal and child health, newborn care, mother–infant attachment, positive parenting practices, child safety, and family well-being.

Strategies to help are typically most effective when designed to address needs beyond substance abuse treatment, such as for co-occurring mental health issues, trauma, housing, child care, employment, parenting, and a range of other personal supports. A family-centered and gender-responsive approach addresses many of these needs in a culturally responsive⁹ manner (Werner, Young, Dennis, & Amatetti, 2007; King, Duan, & Amaro, 2014). When states, tribes, and communities recognize the positive and often cost-effective impact of a collaborative approach, public agencies and private providers have a powerful incentive to work together in alternative and innovative ways.

Overview of Substance-Exposed Infants (SEI) Framework

This guidance leverages and is informed by the five-point intervention framework developed by the NCSACW and funded by SAMHSA and the Administration on Children, Youth, and Families. This framework, which was the organizing foundation for the SAMHSA report *Substance-Exposed Infants: State Responses to the Problem*, serves as a comprehensive model that identifies five major time frames when intervention in the life of an infant can help reduce the potential harm of prenatal substance exposure (Young et al., 2009).

⁹ For more information on cultural competence, see SAMHSA's Treatment Improvement Protocol (TIP) 59 – *Improving Cultural Competence* (<http://store.samhsa.gov/shin/content//SMA14-4849/SMA14-4849.pdf>).

The five points of intervention are:

1. Pre-pregnancy: During this time, interventions can include promoting awareness among women of child-bearing age and their family members of the effects that prenatal substance use can have on infants.
2. Prenatal: During this time, health care providers have the opportunity to screen pregnant women for substance use as part of routine prenatal care and to make referrals that facilitate access to treatment and related services for the women who need these services.
3. Birth: Interventions during this time include health care providers testing newborns for prenatal substance exposure at the time of delivery.
4. Neonatal: During this time, health care providers can conduct a developmental assessment of the newborn and ensure access to services for the newborn as well as the family.
5. Throughout childhood and adolescence: During this time, interventions include the ongoing provision of coordinated services for both child and family.

The framework also illustrates the following key issues:

- The birth event is only one of several opportunities to affect outcomes. Therefore, it is important to understand the extent of those opportunities and which interventions are most needed and most likely to be effective at each point in time.
- Cross-system linkages are necessary to ensure services are coordinated across the spectrum of prevention, intervention, and treatment.

The NCSACW's five-point framework emerged from a multi-year review and analysis of existing policies and practices in 10 states regarding prenatal exposure to alcohol and other drugs. This effort was designed to help state, tribal, and local governments to identify opportunities for strengthening interagency efforts that address prevention, intervention, identification, and treatment of complications

ACOG's 2015 legislative priorities include promoting public health efforts to reduce maternal opioid dependence and NAS as well as opposing punitive legislation against women with opioid dependence whose babies are born with NAS (ACOG, 2015).

related to prenatal substance exposure. The framework focuses on immediate and ongoing services for infants, mothers, and families. The NCSACW reviewed states' policies regarding:

- Pre-pregnancy efforts to engage women with substance use disorders in treatment to prevent prenatal substance exposure in the women's future infants.
- Screening and assessment during pregnancy to ensure that women have access to treatment and needed supports.
- Health care, supportive services at birth, and notification of CPS when infants are identified as having been prenatally affected by illegal substances, as consistent with CAPTA.
- Services to infants with prenatal substance exposure or infants who require care (along with their parents and siblings) during the neonatal period.
- Ongoing coordinated services for this population of children and their families throughout childhood and adolescence (Young et al., 2009).

This review showed a wide variation in state policies and practices related to meeting the needs of infants with prenatal substance exposure, thus highlighting the need for guidance based on best practices and current literature in the field. This guidance also needs to provide recommendations that can be adapted and customized to benefit women and children within the context of each community's unique mix of resources, challenges, and perspectives.

Compared to efforts by individual agencies and systems, collaboration across multiple agencies and systems, coupled with strong leadership and consistent communication, offers a more effective approach, a more efficient way of doing business, and ultimately leads to better outcomes.

This five-point intervention framework highlights opportunities for cross-system collaboration and policy development at each critical point in time, from pre-pregnancy throughout an infant's early years. The framework also integrates recommendations for best practices related to outreach, engagement, treatment, and support for mothers and their infants along the five-point continuum. The framework shows that no single system has the necessary resources, information, or influence needed to adequately serve this vulnerable mother–infant dyad and other involved family members who are likely to need services. All those who have a role in improving outcomes for such families need to collaborate in order to put the necessary policies and practices in place. These collaborations can set the stage for maternal recovery from substance use disorders, child safety, and the well-being of all those involved.

A Guide for Collaborative Planning

The opportunity for practice and policy improvement exists largely because so many different agencies, organizations, and providers have a legal or professional responsibility to act or address the needs of pregnant women with opioid use disorders and their infants. Without a comprehensive coordinated response that includes child welfare and healthcare, including obstetrics, pediatrics, substance abuse

treatment, and mental health professionals, families are not well served. Cross-system initiatives lead to better results by facilitating better communication, clearly defining the roles of the various professionals who serve these families, and maximizing the resources of multiple stakeholders who have a vested interest in accomplishing shared goals.

Efforts that specify the roles and responsibilities of each partner help ensure that efforts from multiple systems to support individuals, families, and communities have a stronger cumulative impact and are sustained over time to address the full range of practice and policy considerations (Young, Nakashian, Yeh, & Amatetti, 2006). However, collaborative practice can be difficult to establish and implement for a number of reasons, including competing priorities, rules in agencies or organizations that conflict with the approaches of others, lack of leadership, confusion about roles, unmet training needs, use of different terminologies, limits on time and resources, information gaps, and mistrust. Communities are often unprepared to provide services to the large number of pregnant women who misuse prescription medications and heroin, and these agencies have not yet organized a coordinated response. In other communities, all of the involved parties might not know the rules, regulations, and practice standards that operate in the various systems. In fact, partner agencies often need to understand what services are available and who the providers are in each system.

To understand the array of local services and overcome the barriers to coordinating services to meet the needs of this population of pregnant woman and their infants, prospective collaborative partners from each of the primary systems of health care, substance abuse treatment, mental health, child welfare, and dependency and Family Drug Courts need to know what questions to ask when they begin their joint planning. These questions must be identified regardless of whether the potential partners' intent is to initiate, expand, or truly integrate their services and systems.

Building the Collaborative Team¹⁰

To build and foster cross-system collaboration, building an effective coordinating team is of paramount importance. This section presents a description of a collaborative team. Ideally, collaborative teams include a steering committee, a core team, and work groups.

The Collaborative Team

Preferably, the state, tribe, or local government creates the collaborative team and endows it with the capacity and resources needed to support and sustain its major initiatives. A well-designed collaborative team can support the plans set in motion and ensure goals are met, especially if the team convenes on a regular and predictable basis and keeps its focus on systems change, improved outcomes, and sustainability.

One way to organize the team is as follows:

- **Steering Committee**—This committee oversees and designates the members of the core team (defined below); facilitates necessary cabinet, council, commission, and legislative policy changes;¹¹ and works to remove system barriers. The committee consists of multidisciplinary top executives, directors, and leaders across each of the collaborating entities. Participation and presence of key decision makers will increase the efficiency and effectiveness of the meetings.

TIP: *Keep steering committee leaders engaged by informing members of the collaborative team's progress so that they are prepared to pave the way for necessary change.*

- **Facilitator**—Guides the team in decision making. The facilitator role can be fulfilled by bringing in an outside facilitator, appointing representatives from the different systems to conjointly fulfill the role, or appointing representatives from the different systems to rotate in the facilitator role. These strategies can help the systems share responsibility, while also avoiding the perception that the initiative is being “run” by one agency. Having system representatives fulfill the facilitator role requires the representative to be aware and understand his or her multiple and potentially conflicting roles. In the facilitator role, system representatives must diligently maintain the distinction between their role as the facilitator and as the system representative. When the boundaries of these roles are delineated and respected, others will be more inclined to trust and respect the boundaries as well. Ideally, the facilitator role, or the various configurations that can fulfill the facilitator role, requires familiarity with the subject matter and how the systems operate (Pennsylvania State University, 2015).

TIP: *Facilitate decision making among multiple systems by appointing a formal facilitator. Facilitating a multidisciplinary team requires skills that differ from those required to direct single-agency work groups; stakeholders from different disciplines do not have jurisdiction over each other, and decision making by decree or majority rule will not work in these situations.*

- **Core Team**—Responsible for implementing policy changes at each organization. The core team is multidisciplinary and consists of mid-management representatives from each

¹⁰ For more information on developing a collaborative team and structure, see Screening and Assessment for Family Engagement, Retention, and Recovery (SAFERR) <https://www.ncsacw.samhsa.gov/resources/SAFERR.aspx>

¹¹ If using federal funding, these actions must be taken in compliance with Section 503(b) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2016 (S. 1695). Section 503(b) provides that no federal funds from the HHS annual appropriations act may be used to pay the “salary or expenses of any grant or contract recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.” <https://www.congress.gov/bill/114th-congress/senate-bill/1695>

collaborating entity in addition to consumers, advocates, and representatives of other organizations, as appropriate.

TIP: *Include no more than six to eight individuals in the core team. Core Team members should have sufficient authority and flexibility to approve agency-level practice and policy changes to sustain the collaborative team's momentum by achieving "quick wins."*

- **Work Groups**—Created by the steering committee to address priorities of the collaborative initiative. Work groups include members of the core team and additional key stakeholders, such as providers and practitioners, consumers and advocates.

TIP: *Give your work groups specific challenges they can address by using first-hand knowledge from key stakeholders regarding effective tools and strategies, such as devising a communication protocol.*

This type of structure can be used at the state, tribal, and local levels. At the local level, for example, the health department might convene the collaborative team. Ideally, all of these entities work closely together to accomplish jointly identified goals and shared priorities for improving practice and policy.

This structure helps ensure:

- Sustainability of the initiative through the authority and endorsement of the steering committee;
- Communication through accountability in the hierarchical and peer-to-peer relationships of the core team;
- Regional broad-level buy-in through the participation and investment of the diverse stakeholders who make up the work groups; and
- Internally supported change through the investment and commitment of multiple systems to achieve collaboratively defined outcomes.

Cross-system teams must consider several steps as they prepare to engage in collaborative planning. These steps, (1) setting the stage for collaboration, (2) engage key stakeholders and establish work groups, (3) define shared goals, and (4) identify strategies and jointly monitor outcomes, are discussed below. Questions are posed to guide the purpose and outcome of each step. *Appendix 1: Facilitators Guide* includes a facilitator's guide and a set of tools to help the development of a work plan, based on prioritization of identified goals. The tools include a Cross-System Guide, to develop a baseline understanding of areas of strength and opportunities for improvement, and five System-Specific Guides, to understand the context of the initiative from multiple points of view. For instance, each system's perspective of the "primary" client (e.g., mother, infant, or family) differs. The identified "primary" client often drives the system's response and goal. For example, the MAT provider may consider the mother as the primary client, with interventions targeted solely at her. In comparison, the infant's neonatologist or pediatrician may identify the infant as the primary client. Although each service provider must provide services within their scope of practice, understanding the impact of opioid use disorders on the mother and infant as well as what services and supports are needed for optimal outcomes requires a mutual understanding of the involved systems. The guides can provide the necessary background for teams before making decisions about—and committing valuable resources to—statewide practice and policy changes.

STEP 1: Setting the Stage for Collaboration

Once the core team has been formed, some general fact gathering and sharing by all team members is necessary so that each member understands:

- What practices and policies are in place in each team member's service system and in the other service systems;
- Partner mandates and priorities that are likely to affect, and possibly limit, their level of involvement;

- The terminology that each team member’s organization uses most frequently and how the organizations define these terms (e.g., “treatment”);
- The baseline resources, resource gaps, and barriers in each system; and
- What needs to be addressed and improved, particularly from the perspective of mothers, children, and family members, to provide the necessary care.

STEP 2: Engage Key Stakeholders and Establish Work Groups

To determine which partners should be involved in the initiative, an assessment of the current level of collaboration is helpful. Questions to answer include: Who is currently working on the issue being tackled? What does each of these individuals or organizations contribute? And, significantly, which key stakeholders are missing from the conversation?

Core team members on the collaborative team should, at a minimum, include child welfare professionals, key dependency court and family drug court professionals, mental health providers, Medicaid officials, and healthcare providers. Healthcare providers include office- and hospital-based obstetricians, pediatricians, neonatologists, primary care providers, hospitalists, medical social workers, and opioid treatment and other substance abuse treatment providers (including residential, intensive outpatient, and outpatient treatment providers).^{12, 13} Other stakeholders, including lead staff from agencies such as Temporary Assistance for Needy Families, maternal and child health agencies, and housing authorities, may also play key roles in the collaborative team.

Other potential participants include organizations that are unique to the community and provide

services for this population of families, such as women’s or children’s health resource centers; early child intervention organizations; and clinical, financial, or legal resource centers as well as representation from tribes in communities with American Indian populations and/or tribal leadership. Finally, it is critical to ensure that pregnant women or mothers representing the target population have a voice in the process and are active participants in planning, informing, communicating, and collaborating.

Key stakeholder participation in the collaborative team is likely to be determined by existing partnerships and whether the overall effort is intended to provide new services, expand existing services, or increase levels of service integration across systems.

STEP 3: Define Shared Goals

Every state, tribe, and community is supported and challenged by its own systems, issues, beliefs, and ideals. On occasion, the existing protocols, culture, and financial constraints may affect the collaborative team’s ability to be successful in coordinating their approach and share accountability for the outcomes. Therefore, each team member needs to evaluate how their system-specific and individual principles and values will lead practice and policy change and understand the perspectives that are influencing the positions and decisions of the other partners.

To create principles for their work together, the team should collectively examine and discuss fundamental questions, such as:

- What is each represented agency’s role in achieving shared priorities and outcomes (e.g., How does child welfare services support parent recovery? How do treatment providers for parents support child safety and permanency and family well-being?)

¹²Dependency courts refer to courts that handle dependency cases involving children and youth under 18, including child maltreatment (see <https://www.childwelfare.gov/pubPDFs/cwandcourts.pdf>).

¹³Family Drug Courts (also referred to as Family Dependency Treatment Courts, Family Treatment Courts, Dependency Drug Courts, and Family Treatment Drug Courts) use a multidisciplinary approach, recognizing that their clients (i.e., parents, children, and families who enter the Family Drug Court) often face a range of challenges in addition to a substance use disorder (see <http://www.cffutures.org/files/publications/FDC-Guidelines.pdf>).

- What does each team member believe about the nature of substance use and substance use disorders?
- Do team members agree on the markers of effective practice and service delivery? What are those markers?
- How is “best interest” defined for infants? For mothers? For families? Do mothers have sufficient input in determining this?
- What do team members or policy leaders believe about the use of MAT for women who are pregnant or breastfeeding?
- What do team members believe constitutes recovery?

STEP 4: Identify Strategies and Jointly Monitor Outcomes

A crucial component of developing a coordinated response is the ongoing transfer of knowledge across professionals, agencies, and organizations. This knowledge transfer enables the team to establish and maintain a shared understanding of evidence-based practices for pregnant women with opioid use disorders and their infants from a multi-system perspective. To facilitate this knowledge transfer, the team needs to:

- Review the desired outcomes for each system by, for example, determining how success is defined and measured, identifying baseline levels for clients, and finding out whether better (or additional) indicators are available to demonstrate progress. For example, hospitals may be focused on positive birth outcomes, child welfare focused on child safety, and substance use disorder treatment agencies may be focused on measures of recovery.
- Determine the metrics (e.g., number of pregnant women treated with MAT) that need to be developed and tracked to effectively measure success over time. This can include assessing what technology is available to track outcomes. Recent developments, such as electronic health records and Health Information Exchanges, can help facilitate communication across systems and, ultimately, be an avenue to measure outcomes.

- Create a method for communicating progress related to key indicators (e.g., a report card or dashboard) to ensure transparency and promote accountability for results.
- Review the plan for sustaining change and determine, for example, how the team will document, maintain, and build on the collaboration’s institutional knowledge.

To facilitate the development of a work plan that addresses the needs of pregnant women with opioid use disorders and their infants, see *Appendix 1: Facilitator’s Guide* for the tools.

Concluding Thoughts

This report provides practical, evidence-informed guidance to help collaborative, cross-disciplinary teams support effective, healthy outcomes for pregnant women with opioid use disorders and their infants. This guide underscores the potential impact of opioid use during pregnancy and the importance of a systems-level approach that is driven and endorsed by state and tribe leadership to mobilize resources and facilitate cross-system practice and policy changes. It also provides a framework for communities to take stock of their current policies and identify areas for improvement. It is the view of the national panel of experts that informed this guide that top-down approaches that do not include the views of local practitioners, other professionals, and families will likely lead to resistance and uneven implementation. For collaborative practices to be successful, all parties involved must witness and experience the benefits.

It is beyond the scope of this guidance to adequately address the entire range of topics related to pregnant women with opioid use disorders and their families; however, it is important to highlight some additional focus areas that states, tribes, and communities might want to factor into their planning and policy development.

Value of Prevention. For the vast majority of women, drug use or misuse begins long before they become pregnant. Therefore, key drivers

for achieving healthier pregnancies and births and better child safety outcomes is ensuring women of childbearing age have better access to effective birth control methods¹⁴ and engaging women of childbearing age who have substance use disorders to seek treatment before they become pregnant. Broad community approaches to preventing opioid use disorders are underway in many states and should be expanded to target opioid use during pregnancy. Current community approaches include SAMHSA's Strategic Prevention Framework Partnerships for Success, which seeks to target the use and misuse of prescription medications and heroin among persons ages 12–25 (SAMHSA, 2014b).

Improved Data Collection, Management, and Reporting. Improved data collection is urgently needed to better illuminate the challenges these families face and to be able to measure the success and effectiveness of different interventions and approaches. The prevalence of substance use during pregnancy is often underreported, mostly because pregnant women feel shame and guilt, aggravated by the societal stigma which is so pervasive in most communities. Most health care systems do not use universal screening for

substance use during pregnancy or delivery, contributing to the lack of data. Community responses to infant prenatal exposure, child welfare referrals, and case dispositions are also unevenly tracked. Identifying crucial indicators, such as referrals to child welfare agencies, as part of the CAPTA requirements and developing ways to collect information would strengthen responses to families and the use of community resources.

As we seek to learn more about how to respond successfully to the unique needs of pregnant women with opioid use disorders, we can draw from and build on lessons from the past. In this guidance document, we have focused on the unique needs of pregnant women with opioid use disorders. However, much of the guidance and principles provided are applicable to all women with substance use disorders and their infants. We hope that strengthening collaborative relationships to respond to this need will ensure that those relationships endure and offer a ready resource for addressing other challenges in the future.

¹⁴Visit the ACOG website for information on contraception, including guidance on which forms of birth control are most appropriate, based on each woman's needs: <http://www.acog.org/Womens-Health/Birth-Control-Contraception>.

Appendix : Facilitator's Guide

This appendix includes six guidance tools to help facilitate a careful, in-depth analysis of current policies, practices, resources, and training needs as related to working with pregnant women with opioid use disorders. Included is a Cross-System Guide to develop a baseline understanding of areas of strength and opportunities for improvement across the systems. As the collaborative team forms and begins to determine the roles and responsibilities of each partner, members need to evaluate their own practices and areas that need improvement. Five System-Specific Guides (mother's medical providers, infant's medical providers, substance use treatment and medication-assisted treatment providers, child welfare, and dependency court) are provided to facilitate understanding the initiative from multiple points of view. These guides can provide teams with needed background information before they make decisions about, and commit valuable resources to, statewide practice and policy changes.

Role of the Facilitator: A facilitator leads the team in using the guides. See *Building the Collaborative Team* on page 18 for additional information on the role of the facilitator.

Considerations for the facilitator and collaborative include:

- Is the team seeking to gain a baseline understanding of policies and practices *across* or *within* systems?
- How will the guides be administered? What format works best—survey, facilitated discussion, or a combination of methods? What are the resource implications?
- When will the guides be administered? What will be the sequencing of the Cross-System and System-Specific Guides?
- How will the results be understood and used to further the work of the collaborative? What are the steps following administration of the guide(s)—development of an action plan?
- Will the guide(s) be administered multiple times to assess the progress of the team or each system?

The following provides information to help answer the above posed questions.

Overview, Cross-System Guide, and System-Specific Guides: The Cross-System Guide is meant to prompt the five primary systems—mother's medical care providers, infant's medical providers, substance use treatment and medication-assisted treatment providers, child welfare, and the dependency court—to better understand the challenges and opportunities in working with pregnant women with opioid use disorders and their infants. The statements posed in the guide present best practices in working with pregnant women with opioid use disorders and will challenge some professionals to rethink the scope of their current role and responsibilities and how these might be adjusted to better serve the needs of pregnant women with opioid use disorders and their families. As collaborative partners respond to the statements, a baseline "inventory" of practices and policies across systems will begin to emerge. Partners will also be asked to prioritize identified issues to facilitate development of a work plan. It is significant to remember, however, that even if team members are satisfied with the present status of certain practices and policies, these practices and policies may pose a concern or present a barrier for one of the partners. In such cases, the whole team will need to work to determine how to resolve these issues.

TIP: *Documenting stakeholders' responses to the statements in the guides will help clarify roles and communicate what each partner is able and willing to provide to support families.*

While the Cross-System Guide seeks to identify challenges and opportunities across systems, the System-Specific Guides seek to identify a baseline “inventory” of practices and policies related to working with pregnant women with opioid use disorders within each system. The System-Specific Guides mirror the five-point intervention framework described in the subsection, *Overview of Substance-Exposed Infants (SEI) Framework*, on page 16. The statements for each system/provider are organized into three intervention time frames: (1) pregnancy, (2) time of birth, and (3) postnatal period and after. The guide for the mother’s medical providers includes a fourth intervention point—pre-pregnancy. These time frames reflect the order in which a pregnant woman typically comes into contact with each system, beginning with a visit to her obstetrician/gynecologist during pregnancy. Similar to the Cross-System Guide, the statements in the System-Specific Guides represent best practices in working with pregnant women with opioid use disorders. The System-Specific Guides are composed of the following:

- 1. Mother’s Medical Care Providers:** This includes the array of health care systems that provide medical care to the mother. Professionals from these systems include the mother’s obstetrician, nurses, and other professionals involved in the mother’s care during pregnancy and during the labor and delivery at the hospital. The team at the birth hospital can also include the anesthesiologist, hospital social worker, lactation specialist, and various nurses (e.g., labor and delivery; aftercare).
- 2. Infant’s Medical Care Providers:** This includes the range of health care systems that provide care for the infant. Professionals from these systems can include neonatologists, nurses, or other specialists who work in the neonatal intensive care unit (NICU); the pediatrician selected by the mother prior to the delivery; and the pediatrician assigned by the birth hospital (or the “on-call” pediatrician).
- 3. Substance Abuse Treatment and Medication-Assisted Treatment Providers:** The substance use treatment system consists of different types of substance use treatment providers that offer a range of services (e.g., counseling, outpatient treatment, residential treatment, educational and vocational services, and medication-assisted treatment). Depending on the type of provider and the scope of services provided by each provider, professionals can include treatment counselors, case managers, peer support specialists, and physicians or nurses who specialize in substance use treatment. Substance abuse treatment and medication-assisted treatment providers can be categorized into three broad groups:
 - Substance Use Treatment Providers: These providers offer a range of services that can include prevention (e.g., education and community awareness), outpatient treatment, residential treatment, and case management. Some treatment facilities provide medication-assisted treatment, either as a Substance Abuse and Mental Health Services Administration (SAMHSA)-certified opioid treatment program (see below for more information) or can have (informal or formal) relationships with medication-assisted treatment providers.
 - Opioid Treatment Programs (OTPs): These are SAMHSA-certified providers. Certification requirements include a medical director who is licensed to practice medicine and has experience in addiction medicine and delivery of or coordination of behavioral health and other services in conjunction with the prescription and administration of medications. The delivery or coordination of psychosocial services can be configured differently, with some OTPs physically housed with or representing a segment of the services available through a substance use treatment provider, and other OTPs who rely on (informal or formal) agreements to ensure delivery of these services.

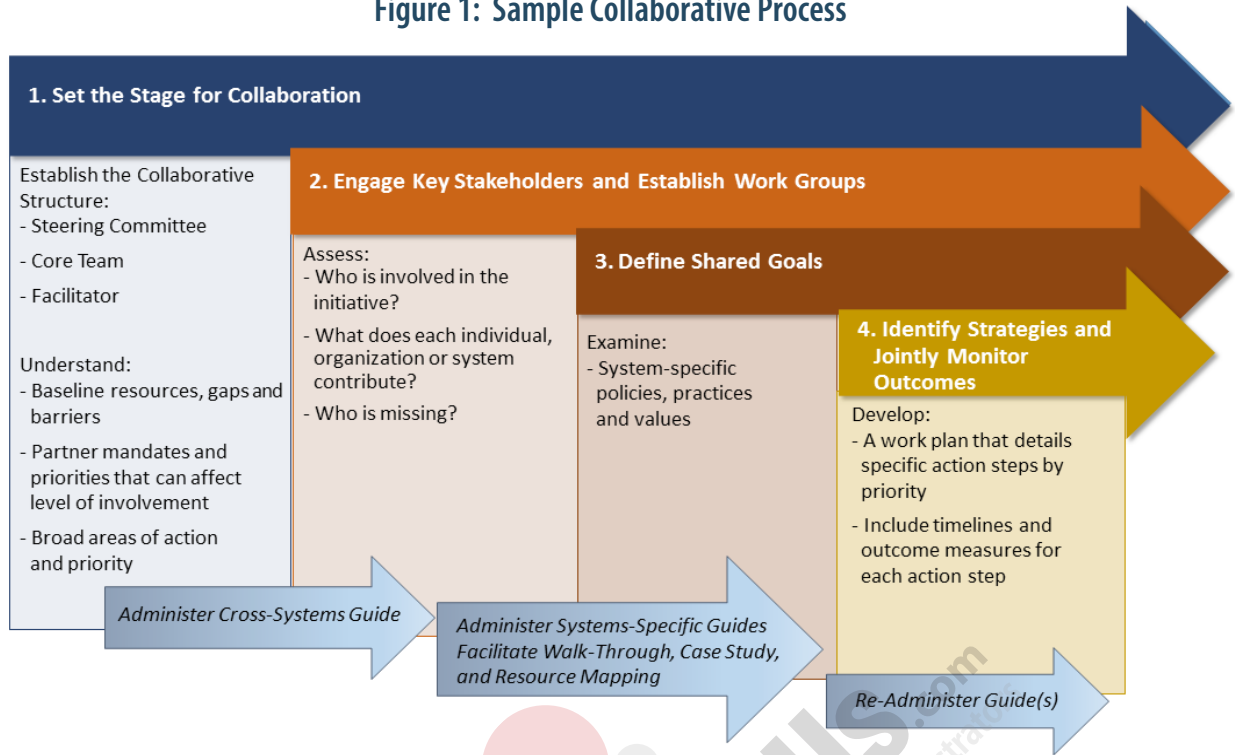
- **Independent Physicians:** These are individual physicians who operate independently from OTPs. They include physicians and/or other medical professionals who prescribe medications for the treatment of opioid use disorders. The different medications carry different licensing and certification requirements (see Appendix 4: Key Features of Medications Approved for Treating Opioid Use Disorders).

- 4. Child Welfare Services:** The child welfare system encompasses a range of services and professionals involved in multiple phases of a child welfare case. Typically, the phases entail (1) receipt of the initial child abuse/neglect report; (2) an investigation or assessment of the allegations to determine child risk and safety, whether the child should remain in the care of the parent(s), whether ongoing services are necessary, and what type of services are necessary (e.g., in-home or out-of-home care for the child and whether oversight by the dependency court is needed); (3) ongoing case management to support the family in achieving goals, including reunification; and (4) permanency planning (e.g., adoption, legal guardianship, emancipation). Usually, a different social worker is assigned to each phase. Multiple social workers can also be assigned at a single point in time, such as during phase transition, or permanency planning can occur concurrently with reunification planning.
- 5. Dependency Courts:** The dependency court system makes judicial decisions regarding children who have been removed from parental care. Decisions are based on the Adoption and Safe Families Act, the federal child welfare legislation regarding children who have been removed from their parents. A variety of professionals comprise the dependency court system. These include the judge, parent's attorney, child's attorney, the attorney who represents child welfare, and other professionals who come together at different hearings to determine whether a child has been rightfully removed from parental care, whether the abuse/neglect allegations should be substantiated, and decisions on reunification and other permanency options.

Which Guide Should Be Used? The guides can be used in a variety of ways and facilitated through different methods (e.g., a web-based survey or data collection tool or as part of a guided discussion), such as by:

- **Facilitating the Cross-System Guide as a Stand-Alone Tool:** A collaborative team can complete the Cross-System Guide to understand the strengths and opportunities for improvement in policies and practices across systems. The results of the guide can lay the groundwork for a collaborative action plan.
- **Facilitating Both the Cross-System and System-Specific Guides:** Following completion of the Cross-System Guide, the team can choose to have each partner complete its System-Specific Guide to identify areas of strength and opportunities for improvement within each system. The results of the System-Specific Guides can form the basis for action plans specific to each system that can inform the larger systemic action plan. Or, the results of the Cross-System Guide can help narrow the scope of the area that the team wants to prioritize. For instance, if priority and preferred access for pregnant women to medication-assisted treatment is identified as a priority area, the team can decide to focus on the guide intended for substance abuse treatment and medication-assisted treatment providers. Or, if the care of prenatally exposed infants is identified as an area needing discussion, the team can focus on the guides geared toward the infant's medical care providers and child welfare services. Used together, the Cross-System and System-Specific Guides can build the foundation for a comprehensive action plan that addresses the larger systemic issues as well as the issues specific to each individual system. For more information on recommended steps to facilitate a collaborative process, see *Figure 1* below and *A Guide for Collaborative Planning* on page 17.

Figure 1: Sample Collaborative Process



- Facilitating the System-Specific Guides as a Stand-Alone Tool:** The System-Specific Guides can be completed prior to or as a stand-alone from the Cross-System Survey. This configuration may be most appropriate for systems that are seeking to improve policy and practice in working with parenting and pregnant women with opioid use disorders but have not yet formulated a team approach. The results of the guide can then be used to examine and introduce policy and practice within the individual system and can serve as a launching point to facilitate a collaborative process.

Understanding the Results: To understand the level of agreement or extent to which the best practices discussed in the guides permeate the system, assign numerical values to the responses. The responses for the level of agreement are based on a Likert scale from 1–3, with *No* assigned a numerical value of 1, *To Some Extent* assigned a numerical value of 2, and *Yes* assigned a numerical value of 3. Items that receive *Not Sure* are assigned a score of 0 and are not included in the calculations. Simple calculations will result in a mean score.

A potential way of understanding the level of agreement on the extent that a practice exists is to examine mean scores by the seven topic areas (perspective, approach, coordination, service gaps and daily practice, reimbursement and access, training and staff development, and quality and outcome monitoring) that the Cross-System Guide is organized around. Areas that receive a higher mean may indicate a higher level of agreement and perhaps a lower likelihood that action is needed. Helpful tips for understanding the responses include:

- Focus on areas that reflect a lower mean, as this may indicate that action in that particular area is necessary.
- Focus on areas that reflect a high degree of uncertainty (e.g., a large number of respondents indicated *Not Sure*). Areas of uncertainty require further exploration to understand what is driving the uncertainty. In this situation, it would be helpful to examine the responses to the individual statements within the identified area to facilitate the discussion.

- Understand that the level of agreement may not correlate with how respondents prioritize each item. For instance, in the Cross-System Survey, the understanding and acceptance of medication-assisted treatment as an evidence-based treatment for pregnant women may result in a high degree of uncertainty, as systems may not be aware of the other systems' approaches in working with pregnant women with opioid use disorders. At the same time, respondents may rate the issue as an area that requires immediate action as a step towards removing barriers for pregnant women in accessing medication-assisted treatment. Similarly, respondents may be uncertain of the extent to which policies and protocols that facilitate access to medication-assisted treatment permeate the larger system. In this situation, respondents may also indicate that immediate action is necessary.

Another example can involve policies or practices that respondents identify as not existing on a wide scale (e.g., respondents indicate a low level of agreement), yet they may indicate that the issue does not require immediate action. For instance, respondents may indicate that a trauma-informed approach in working with pregnant women with opioid use disorders does not exist across systems. Yet, respondents may rate the issue as having a lower priority for action. This does not mean that the team feels that the issue is unimportant. Instead, team members are able to prioritize identified gaps and barriers to inform the development of an action plan.

TIP: *Having an understanding of both the level of agreement and the priority associated with each practice or policy area will facilitate the development of an action plan.*

Recognize that the range of respondents who complete the guides can impact the overall findings. For instance, a Cross-System Guide that is completed by a group that is composed of mostly child welfare representatives may result in a high level of uncertainty for the best practice items related to substance use treatment. Since each system is composed of a variety of diverse professionals, understanding the range of professionals who complete the System-Specific Guides is also helpful. For instance, the child welfare specific guide includes best practices in investigating reports involving prenatal exposure to opioids. If the guide is completed by a group that has a small number of investigating social workers, there may be a high level of uncertainty found for the items related to responding to a child abuse/neglect allegation. "Unsure" responses will direct the team to areas where more information is needed. Included with the guides are sample demographic questions that can be used to understand the range of respondents.

Operationalizing the Results: Using the guides will result in a baseline understanding of strengths and challenges that can be used to inform an action plan. The action plan can be further informed through other diagnostic processes; some collaborative work groups have used case studies, system walk-throughs, or resource mapping. These exercises help to further illuminate:

- What needs to be addressed and improved;
- Gaps and barriers in existing programs, services, and resources; and
- Resources and action steps needed to close the gaps and eliminate the identified barriers.

Conducting a system walk-through or collaborative examination of a case study can illuminate the gaps in services from the perspective of the mother. A walk-through can entail a literal (e.g., physical) walk-through of the experience of a pregnant woman as she goes through each of the systems, or it can entail a simulated walk-through, with stakeholders sharing their experience and knowledge of what happens at the client level. The purpose of a walk-through is to identify points in the process in which a pregnant woman may encounter roadblocks (e.g., she indicates that she needs substance use treatment at a prenatal appointment but is not connected to treatment services).

Examining a case study can also serve the same purpose. It is helpful to use a case that is reflective of each community's issues. If possible, an actual case (that has identifying information redacted), should be used. The walk-through and case study can be organized by different intervention points: prenatal/pregnancy, labor and delivery, postpartum, and beyond (see the *Substance-Exposed Infants [SEI] intervention Framework* described on page 16 for additional information).

Resource mapping can help align resources and policies to the goals identified in the action plan (University of Minnesota, 2005). For instance, the results of the Cross-System Guide might identify the screening and assessment of prenatally exposed infants as a priority area. Resource mapping can help identify the degree to which screening and assessment practices reach women and infants in the community, the funding sources available for screening and assessment, barriers or capacity issues, and related legislation or policies that influence practices. It may be helpful to organize the mapping process by the SEI intervention framework.

Instructions to Complete the Guides: The statements represent a policy or practice issue.

Respondents are to indicate their agreement with *No, To Some Extent, Yes, or Not Sure* and to prioritize each statement with *Immediate, 2 years, or 3–5 years*.

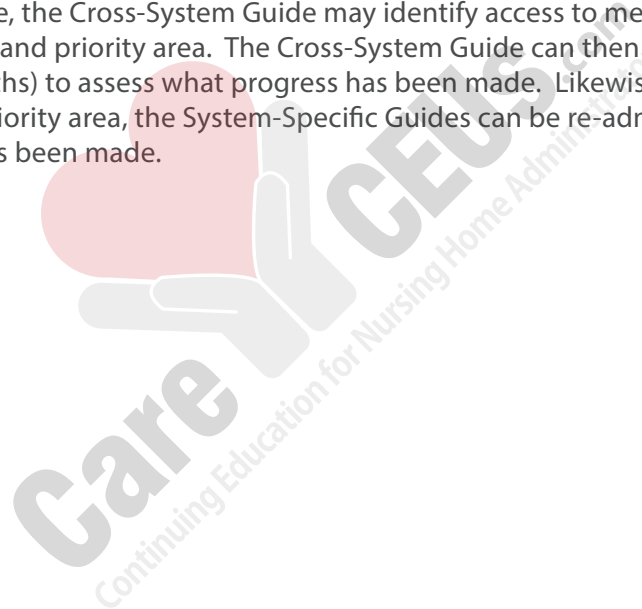
Respondents are also encouraged to include strengths, challenges, and ideas for improvement (in the space provided for Recommendations/Comments), while answering the questions to facilitate the team's development of mission and goals. When reviewing each question, have respondents consider the following:

- The extent that the policy or practice is occurring.
 - Cross-System Guide: The intent is to come to a general understanding of the underlying policies and practices across disciplines that shape the larger systemic response to pregnant women with opioid use disorders. Respondents should answer on behalf of the state, tribe, or local jurisdiction (e.g., the community that the collaborative encompasses). For instance, when responding to whether a formal system of care coordination (e.g., information-sharing agreements) is in place, respondents should respond based on their experience and knowledge of the systemic response. Respondents are encouraged to include examples of practices or policies that cannot be generalized to the larger system in the space provided for recommendations and comments or to share them as part of discussions.
 - Systems-Specific Guides: The intent is to understand the policies and practices within each discipline's sphere of practice. Respondents should base their responses on their experience and knowledge of the individual system and individual organizations or facilities that they represent. This will help identify innovative strategies and practices that are being implemented at the local level.

TIP: *The guides present a range of policies and practices related to working with pregnant women with opioid use disorders. At the onset of the collaborative effort or during the first administration of the guide(s), facilitators can expect push back from stakeholders, particularly on items that are perceived as unattainable, or the gold standard. Re-assessing stakeholders' responses to these items as the team progresses is particularly informative of the collaborative's growth (see Measuring Progress, below).*

- Are respondents able to answer the posed questions? If not, who can answer it and is that person or group at the table?
- Are respondents satisfied with the practice that the answer implies? If not, is changing the practice solely within the respondents' control?
- If change requires collaboration, who is needed to make the change?

Measuring Progress: The Cross-System Guide and System-Specific Guides will give respondents a baseline understanding, or measurement, of policies and practices related to working with pregnant women with opioid use disorders. These guides can also be used multiple times to measure the team's progress. For instance, the Cross-System Guide may identify access to medication-assisted treatment as a major barrier and priority area. The Cross-System Guide can then be administered later in time (e.g., 6–12 months) to assess what progress has been made. Likewise, if training is identified as a barrier and priority area, the System-Specific Guides can be re-administered to determine what progress has been made.



Guide 1: Cross-System Guide

Introduction: The statements in this guide are to help establish a baseline understanding of the practices and policies used across systems in working with pregnant women with opioid use disorder. Having a baseline understanding of the practices and policies will help teams evaluate the strengths and challenges they face, which in turn will help them prioritize and develop goals for the collaborative. The statements represent a policy or practice issue, which are organized by seven content areas: Perspectives, Approach, Coordination, Reimbursement and Access, Service Gaps and Daily Practice, Training and Staff Development, and Quality and Outcome Monitoring.

Who Should Complete This Guide? This guide should be completed by members in the five primary systems: the mother’s medical care providers, the infant’s medical providers, substance use treatment and medication-assisted treatment providers, child welfare, and the dependency court. Ideally, gathering responses from the five primary systems will result in a broader understanding. However, guides completed by representatives of only some of the systems are still helpful. The analysis will need to take into account the distribution of responses from each system.

I. Cross-System Guide	
Demographics	
Primary System	
<ul style="list-style-type: none"> <input type="radio"/> Mother’s Medical Provider <input type="radio"/> Substance Use Treatment and Medication-Assisted Treatment <input type="radio"/> Infant’s Medical Provider <input type="radio"/> Child Welfare 	<ul style="list-style-type: none"> <input type="radio"/> Family Dependency Court <input type="radio"/> Public Health (e.g. Early Intervention, Maternal Health) <input type="radio"/> Other (describe)
If you represent Mother’s Medical Provider, select which best represents your role	
<ul style="list-style-type: none"> <input type="radio"/> OB/GYN <input type="radio"/> OB/GYN with board specialty in addiction medicine <input type="radio"/> Nurse (prenatal care) <input type="radio"/> Nurse (labor and delivery) 	<ul style="list-style-type: none"> <input type="radio"/> Anesthesiologist <input type="radio"/> Lactation Consultant <input type="radio"/> Other (describe; e.g. Hospital Social Worker)
If you represent Substance Use Treatment and Medication-Assisted Treatment, select all that apply	
<ul style="list-style-type: none"> <input type="radio"/> Detox <input type="radio"/> Outpatient <input type="radio"/> Intensive Outpatient 	<ul style="list-style-type: none"> <input type="radio"/> Residential Treatment <input type="radio"/> Medication-Assisted Treatment <input type="radio"/> Other (describe)
If you represent Infant’s Medical Provider, select which best represents your role	
<ul style="list-style-type: none"> <input type="radio"/> Pediatrician <input type="radio"/> Neonatologist 	<ul style="list-style-type: none"> <input type="radio"/> NICU Nurse <input type="radio"/> Other (describe)
If you represent Child Welfare, select which best represents your role	
<ul style="list-style-type: none"> <input type="radio"/> Child Protection (Emergency Response) <input type="radio"/> Family Reunification/Maintenance (Case Carrying) <input type="radio"/> Adoption/Legal Guardianship (Permanency Planning) 	<ul style="list-style-type: none"> <input type="radio"/> Tribal <input type="radio"/> Other (describe)
If you represent Dependency/Family Court, select which best represents your role	
<ul style="list-style-type: none"> <input type="radio"/> Judge <input type="radio"/> Child Attorney <input type="radio"/> Parent Attorney 	<ul style="list-style-type: none"> <input type="radio"/> Child Welfare Attorney <input type="radio"/> Child Advocate (e.g. CASA, GAL) <input type="radio"/> Other (describe)
If you represent Public Health (e.g. Early Intervention, Maternal Health), select which best represents your role	
<ul style="list-style-type: none"> <input type="radio"/> Home Visitor <input type="radio"/> Public Health Nurse 	<ul style="list-style-type: none"> <input type="radio"/> Outreach and Education <input type="radio"/> Other (describe)

I. Cross-System Guide (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Perspective						
1. Medication-assisted treatment is understood and accepted as an evidence based treatment for pregnant women who have an opioid use disorder.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Approach						
2. Policy and protocols that facilitate access to medication-assisted treatment for pregnant women with opioid use disorders are in place. In the space provided for recommendations/comments, describe protocols, practices, etc. that facilitate or discourage pregnant women from accessing medication-assisted treatment (e.g. priority access; policies that state that pregnant women should not receive medication-assisted treatment; mutual aid groups that do not support medication-assisted treatment)	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
3. Our approach is guided by principles that are evidence based and trauma informed.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
4. Our approach is culturally responsive.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

I. Cross-System Guide (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Coordination						
<p>5. Our agency has a good working relationship with the other key agencies.</p> <p>In the space provided for recommendations/comments, describe areas of strength and opportunities for improvement.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>6. A formalized system of care coordination between systems is in place (e.g., information sharing agreements, MOUs).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Service Gaps and Daily Practice						
<p>7. Pregnant women with substance use disorders are identified</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>8. Medication-assisted treatment for pregnant women is available.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>9. Specialized prenatal care (e.g., obstetricians who are knowledgeable in addiction medicine) is available for pregnant women with opioid use disorders.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

I. Cross-System Guide (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Service Gaps and Daily Practice (cont.)						
<p>10. The appropriate levels of care (e.g., residential substance use treatment programs) for pregnant women are available.</p> <p>In the space provided under Recommendations/Comments, describe whether residential treatment programs are available for mothers and their infants/children.</p>	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	
<p>11. The full range of services (e.g., individual and group counseling, residential, etc.) is provided in conjunction with medication-assisted treatment.</p>	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	
<p>12. Newborns and infants who have been prenatally exposed to opioids are identified.</p>	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	
<p>13. Ongoing care and monitoring is available for infants who have been prenatally exposed to opioids.</p>	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	

I. Cross-System Guide (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Reimbursement and Access						
<p>14. Policies are in place to assist pregnant women who have financial obstacles when trying to access and maintain services for the treatment of opioid use disorders (e.g., medication-assisted treatment; outpatient or residential treatment; individual and group counseling; other services).</p> <p>In the space provided under Recommendations/Comments:</p> <ul style="list-style-type: none"> Describe whether the point in time (e.g., pregnancy, following birth, postpartum) or case specifics (e.g., infant removed from parental care) affect access. Describe how medication-assisted treatment and other substance use treatment services are made available (Medicaid, insurance exchanges, other publicly funded programs, etc.). 	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	
<p>15. Priority and preferred access* to substance use treatment and medication-assisted treatment for pregnant women is enforced.</p> <p>*As required by the Substance Abuse Prevention and Treatment Block Grant and opioid treatment program certification standards.</p>	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	
<p>16. There are policies in place to address funding obstacles in providing ongoing care (e.g., following hospital discharge) to infants who are prenatally exposed.</p> <p>In the space provided under Recommendations/Comments, describe the policies, practices, etc.</p>	No	To Some Extent	Yes	Not Sure	<p>1 (Immediate)</p> <p>2 (2 Years)</p> <p>3 (3–5 Years)</p>	

I. Cross-System Guide (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Training and Staff Development						
17. The core service providers (i.e., mother's medical providers, infant's medical providers, substance use and medication-assisted treatment, child welfare, and dependency court) are knowledgeable on the treatment of opioid use disorder in pregnancy and on the care and treatment of prenatally exposed infants.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Quality and Outcome Monitoring						
18. Partners have a shared understanding of outcomes that includes both the mother and the infant (e.g., the overall goal includes mother, infant, and family well-being).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
19. Data is tracked and shared between systems to monitor outcomes. In the space provided under Recommendations/Comments, describe how data is shared (e.g., Prescription Drug Monitoring Programs).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
20. Programs and service providers have implemented quality assurance methods.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

Guide 2: Mother's Medical Providers

Introduction: The statements in this guide are to help establish a baseline understanding of the practices and policies used within the systems to which the mother's medical providers belong. The statements are grouped into four time frames: pre-pregnancy, pregnancy, labor and delivery, and postpartum and beyond. Having a baseline understanding of the practices and policies will help teams evaluate the strengths and challenges specific to the mother's medical care

Who Should Complete This Guide? The mother's medical care providers should complete this guide; these include the obstetrician/gynecologist (OB/GYN) and other professionals involved in her care. Other professionals include nurses who work with the OB/GYN throughout the prenatal period, anesthesiologists, and others who comprise the labor and delivery team at the birth hospital.

II. Mother's Medical Providers						
	Level of Agreement			Priority for Action	Recommendations/ Comments	
Pre-Pregnancy						
1. All women of <u>childbearing age</u> are routinely screened for substance use, including opioid use and abuse at routine visits (e.g., primary care, well-woman, and family planning visits).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
2. Women identified to be using opioids are educated about the risk of use during pregnancy and offered contraceptives.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
3. Women identified to be misusing or dependent on opioids are linked to treatment services.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Pregnancy						
4. All <u>pregnant women</u> are screened for substance use (e.g., universal screening vs. selective screening).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

II. Mother's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Pregnancy (cont.)						
5. Staff are nonjudgmental and supportive of pregnant women with opioid use disorders.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
6. Staff understand and are supportive of medication-assisted treatment as an evidence-based treatment for opioid use disorders during pregnancy.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
7. Protocols and screening tools are in place to determine how substance use during pregnancy is identified (e.g., SBIRT-Screening, Brief Intervention and Referral to treatment). In the space provided under Recommendations/Comments, describe the protocols, what tools are used, etc.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
8. Women are informed about our screening and testing policies at the first prenatal visit and on how the information will be used (e.g., mandated reporting under criminal and civil child welfare laws).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

II. Mother's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Pregnancy (cont.)						
<p>9. Protocols are in place to ensure that women are referred to medication-assisted and other substance use treatment services (e.g., SBIRT).</p> <p>In the space provided under Recommendations/Comments, describe policies, protocols, etc., that facilitate access to treatment (e.g., safe harbor legislation).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>10. Specialized prenatal care is available (e.g., OB/GYNs who are knowledgeable in working with pregnant women with opioid use disorders).</p> <p>In the space provided under Recommendations/Comments, describe how specialized prenatal care and other services are provided (e.g., specialty clinics).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>11. Protocols are in place to coordinate services and share information with the mother's medication-assisted treatment and other substance use treatment services (e.g., information on medication doses is shared).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>12. Programs and services are in place to help reduce the fetus's exposure to HIV and other communicable diseases.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

II. Mother's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Pregnancy (cont.)						
<p>13. The mother's birth plan includes considerations* specific to opioid use disorders.</p> <p>*Considerations include preparing the mother for the potential impact of prenatal exposure on the newborn and supporting and preparing the mother to cope with safely taking any needed medication for pain management during the labor and postpartum phases.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
14. Decisions are made with the woman's input.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
15. Protocols are in place to make a child welfare referral if a pregnant woman has other children and safety concerns exist.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Birth						
<p>16. The labor and delivery hospital's protocol on screening for opioid use (e.g., drug testing) includes asking the mother for permission.</p> <p>In the space provided under Recommendations/Comments, briefly describe the protocol (e.g., all women are screened, or if universal screening is not the protocol, what guides decisions on who is screened?).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
17. The labor and delivery hospital staff know how to address the needs of women with opioid use disorders (e.g., pain management, caring for a newborn who has been prenatally exposed, and breast-feeding guidelines).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

II. Mother's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Birth (cont.)						
<p>18. The labor and delivery hospital staff support mother–infant bonding for cases involving prenatal opioid exposure (e.g., rooming together, breast-feeding).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>19. A referral* is made to child welfare in situations involving newborns who are prenatally exposed.</p> <p>In the space provided under Recommendations/Comments, describe the protocol, practice, etc. Is it different for cases involving illicit substances, medication-assisted treatment for opioid use disorders, use or misuse of prescription medications?</p> <p>*As required by the Child Abuse Prevention and Treatment Act (CAPTA).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>20. Mothers are notified and provided support when a referral to child welfare is made.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>21. A representative from the birth hospital is involved in the development of a plan of safe care* (e.g., safe discharge to the parents' home after the infant's inpatient treatment is complete).</p> <p>In the space provided under Recommendations/Comments, describe how the plan of safe care is developed, what it typically entails, and whether its development involves a coordinated approach with child welfare and other service providers.</p> <p>*As required by CAPTA</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

II. Mother's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Birth (cont.)						
22. Systems are in place to monitor and track cases involving prenatal exposure (e.g., birth and well-being outcomes that are associated with opioid use disorders).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Postnatal Period and After						
23. Mothers receive contraceptive services, if appropriate.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
24. Ongoing care is coordinated across health and social service systems (e.g., women are referred to medication-assisted treatment and other substance use treatment services, or services are coordinated if the woman is already receiving treatment). In the space provided under Recommendations/Comments, describe how services are coordinated and the funding mechanisms that support coordination (e.g., Family Centered Medical Home, Home Visiting Program).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

Guide 3: Infant’s Medical Providers

Introduction: The statements in this guide are to help establish a baseline understanding of the practices and policies used within the systems to which the infant’s medical providers belong. The statements represent a policy or practice issue and are grouped into two time frames: birth and postnatal/beyond. Having a baseline understanding of the practices and policies will help teams evaluate the strengths and challenges specific to the infant’s medical care.

Who Should Complete This Guide? The infant’s medical care providers should complete this guide; this includes the range of professionals responsible for the care of the infant, such as the pediatrician assigned by the birth hospital (or the “on-call” pediatrician), the neonatologist, the pediatrician selected by the mother prior to delivery, and the nurses or other specialists who work in the neonatal intensive care unit (NICU).

III. Infant’s Medical Providers						
	Level of Agreement				Priority for Action	Recommendations/ Comments
Birth						
1. We are supportive of and understand medication-assisted treatment as an evidence-based treatment approach for the treatment of opioid use disorders during pregnancy.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
2. We have a protocol on identifying and treating infants with neonatal abstinence syndrome (NAS). In the space provided under Recommendations/Comments, describe how a NAS diagnosis is made and what the treatment includes (e.g., how are decisions on nonpharmacological and pharmacological treatment methods made).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
3. The labor and delivery hospital has a pediatrician available who is experienced in working with infants with NAS and women with substance use disorders.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

III. Infant's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Birth (cont.)						
4. Parents are educated about what to expect after delivery and how to support the prenatally exposed infant in the hospital and at home.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
5. We support breastfeeding (when appropriate) and other practices that support mother–infant bonding for situations involving prenatal opioid exposure	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
6. A referral is made to child welfare* in situations involving newborns who are prenatally exposed. *As mandated by the Child Abuse Prevention and Treatment Act (CAPTA).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
7. Mothers are notified and provided support when a referral to child welfare has been made.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

III. Infant's Medical Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Birth (cont.)						
<p>8. We ensure that a follow-up plan is in place to ensure the infant's safe discharge (e.g., CAPTA plan of safe care).</p> <p>In the space provided under Recommendations/Comments, describe how the plan of safe care is developed, what it typically entails, and whether its development involves a coordinated approach with child welfare and other service providers.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Postnatal Period and After						
<p>9. Access to specialized pediatric care (e.g., ongoing NAS treatment) and early intervention services are available and facilitated.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>10. Ongoing care is coordinated across health and social services.</p> <p>In the space provided under Recommendations/Comments, describe how services are coordinated and the funding mechanisms that support coordination (e.g., family-centered medical home; home visiting program).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

Guide 4: Substance Use Treatment and Medication-Assisted Treatment Providers

Introduction: The statements in this guide are to help establish a baseline understanding of the practices and policies used within the systems to which substance use treatment and medication-assisted treatment providers belong. The statements represent a policy or practice issue and are grouped into three time frames: pregnancy, birth, and postnatal/beyond. Having a baseline understanding of the practices and policies will help teams evaluate the strengths and challenges specific to substance use treatment and medication-assisted treatment providers.

Who Should Complete This Guide? Substance use treatment and medication-assisted treatment providers should complete this guide; these include (1) treatment facilities that do or do not provide medication-assisted treatment, (2) opioid treatment providers, and (3) independent physicians who provide medication-assisted treatment. The majority of the statements in this guide are applicable across the three general groups of substance use treatment and medication-assisted treatment providers.

IV. Substance Use Treatment and Medication-Assisted Treatment Providers						
	Level of Agreement				Priority for Action	Recommendations/Comments
Pregnancy						
1. We coordinate care with the mother's OB/GYN, other medical providers, and child welfare (e.g., sharing information on the mother's progress in substance use treatment and in developing the mother's birth plan, including pain management considerations).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
2. We use validated and evidence-based assessments to determine the optimal treatment plan for pregnant women with opioid use disorders.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

IV. Substance Use Treatment and Medication-Assisted Treatment Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Pregnancy (cont.)						
<p>3. <i>For OTPs and independent physicians:</i> We ensure access to psychosocial services.</p> <p>In the space provided under Recommendations/Comments, describe how care is coordinated (e.g., sharing information on changes in the mother's medication doses).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>4. For substance use treatment providers who do not provide medication-assisted treatment:</p> <p>We ensure access to medication-assisted treatment.</p> <p>In the space provided under Recommendations/Comments, describe:</p> <ul style="list-style-type: none"> ▪ How care is coordinated with medication-assisted treatment providers (e.g., sharing information on parents' progress in treatment), or ▪ If pregnant women are not referred to medication-assisted treatment, explain why (e.g., medication-assisted treatment providers do not accept pregnant women, we believe that medication-assisted treatment is unsafe for the infant, or that abstinence is the best practice for pregnant women). 	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

IV. Substance Use Treatment and Medication-Assisted Treatment Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Pregnancy (cont.)						
5. We provide priority and preferred access for pregnant women*. *As required by the Substance Abuse Prevention and Treatment Block Grant and OTP certification standards.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
6. We support mothers to prepare for the birth process (e.g., pain management considerations for labor and delivery, the potential impact of prenatal opioid exposure, breastfeeding guidelines).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
7. We have Safe Harbor laws, which can facilitate access to treatment by protecting against liability or penalty, as long as set conditions have been met.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Birth						
8. Our residential and other treatment programs have slots for mothers with opioid use disorders and their babies who may have neonatal abstinence syndrome.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

IV. Substance Use Treatment and Medication-Assisted Treatment Providers (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Birth (cont.)						
<p>9. We have a role in developing a plan of safe care* for the infant.</p> <p>In the space provided under Recommendations/Comments, describe how the plan of safe care is developed, what it typically entails, and whether its development involves a coordinated approach with child welfare and other service providers.</p> <p>*As required by the Child Abuse Prevention and Treatment Act (CAPTA).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Postnatal Period and After						
<p>10. Ongoing care is coordinated across health and social services (e.g., information is shared on the mother’s progress in treatment, progress in medication-assisted treatment, and relapse).</p> <p>In the space provided under Recommendations/Comments, describe the protocols, strategies, etc., that facilitate care coordination and the funding mechanisms that support coordination (e.g., participation on a child safety team).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

Guide 5: Child Welfare

Introduction: The statements in this guide are to help establish a baseline understanding of the practices and policies within the child welfare system. The statements represent a policy or practice issue and are grouped into three time frames: pregnancy, birth, and postnatal/beyond. Having a baseline understanding of the practices and policies will help teams evaluate the strengths and challenges specific to child welfare.

Who Should Complete This Guide? The range of child welfare professionals should complete this guide; these include emergency response (investigation) social workers; case-carrying social workers; and those in supervisory, management, and administrative positions who work on cases involving pregnant women with opioid use disorders and their infants.

V. Child Welfare						
	Level of Agreement				Priority for Action	Recommendations/ Comments
Pregnancy						
1. Our agency supports and understands medication-assisted treatment as an evidence-based approach for the treatment of opioid use disorders during pregnancy.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
2. Our agency’s policy on medication-assisted treatment is clear to the other systems.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
3. Staff receive training on evidence-based treatment for substance use disorders, including medication-assisted treatment.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
4. Staff understand that best outcomes for pregnant women on medication-assisted treatment occur when they are also engaged in psychosocial services.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

V. Child Welfare (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Pregnancy (cont.)						
<p>5. Staff understand that pregnant women should receive priority or preferred access* to publicly funded, medication-assisted and other treatment services.</p> <p>*As required by the Substance Abuse Prevention and Treatment Block Grant and OTP certification standards.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>6. We can provide supportive intervention and safety assessments for women during pregnancy who are receiving medication-assisted treatment and other treatment services.</p> <p>In the space provided under Recommendations/Comments, describe the policies, practices, programs, etc., that facilitate interventions during pregnancy (e.g., Safe Harbor laws, Home Visiting programs, Alternative/ Differential Response).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Birth						
<p>7. Our goal is to maintain the safety of the infant, while supporting the ability of mothers and infants to remain together.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

V. Child Welfare (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Birth (cont.)						
<p>8. We have a protocol that provides clear guidance on child removal and opening cases in situations involving prenatal exposure to opioids (e.g., referrals from hospitals as required by the Child Abuse Prevention and Treatment Act [CAPTA]).</p> <p>In the space provided under Recommendations/Comments, briefly describe the protocol: Does the guidance differ based on prescribed vs illicit use? Are workers asked to coordinate with other service providers (e.g., determining whether parents are in treatment, receiving medication-assisted treatment)? Do you have a unit dedicated to cases involving prenatal exposure?</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>9. Our protocol on responding to cases involving prenatal exposure includes guidance on developing the CAPTA plan of safe care.</p> <p>In the space provided under Recommendations/Comments, describe how the plan of safe care is developed, what it typically entails, and whether its development involves a coordinated approach with substance use treatment, medical, and other service providers.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

V. Child Welfare (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Birth (cont.)						
<p>10. Our protocol on responding to cases involving prenatal exposure includes a referral* for a development screening and early intervention services for children ages 0–3.</p> <p>* As required by CAPTA</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>11. We track the total number of cases involving prenatal exposure and their outcomes.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>12. We support attachment opportunities for infants and mothers with opioid use disorders, such as rooming together and breastfeeding, when these opportunities are not contraindicated.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Postnatal Period and After						
<p>13. We ensure that our assessments address the full range of medical, clinical and social support needs experienced by our families (e.g., during the investigation, to develop the case plan, to prepare the family for reunification).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

V. Child Welfare (cont.)

	Level of Agreement				Priority for Action	Recommendations/ Comments
Postnatal Period and After (cont.)						
<p>14. We understand and are equipped to facilitate access to the supports families need for long-term stability (e.g., ongoing medication-assisted treatment and other substance use treatment services, early intervention services for infants, home visiting services).</p> <p>In the space provided under Recommendations/Comments, describe how care coordination is facilitated (e.g., by ongoing communication with treatment providers on the mother's progress in recovery).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>15. We use a consistent protocol for making decisions on reunification and case closure.</p> <p>In the space provided under Recommendations/Comments, describe how decisions are made (e.g., a shared understanding of what defines treatment success; how relapse is addressed).</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
<p>16. For agencies that use a differential response program: Our agency has a system to ensure that families referred to community agencies to address opioid use disorders receive medication-assisted and other needed treatment services.</p>	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

Guide 6: Dependency Court and Family Drug Court

Introduction: The statements in this guide are to help establish a baseline understanding of the practices and policies within the dependency court system. The statements represent a policy or practice issue and are grouped into three time frames: pregnancy, birth, and postnatal/beyond. Having a baseline understanding of the practices and policies will help teams evaluate the strengths and challenges specific to dependency courts.

Who Should Complete This Guide? Dependency court professionals should complete this guide; these include judges, children’s attorneys, parents’ attorneys, and attorneys representing child welfare.

VI. Dependency Court and Family Drug Court						
	Level of Agreement			Priority for Action	Recommendations/Comments	
Pregnancy						
1. We understand and are supportive of medication-assisted treatment as an evidence-based approach for pregnant women with opioid use disorders.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
2. We help facilitate access to medication-assisted treatment for pregnant women with opioid use disorders. In the space provided under Recommendations/Comments, describe protocols, etc., that facilitate access (e.g., Safe Harbor laws).	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
3. We accept the clinical decisions that medical and substance use treatment professionals recommend on the treatment of opioid use disorders.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

VI. Dependency Court and Family Drug Court (cont.)

	Level of Agreement				Priority for Action	Recommendations/Comments
Birth						
4. We understand what information is needed from each service provider (i.e., substance use treatment, medication-assisted treatment, child welfare, and medical providers) to make decisions regarding child safety, placement, and permanency.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
5. We help ensure that care for infants is provided and coordinated.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
6. We have a role in shaping the plan of safe care, mandated by the Child Abuse Treatment and Prevention Act (CAPTA), for cases involving prenatal substance exposure. In the space provided under Recommendations/Comments, describe how the plan of safe care is developed, what it typically entails, and whether its development involves a coordinated approach with child welfare and other service providers.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
7. We are familiar with best practices for mother–infant attachment (e.g., breastfeeding) for women receiving medication-assisted treatment.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	
Postnatal Period and After						
8. <i>For communities with a family treatment drug court (FTDC):</i> The FTDC allows new mothers to receive medication-assisted treatment and remain eligible to participate in the program.	No	To Some Extent	Yes	Not Sure	1 (Immediate) 2 (2 Years) 3 (3–5 Years)	

Appendix : Training Needs and Resources

Training Needs

The national work group of experts that developed the recommendations in this report identified common barriers and strategies to improve system linkages to serve pregnant and parenting women with opioid use disorders more effectively. Through this effort, the group identified the following training needs:

- **Medication-Assisted Treatment (MAT):** evidence-based care and use of MAT (including for MAT providers), use and efficacy of MAT during pregnancy, and complications of MAT with other prescriptions (i.e., opioid pain medications)
- **Substance Use, Misuse, and Addiction:** addiction, substance abuse treatment, recovery and opioids, what family-centered treatment means and includes, trauma-informed treatment (including trauma associated with loss of child custody), recovery definitions and practices, and characteristics of gender-responsive treatment
- **Role of Child Welfare Agencies:** role of child welfare agencies and policies regarding removal of infants from parents and visitation for children in out-of-home care
- **Screening and Assessment:** best practices for toxicology screening of both women and infants in medical settings, how to interpret drug screen results, brief screening interviews to differentiate between active and well-controlled substance use disorder, understanding sudden infant death syndrome risks and preventative efforts, screening and monitoring for newborns, interventions for neonatal abstinence syndrome (NAS), and assessments of developmental needs in newborns and infants
- **System Linkages and Information Sharing:** how, when, and where to refer women for treatment and other services and which women to transfer; how and where to refer children for developmental services; and how to gather more information from medical providers
- **Pregnancy and Family Planning:** asking about pregnancy in non-medical settings and effective family planning counseling in medical settings as a general standard for all patients, including during pregnancy and after delivery

Federal, National, and International Guidelines

Numerous resources are available to help states, local agencies and organizations, and providers establish policies, guidelines, and protocols to support pregnant women with opioid use disorders, their newborns, and other family members. The following resources provide information for health care, substance use treatment, child welfare, and dependency court professionals.

- **Academy of Breastfeeding Medicine.** Reece-Stremtan, S. & Marinelli, K. A. (2015). *ABM Clinical Protocol #21: Guidelines for breastfeeding and substance use or substance use disorder, revised 2015*. *Breastfeeding Medicine*, 10(3) 135–141. This literature based protocol serves as guidelines for the care of breastfeeding mothers and their infants. The protocol does not delineate an exclusive course of treatment or serve as standards of medical care. Retrieved from <http://www.bfmed.org/Media/Files/Protocols/Guidelines%20for%20Breastfeeding%20and%20Substance%20Use%20or%20Use%20Disorder.pdf> (accessed January 20, 2016).
- **American Academy of Pediatrics.** Hudak, M. L., & Tan, R. C. (2012). *Neonatal drug withdrawal*. *Pediatrics*, 129(2), e540–e560. Retrieved from <http://pediatrics.aappublications.org/content/129/2/e540> (accessed August 19, 2015). These guidelines and policy recommendations

are designed for hospitals, pediatricians, and neonatologists providing care for opioid-exposed infants at risk of NAS.

- **American Psychiatric Association.** Kleber, H. D., Weiss, R. D., Anton, R. F. Jr., George, T. P., Greenfield, S. F., Kosten, T. R., & Connery, H. S. (2006). *Practice guideline for the treatment of patients with substance use disorders (2nd ed.)*. Arlington, VA: American Psychiatric Association. Retrieved from http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf (accessed August 19, 2015). These guidelines offer treatment recommendations and tools for creating individualized treatment plans based on patient needs.
- **American Society for Pain Management Nursing.** Oliver, J., Coggins, C., Compton, P., Hagan, S., Matteliano, D., Stanton, M., & Turner, H. N. (2012). *American Society for Pain Management Nursing position statement: Pain management in patients with substance use disorders*. *Pain Management Nursing*, 13(3), 169–183. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3741053> (accessed August 19, 2015). This position statement, endorsed by the International Nurses Society on Addictions, includes clinical practice recommendations based on current evidence. The authors state that all patients with pain, including those with substance use disorders, have the right to be treated with dignity, respect, and high-quality pain assessment and management.
- **American Society of Addiction Medicine.** American Society of Addiction Medicine. (2015). *National Practice Guideline for Medications for the Treatment of Opioid Use Disorder*. Chevy Chase, MD: American Society of Addiction Medicine. Retrieved from <http://www.asam.org/quality-practice/guidelines-and-consensus-documents/npg> (accessed August 19, 2015). This guideline aids in clinical decision making and patient management in the treatment of opioid use disorders. Included are recommendations for assessment, diagnosis, and treatment.
- **American Society of Addiction Medicine.** American Society of Addiction Medicine. (2013). *Advancing access to addiction medications: Implications for opioid addiction treatment*. Chevy Chase, MD: American Society of Addiction Medicine. Retrieved from http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final.pdf?sfvrsn=25 (accessed August 19, 2015). This systematic review of empirical research focuses on the effectiveness of pharmacotherapies (e.g., methadone, buprenorphine, buprenorphine plus naloxone, naltrexone, and extended-release naltrexone) in the treatment of opioid use disorders.
- **Association of State and Territorial Health Officials.** Association of State and Territorial Health Officials. (2014). *Neonatal abstinence syndrome: How states can help advance the knowledge base for primary prevention and best practices of care*. Retrieved from <http://www.astho.org/Prevention/NAS-Neonatal-Abstinence-Report> (accessed August 19, 2015). This document describes a state-level approach to addressing NAS and includes examples of what states have implemented to address the issue.
- **World Health Organization.** World Health Organization. (2014). *Guidelines for the identification and management of substance use and substance use disorders in pregnancy*. Geneva: World Health Organization. Retrieved from http://apps.who.int/iris/bitstream/10665/107130/1/9789241548731_eng.pdf?ua=1 (accessed August 19, 2015). These guidelines contain recommendations for health care providers on the identification and care management of women who are pregnant or have recently had a child and who use alcohol or drugs or have a substance use disorder to ensure healthy outcomes for pregnant women and their infants.
- **Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies (DPT).** Retrieved from <http://www.samhsa.gov/medication-assisted-treatment/about> (accessed August 19, 2015). DPT manages the day-to-day regulatory oversight activities on the use of opioid agonist medications (methadone and

buprenorphine). These activities include supporting the certification and accreditation of more than 1,250 opioid treatment programs. DPT also implements the Drug Addiction Treatment Act of 2000 (DATA 2000), which expands the clinical context of medication-assisted opioid addiction treatment by allowing qualified physicians to dispense or prescribe approved medications for the treatment of opioid use disorders in treatment settings other than the traditional opioid treatment program. DPT supports the training of medical and substance abuse professionals on a variety of treatment issues, including on medication-assisted treatment for opioid use disorders.

- **Center for Substance Abuse Treatment.** Center for Substance Abuse Treatment. (2004). *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction*. A Treatment Improvement Protocol (TIP) Series 40. HHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <http://store.samhsa.gov/product/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction/SMA07-3939> (accessed August 19, 2015). These practice guidelines are designed to help physicians make decisions about using buprenorphine to treat opioid use disorders. The document includes information on patient assessment; protocols for opioid withdrawal; and the treatment of pregnant women, teens, and polysubstance users.
- **Center for Substance Abuse Treatment.** Center for Substance Abuse Treatment. (2010). *Drug-testing in child welfare: Practice and policy considerations*. HHS Pub. No. (SMA) 10-4556. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.ncsacw.samhsa.gov/files/DrugTestinginChildWelfare.pdf> (accessed August 19, 2015). This guide helps child welfare policy makers develop practice and policy protocols regarding drug testing in child welfare practice. This guidance describes issues that policy makers must address to include drug testing in the comprehensive assessment and monitoring that child welfare agencies provide.
- **Center for Substance Abuse Treatment.** Center for Substance Abuse Treatment. (2005). *Medication-assisted treatment for opioid addiction in opioid treatment programs*. A Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <http://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs/SMA12-4214> (accessed August 19, 2015). TIP 43 offers a detailed description of medication-assisted treatment for opioid use disorders, including comprehensive maintenance treatment, detoxification, and medically supervised withdrawal. It also discusses screening, assessment, and administrative and ethical issues.
- **Substance Abuse and Mental Health Services Administration.** Substance Abuse and Mental Health Services Administration. (2011). *Managing chronic pain in adults with or in recovery from substance use disorders*. A Treatment Improvement Protocol (TIP) Series 54. HHS Publication No. (SMA) 12-4671. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <http://store.samhsa.gov/shin/content/SMA12-4671/TIP54.pdf> (accessed August 19, 2015). TIP 54 gives clinicians practical guidance and tools for treating chronic pain in adults with a history of substance use. The document also discusses chronic pain management, including treatment with opioids, and offers information about substance use disorder assessments and referrals.
- **Substance Abuse and Mental Health Services Administration.** Substance Abuse and Mental Health Services Administration. (2009). *Substance abuse treatment: Addressing the specific needs of women*. A Treatment Improvement Protocol (TIP) Series 51. HHS Publication No. (SMA) 14-4426. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <http://store.samhsa.gov/shin/content/SMA14-4426/SMA14-4426.pdf> (accessed August 19, 2015). Tip 51 helps providers offer treatment to women with substance use disorders and reviews gender-specific research and best practices, such as common patterns of initiation of substance use among women and treatment issues and strategies.

- **Substance Abuse and Mental Health Services Administration.** Werner, D., Young, N. K., Dennis, K., & Amatetti, S. (2007). *Family-centered treatment for women with substance use disorders: History, key elements, and challenges*. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from http://samhsa.gov/sites/default/files/family_treatment_paper508v.pdf (accessed August 19, 2015). This guide describes the effects of family-centered treatment on treatment retention and other outcomes in women, children, and other family members.
- **Substance Abuse and Mental Health Services Administration.** Young, N. K., Nakashian, M., Yeh, S., & Amatetti, S. (2006). *Screening and assessment for family engagement, retention, and recovery (SAFERR)*. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.ncsacw.samhsa.gov/files/SAFERR.pdf> (accessed August 19, 2015). SAFERR is a collaborative model to help child welfare, substance use disorder treatment, and family court professionals make informed decisions when determining outcomes for children and families affected by substance use disorders. This guide provides strategies to help improve collaborative capacities across systems.
- **Substance Abuse and Mental Health Services Administration.** Young, N. K., Gardner, S., Otero, C., Dennis, K., Chang, R., Earle, K., & Amatetti, S. (2009). *Substance-exposed infants: State responses to the problem*. HHS Pub. No. (SMA) 09-4369. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.ncsacw.samhsa.gov/files/Substance-Exposed-Infants.pdf> (accessed August 19, 2015). This report provides an in-depth review of state legislation and regulations, interagency agreements, and budget allocations related to substance-exposed infants; documents policies in 10 states that address one or more of five intervention points; and summarizes national research on other state policies focused on substance-exposed infants.

State Guidelines

- **Maine:** Division of Population Health. (2013). *Children with special health needs*. Retrieved from <http://www.maine.gov/dhhs/mecdc/population-health/mch/cshn/> (accessed August 19, 2015). Maine's Snuggle ME project includes tools and practice guidelines for obstetricians and pediatricians caring for pregnant women and their newborns to screen and treat pregnant women with substance use disorders for alcohol or other prescribed or nonprescribed substances, such as methadone, buprenorphine, and oxycodone.
- **Vermont:** Vermont Department of Health, Division of Alcohol and Substance Abuse Programs, & Department of Vermont Health Access. *Vermont guidelines for medication assisted treatment (MAT) for pregnant women*. (n.d.). Retrieved from http://www.uvm.edu/medicine/vchip/documents/VCHIP_4MAT_GUIDELINES.pdf (accessed August 19, 2015). This guidance provides a consolidated set of recommendations for managing opioid use disorders during pregnancy.
- **Washington:** Washington State Department of Health. (2012). *Substance abuse during pregnancy: Guidelines for screening*. Olympia, WA: Washington State Department of Health. Retrieved from http://aia.berkeley.edu/media/pdf/WA_15_PregSubs_E12L.pdf (accessed August 19, 2015). This best-practice guide on screening pregnant women for substance use and misuse is for health care professionals; the document also provides information and resources on treatment.

Webinars and Conference Presentations

- **Children and Family Futures. (2014).** *Medication assisted treatment during pregnancy, postnatal and beyond.* Retrieved from <http://www.cffutures.org/presentations/webinars/medication-assisted-treatment-during-pregnancy-postnatal-and-beyond> (accessed August 19, 2015). This presentation describes the use of MAT to treat opioid use disorders in pregnant women and the effects of this use on relationships among treatment providers, dependency courts, and child welfare agencies.
- **Young, N. K. (2013).** *Medication assisted treatment (MAT): A component of comprehensive treatment for substance use disorders.* Retrieved from <http://www.cffutures.org/files/presentations/TN%20MAT-NAS%207-2013.pdf> (accessed August 19, 2015). This presentation addresses the brain science around addiction and the use of MAT as part of an evidence-based, holistic treatment approach, with a focus on MAT during pregnancy, after birth, and beyond.
- **Fields, J., Mann, L., & DeCerchio, K. (2012).** *Understanding medication-assisted treatment for families affected by parental substance use disorders.* Presentation at 18th National Conference on Child Abuse & Neglect, Washington, DC, April 16–20, 2012. Retrieved from http://www.cffutures.org/files/conference2011/sessions/A11/PPT-Understanding_MAT_for_Families.pdf (accessed August 19, 2015). This presentation describes the epidemic rise in prescription drug use and misuse and the need for persons working with children and families to understand the efficacy, use, and implications of MAT for families receiving child welfare services.
- **Gardner, S., Chasnoff, I., Green, S., & Kurgans, M. (2012).** *Identifying and responding to the needs of substance-exposed infants and their families—It takes a collaborative.* Presentation at 18th National Conference on Child Abuse & Neglect, Washington, DC, April 16–20, 2012. Retrieved from http://www.cffutures.com/files/presentations/SEI_OCAN_Final.pdf (accessed August 19, 2015). This presentation highlights effective programmatic responses to the needs of children and families by describing the prevalence and impact of prenatal exposure on children and families, practice and policy implications, strategies for building and expanding collaborative efforts to address the needs of this population, and examples of successful national and statewide programs.
- **Breitenbucher, P., Panzarella, P., & Moy, S. (2012).** *Drug testing: Managing resources for better outcomes.* Retrieved from <http://www.cffutures.org/files/presentations/DrugTestingManagingResourcesForBetterOutcomesOCAN.pdf> (accessed August 19, 2015). This presentation provides insight into why drug testing is important in child welfare and key considerations for developing a drug-testing policy.
- **Clodfelter, P., Haskins, K., & Young, N. K. (2014).** *Closed doors or welcome mat? Opening the way for medical assisted treatment in FDC.* Retrieved from <http://www.cffutures.org/presentations/webinars/closed-doors-or-welcome-mat-opening-way-medical-assisted-treatment-fdc> (accessed August 19, 2015). This webinar presentation from the Office of Juvenile Justice and Delinquency Prevention's Office of Justice Programs provides an overview of MAT and key considerations for opening doors for this population as well as practice and policy examples and implications for collaborative practice between child welfare agencies, treatment programs, and courts.
- **National Abandoned Infants Assistance Resource Center. (2009).** *Collaborative approaches to identifying and serving substance exposed newborns: Lessons learned from four demonstration projects.* Retrieved from <http://aia.berkeley.edu/training/online/webcasts/sen> (accessed August 19, 2015). Representatives from four federally funded demonstration projects share their experiences in developing policies and procedures to comply with the federal Child Abuse

Prevention and Treatment Act mandates related to infants affected by illegal substance use or withdrawal symptoms resulting from prenatal exposure or a fetal alcohol spectrum disorder. The presenters discuss their challenges in multidisciplinary collaboration and the strategies they used to overcome those challenges.

- **The Providers' Clinical Support System for Opioid Therapies (PCSS-O).** The PCSS-O is a consortium of professional health care organizations, including the American Medical Association, American Academy of Addiction Psychiatry, American Psychiatric Association, and International Nurses Society on Addictions. The consortium offers trainings on the safe and effective use of opioid medications. Selected presentations include and can be accessed from <http://pcss-o.org/> (accessed August 19, 2015).
 - *Treating Women for Opioid Dependence During Pregnancy and the Postpartum Period: The Importance of Science and Clinical Care Informing Each Other.* Discusses the benefits and risks of providing methadone, buprenorphine, or medication-assisted withdrawal during pregnancy for the mother, fetus, and newborn. Examines different approaches for addressing opioid use disorders during pregnancy and the postpartum period.
 - *Parenting and Concerns of Pregnant Women in Buprenorphine Treatment.* Discusses emerging trends in prescription drug use and misuse, maternal opioid use, NAS, parenting, and child welfare. Discusses discrepancies between parenting concerns and parenting skills of pregnant women with opioid use disorders, the development of an integrated model of behavioral and medical treatment, and policy recommendations.
 - *Buprenorphine Clinic: A Multidisciplinary Model for Opioid Maintenance Therapy.* Reviews introductory and background information on the design, implementation, and evaluation of a multidisciplinary outpatient buprenorphine clinic for opioid maintenance therapy.
 - *Assessment of Patients with Chronic Pain and Co-Occurring Substance Use.* Addresses the types of screening used to determine an appropriate assessment for pain and addiction to aid physicians in determining whether long-term opioid medications are a viable option for a patient with chronic pain.
 - *Treating Chronic Pain with Prescription Opioids in the Person with Substance Use Disorders: Relapse Prevention & Management.* Provides a comprehensive understanding of treating chronic pain with prescription opioids in the person with substance use disorders.

Online Tutorials

National Center on Substance Abuse and Child Welfare, Substance Abuse and Mental Health Services Administration, (2007).

- **Tutorial 1:** *Understanding child welfare and the dependency court: A guide for substance abuse treatment professionals.* Retrieved from <https://www.ncsacw.samhsa.gov/tutorials/tutorialDesc.aspx?id=26> (accessed November 6, 2015). This tutorial provides comprehensive information regarding child welfare issues for substance abuse treatment professionals.
- **Tutorial 2:** *Understanding substance use disorders, treatment and family recovery: A guide for child welfare professionals.* Retrieved from <https://www.ncsacw.samhsa.gov/tutorials/tutorialDesc.aspx?id=27> (accessed November 6, 2015). This primer addresses addiction, substance abuse treatment and recovery, treatment readiness and treatment effectiveness, cross-system communication and collaboration, and contact information for other national resources.

- **Tutorial 3:** *Understanding substance use disorders, treatment, and family recovery: A guide for legal professionals.* Retrieved from <https://www.ncsacw.samhsa.gov/tutorials/tutorialDesc.aspx?id=28> (accessed November 6, 2015). This primer addresses addiction, treatment and recovery, the impact of substance abuse on children and families, child welfare timetables and their impact on parenting, cross-system communication and collaboration, and contact information for other national resources.

Brochures for Parents and Other Consumers

- **Nurse Family Partnership.** *Caring for babies who have been exposed to drugs or alcohol.* Retrieved from http://www.cffutures.org/files/publications/SEI%20Brochure_Final.pdf (accessed August 19, 2015). This brochure is designed for parents and caregivers of infants with prenatal substance exposure. It offers caregiving tips for soothing a baby as well as resources in the Sacramento, California, region. Those interested in personalizing this brochure in a given region should send an e-mail to ncsacw@cffutures.org to request a customizable version.

Resource Locators

- **Substance Abuse and Mental Health Services Administration.** *Buprenorphine physician and treatment program locator.* Retrieved from <http://dpt2.samhsa.gov/treatment/directory.aspx> (accessed August 19, 2015). This directory enables providers to locate physician(s) and treatment program(s) authorized to treat opioid addiction with buprenorphine in a particular state. This site also has a link to a page for pharmacists to verify whether a prescribing physician has a valid Drug Addiction Treatment Act (DATA) of 2000 waiver.
- **National Alliance of Advocates for Buprenorphine Treatment.** *Treatment match.* Retrieved from <http://www.treatmentmatch.org/index.cfm> (accessed August 19, 2015). This anonymous, free, and confidential service connects people seeking treatment for addiction with treatment providers.
- **Substance Abuse and Mental Health Services Administration.** *Opioid treatment program directory.* Retrieved from <http://dpt2.samhsa.gov/treatment/directory.aspx> (accessed August 19, 2015). This online directory allows providers to search for treatment programs by state.

Organization Websites and Reports

- **American Association for the Treatment of Opioid Dependence.** <http://www.aatod.org>. This association enhances the quality of patient care in treatment programs by promoting the growth and development of comprehensive opioid treatment services throughout the United States.
- **Legal Action Center.** <http://lac.org/>. Legal Action Center is the only nonprofit law and policy organization in the United States whose sole mission is to fight discrimination against people with histories of addiction, HIV/AIDS, or criminal records and to advocate for sound public policies in these areas. Legal Action Center has published the following reports:
 - **Legal Action Center. (2011).** *Legality of denying access to medication assisted treatment in the criminal justice system.* New York and Washington, DC: Legal Action Center. Retrieved from http://www.lac.org/doc_library/lac/publications/MAT_Report_FINAL_12-1-2011.pdf (accessed August 19, 2015). This report analyzes the circumstances in which the denial of MAT violates federal antidiscrimination laws and the U.S. Constitution.

- **Legal Action Center. (2010).** *Confidentiality of alcohol and drug records in the 21st century.* New York and Washington, DC: Legal Action Center. Retrieved from [http://lac.org/wp-content/uploads/2014/12/Confidentiality of Alcohol and Drug Records in the 21st Century-1-20-10.pdf](http://lac.org/wp-content/uploads/2014/12/Confidentiality_of_Alcohol_and_Drug_Records_in_the_21st_Century-1-20-10.pdf) (accessed August 19, 2015). This report discusses effective ways to increase communication between providers of alcohol and drug treatment and recovery services and other health care professionals while maintaining patient privacy.

For additional resources, contact the **National Center on Substance Abuse and Child Welfare:**
Phone: 1-866-493-2758; website: www.ncsacw.samhsa.gov; e-mail: ncsacw@cffutures.org



Appendix : Key Features of Medications Approved for Treating Opioid Use Disorders^{1,2}

Prescribing Considerations	Extended-Release Injectable Naltrexone ³	Methadone ⁴	Buprenorphine ⁵
Frequency of Administration	Monthly ⁶	Daily	Daily (also alternative dosing regimens)
Route of Administration	Intramuscular (IM) injection into the gluteal muscle by a physician or other health care professional. ⁶	Orally as liquid concentrate, tablet, or oral solution of diskette or powder.	Oral tablet or film is dissolved under the tongue.
Who May Prescribe or Dispense	Any individual who is licensed to prescribe medicines (e.g., physician, physician assistant, nurse practitioner) may prescribe and/or order administration by qualified staff.	SAMHSA-certified OTPs dispense methadone for daily administration either on site or, for stable patients, at home.	Physicians must have board certification in addiction medicine or addiction psychiatry and/or complete special training to qualify for the federal waiver to prescribe buprenorphine, but any pharmacy can fill the prescription. There are no special requirements for staff members who dispense buprenorphine under the supervision of a waived physician.

¹ Substance Abuse and Mental Health Services Administration. (2014). Table 1 is reproduced with modifications from: Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. HHS Publication No. (SMA) 14-4892R. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <http://store.samhsa.gov/shin/content//SMA14-4892R/SMA14-4892R.pdf> (accessed August 19, 2015). See source document for references.

² The table highlights some properties of each medication. It does not provide complete information and is not intended as a substitute for the package inserts or other drug reference sources used by clinicians (see <http://www.dailymed.nlm.nih.gov> for current package inserts). For patient information about these and other drugs, visit the National Library of Medicine's MedlinePlus (<http://www.medlineplus.gov>). Whether a medication should be prescribed and in what amount are matters to be discussed between an individual and his or her health care provider. The prescribing information provided here is not a substitute for the clinician's judgment, and the National Institutes of Health and SAMHSA accept no liability or responsibility for the use of the information in the care of individual patients.

³ The brand name for naltrexone is Vivitrol®.

⁴ The brand names for methadone are Dolophine® and Methadose™.

⁵ The brand names for the combination medication buprenorphine/naloxone is Suboxone® and Zubsolv®.

⁶ Naltrexone hydrochloride tablets (50 mg each) are also available for daily dosing.

Prescribing Considerations	Extended-Release Injectable Naltrexone ³	Methadone ⁴	Buprenorphine ⁵
Pharmacologic Category	Opioid antagonist ⁷	Opioid agonist	Opioid partial agonist Buprenorphine's partial agonist effect relieves withdrawal symptoms resulting from cessation of opioids. This same property will induce a syndrome of acute withdrawal in the presence of long-acting opioids or sufficient amounts of receptor-bound full agonists. Naloxone, an opioid antagonist, is sometimes added to buprenorphine to make the product less likely to be abused by injection.



⁷ Opioid agonists bind to brain receptors, producing feelings of euphoria, sedation, and pain relief. When used to treat opioid use disorders, agonists occupy brain receptors to block the effects of other opioids. Partial opioid agonists bind to brain receptors without completely stimulating them, producing a “ceiling effect” so that taking more of the medication does not increase euphoria or sedation. Opioid antagonists bind to brain receptors and block or sometimes reverse the effects of opioids (e.g., feelings of euphoria). For more information, see <http://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs/SMA12-4214>.

Prescribing Considerations	Extended-Release Injectable Naltrexone ³	Methadone ⁴	Buprenorphine ⁵
<p>Clinical Uses/Ideal Candidates</p>	<p>Prevention of relapse to opioid use disorders following opioid detoxification; studies suggest benefits for patients who are experiencing increased stress or other relapse risks (e.g., visiting places of previous drug use, loss of spouse, loss of job).</p> <p>Appropriate for patients who have been detoxified from opioids and who are being treated for a co-occurring alcohol use disorder.</p> <p>Extended-release naltrexone should be part of a comprehensive management program that includes psychosocial support.</p> <p>Other good candidates include persons with a short or less severe addiction history or who must demonstrate to professional licensing boards or criminal justice officials that their risk of opioid use is low.</p>	<p>Detoxification and maintenance treatment of opioid use disorders.</p> <p>Patients who are motivated to adhere to the treatment plan and who have no contraindications to methadone therapy.</p> <p>Methadone should be part of a comprehensive management program that includes psychosocial support.</p>	<p>Treatment of opioid use disorders.</p> <p>Patients who are motivated to adhere to the treatment plan and who have no contraindications to buprenorphine therapy.</p> <p>Buprenorphine should be part of a comprehensive management program that includes psychosocial support.</p>

Prescribing Considerations	Extended-Release Injectable Naltrexone ³	Methadone ⁴	Buprenorphine ⁵
<p>Contraindications</p>	<p>Contraindicated in patients receiving long-term opioid therapy.</p> <p>Contraindicated in patients who are engaged in current opioid use (as indicated by self-report or a positive urine drug screen) or who are on buprenorphine or methadone maintenance therapy, as well as in those currently undergoing opioid withdrawal.</p> <p>Contraindicated in patients with a history of sensitivity to polylactide-co-glycolide, carboxymethylcellulose, or any components of the diluent.</p> <p>Should not be given to patients whose body mass precludes IM injection with the 2-inch needle provided; inadvertent subcutaneous injection may cause a severe injection site reaction.</p> <p>Should not be given to anyone allergic to naltrexone.</p>	<p>Contraindicated in patients who are hypersensitive to methadone hydrochloride or any other ingredient in methadone hydrochloride tablets, diskettes, powder or liquid concentrate.</p> <p>Contraindicated in patients with respiratory depression (in the absence of resuscitative equipment or in unmonitored settings) and in patients with acute bronchial asthma or hypercarbia.</p> <p>Contraindicated in any patient who has or is suspected of having a paralytic ileus.</p>	<p>Contraindicated in patients who are hypersensitive to buprenorphine or naloxone.</p>

Prescribing Considerations	Extended-Release Injectable Naltrexone ³	Methadone ⁴	Buprenorphine ⁵
<p>Warnings</p>	<p>Use with caution in patients with active liver disease, moderate to severe renal impairment, and women of childbearing age.</p> <p>Discontinue in the event of symptoms or signs of acute hepatitis.</p> <p>As with any IM injection, extended-release injectable naltrexone should be used with caution in patients with thrombocytopenia or any coagulation disorder (e.g., hemophilia, severe hepatic failure); such patients should be closely monitored for 24 hours after naltrexone is administered.</p> <p>Patients may become sensitive to lower doses of opioids after treatment with extended-release injectable naltrexone. This could result in potentially life-threatening opioid intoxication and overdose if previously tolerated larger doses are administered.</p> <p>Clinicians should warn patients that overdose may result from trying to overcome the opioid blockade effects of naltrexone.</p>	<p>Methadone should be used with caution in elderly and debilitated patients; patients with head injury or increased intracranial pressure; patients who are known to be sensitive to central nervous system depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease; and patients with comorbid conditions or concomitant medications that may predispose to dysrhythmia or reduced ventilatory drive.</p> <p>Methadone should be administered with caution to patients already at risk for development of prolonged QT interval or serious arrhythmia.</p> <p>The label includes a warning about somnolence that may preclude driving or operating equipment.</p>	<p>Caution is required in prescribing buprenorphine to patients with polysubstance use and those who have severe hepatic impairment, compromised respiratory function, or head injury.</p> <p>Significant respiratory depression and death have occurred in association with buprenorphine, particularly administered intravenously or in combination with benzodiazepines or other central nervous system depressants (including alcohol).</p> <p>Buprenorphine may precipitate withdrawal if initiated before patient is in opioid withdrawal, particularly in patients being transferred from methadone.</p> <p>The label includes a warning about somnolence that may preclude driving or operating equipment.</p>

Prescribing Considerations	Extended-Release Injectable Naltrexone ³	Methadone ⁴	Buprenorphine ⁵
Use in Pregnant and Postpartum Women	<p>Pregnancy: FDA pregnancy category C⁸</p> <p>Nursing: Transfer of naltrexone and 6β-naltrexol into human milk has been reported with oral naltrexone. Because animal studies have shown that naltrexone has a potential for tumorigenicity and other serious adverse reactions in nursing infants, an individualized treatment decision should be made whether a nursing mother will need to discontinue breast feeding or discontinue naltrexone.</p>	<p>Pregnancy: FDA pregnancy category C⁸</p> <p>Methadone has been used during pregnancy to promote healthy pregnancy outcomes for more than 40 years. Neonatal abstinence syndrome may occur in newborn infants of mothers who received medication-assisted treatment with methadone during pregnancy. Individualized treatment decisions balancing the risk and benefits of therapy should be made with each pregnant patient.</p> <p>Nursing: Mothers maintained on methadone can breastfeed if they are not HIV positive, are not abusing substances, and do not have a disease or infection in which breastfeeding is otherwise contraindicated.</p>	<p>Pregnancy: FDA pregnancy category C⁸</p> <p>Neonatal abstinence syndrome may occur in newborn infants of mothers who received medication-assisted treatment with buprenorphine⁹ during pregnancy. Individualized treatment decisions balancing the risk and benefits of therapy should be made with each pregnant patient.</p> <p>Nursing: Buprenorphine and its metabolite norbuprenorphine are present in low levels in human milk and infant urine. Available data are limited but have not shown adverse reactions in breastfed infants.</p>
Potential for Abuse and Diversion	No	Yes	Yes

⁸ In December 2014, the FDA published the Requirements for Pregnancy and Lactation Labeling Rule. The nomenclature is not used in the final rule, which requires the removal of the Pregnancy Categories A, B, C, D, and X from all human prescription drug and biological product labeling. Labeling is based on descriptive subsections for pregnancy exposure and risk, lactation, and effects to reproductive potential for females and males. Retrieved from <http://www.gpo.gov/fdsys/pkg/FR-2014-12-04/pdf/2014-28241.pdf> (accessed August 19, 2015).

⁹ Buprenorphine without naloxone is recommended for use in pregnancy.

Appendix : Children and Recovering Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study

Disclaimer: The views, opinions, and content of this publication are those of the authors and do not necessarily reflect the views, opinions, or policies of the Substance Abuse and Mental Health Services Administration (SAMHSA) or of the U.S. Department of Health and Human Services (HHS). Resources listed in this document are not all-inclusive and inclusion in this list does not constitute an endorsement by SAMHSA or HHS.

Overview and Purpose

The purpose of this document is to provide an in-depth case study of a community-developed, coordinated, and comprehensive approach to caring for families affected by opioid use disorders (e.g., heroin or opioid prescription medications). The Children and Recovering Mothers (CHARM) Collaborative in Burlington, Vermont, is a multidisciplinary group of agencies serving women with opioid use disorders and their families during pregnancy and infancy. This report describes and examines two aspects of the CHARM Collaborative: (1) the multiple points of intervention for families and (2) the elements of collaborative practice across systems.

There are multiple intervention opportunities for pregnant women with opioid use disorders and their newborns across service systems and professionals, beginning before pregnancy and continuing throughout a child's developmental milestones. The National Center on Substance Abuse and Child Welfare, funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Administration for Children and Families, created a five-point framework that addresses screening, assessment, referral, and engagement across all stages of development for affected children (Young et al., 2009). According to the framework, interventions can reduce the potential harm of prenatal and postnatal substance exposure at five intervention points: (1) before pregnancy, (2) during pregnancy, (3) at birth, (4) during the neonatal period, and (5) throughout childhood and adolescence.

The case study narrative in this report describes the history of CHARM and the policies and practices developed across the intervention points in the five-point framework. This document also provides examples of collaborative practices implemented by CHARM. Collaborative practice can be defined as the use of 10 system linkage elements by two or more systems, agencies, or providers to improve child and family outcomes (Children and Family Futures, 2011). The 10 elements of system linkages are: (1) underlying values and principles of collaboration, (2) screening and assessment, (3) engagement and retention in care, (4) services to children of parents with substance use disorders, (5) joint accountability and shared outcomes, (6) information and data systems, (7) budgeting and program sustainability, (8) training and staff development, (9) collaboration with related agencies, and (10) collaboration with the community and supporting families. This report examines CHARM Collaborative practices across the 10 elements of system linkage. State and community collaborative groups can use this information to guide their efforts to implement collaborative practices in their own communities.

A. History and Description of the CHARM Collaborative

Early Need

In 1998, a physician specializing in addiction at the Fletcher Allen Health Care Hospital in Burlington, Vermont, met a young pregnant woman who was seeking treatment for an opioid use disorder, because she was concerned about her baby. The physician knew that medication-assisted treatment (MAT) was the best option for the woman and her unborn child, and he wanted to prescribe methadone. At that time, however, no methadone clinics or opioid treatment programs (OTPs) existed in Vermont, and the Controlled Substances Act of 1970 limited the ability of physicians to prescribe methadone directly to patients.

Under the Controlled Substances Act of 1970, physicians could request waivers from the State Opioid Treatment Authority to prescribe methadone to identified patients as part of their medical practice. The Burlington physician applied for and received a waiver for the first woman. Within a year, he received waivers to treat two additional pregnant women who had opioid use disorders. The demand for treatment grew quickly, so the physician continued to request and obtain waivers to treat several pregnant women, until the first methadone clinic in Vermont opened in 2002 at Fletcher Allen Health Care Hospital. This physician worked with an obstetrician and neonatologist from this hospital to coordinate care for pregnant women with opioid use disorders.

Creation of the CHARM Collaborative

These early efforts to provide care for women with opioid use disorders during pregnancy became the CHARM Collaborative. Today, CHARM provides comprehensive care coordination for pregnant women with opioid use disorders and consultation for child welfare, medical, and addiction professionals across Vermont. In 2013, the CHARM Collaborative supported 194 women and their infants and families.

Effectively treating and supporting pregnant women with opioid use disorders and their families requires a comprehensive approach. Before the CHARM Collaborative was formally established in 2002, two groups of professionals worked together to coordinate care for their shared patients in Burlington.

At Fletcher Allen Hospital, an addiction specialist joined two other physicians from the Comprehensive Obstetric and Gynecological Specialty (COGS) clinic and the Neonatal Medical Follow-up Clinic (NeoMed) at the hospital to address the needs of the families they were treating. This group's primary goal was to make sure that each woman with an opioid use disorder and her infant received the services they needed, including substance abuse counseling, nutrition support from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and home-visiting services for prenatal and early childhood support.

Burlington, Vermont

The population of Vermont is approximately 626,000, and the population of Burlington, the state's largest city, is approximately 42,000. Burlington lies on Lake Champlain in the northwest part of the State. The University of Vermont Medical Center (formerly Fletcher Allen Health Care Hospital) is the only hospital in Burlington.

Members of a second group of community-based professionals were also working together to support pregnant women with opioid use disorders and their families; they were from Lund¹, a comprehensive treatment center and family support agency; the Howard Center, a substance abuse treatment provider; and the State Alcohol and Drug Abuse Program (ADAP).

By 2002, the two groups had begun working together informally. At that time, the demand for access to MAT for pregnant women (among other populations) was continually growing. Several state agencies, such as the Division of Maternal and Child Health's ADAP (including the Women's Treatment Programs and Opioid Treatment Authority), began discussing ways to address these emerging issues with the U.S. Drug Enforcement Agency. The efforts of this group resulted in two critical outcomes: (1) the development of the first methadone clinic in Vermont and (2) the decision to provide an outside facilitator from the KidSafe Collaborative of Chittenden County, Vermont, to help the two informal groups establish a more formal care-coordination effort. The KidSafe Collaborative supports multiple cross-agency collaborations to prevent and address child abuse and neglect in Burlington.

The six initial members of the collaborative were a physician and addiction specialist, an obstetrician, a neonatologist, the ADAP women's services coordinator, and the directors of Lund and the Howard Center. This team served many families who were receiving child welfare services from the Vermont Department of Children and Families (VDCF), and the group wanted VDCF representatives to join the collaborative. However, the addition of VDCF created conflicts among collaborative members, primarily regarding information sharing. Many collaborative members were unsure of how to share patient information while still adhering to confidentiality laws and regulations. For example, under federal mandates to protect child safety, VDCF was obligated to act on any information revealing potential child safety concerns. Substance abuse treatment providers were also reluctant to share client information that might put their clients at risk of involvement in the child welfare system. Collaborative members agreed that all stakeholders needed to be at the table to ensure child safety and promote family well-being, so they made a commitment to identify a solution to this information-sharing challenge. VDCF was ultimately able to participate in the collaborative.

To address this confidentiality concern, the collaborative created a memorandum of understanding (MOU; see *Attachment A: CHARM Collaborative Memorandum of Understanding*) and

Vermont Statute

Title 33: Human Services

Chapter 49: Child Welfare Services

§4917. Multidisciplinary Teams; Empaneling

The Commissioner or his or her designee may empanel a multidisciplinary team or a special investigative multitask force team or both wherever in the state there may be a probable case of child abuse or neglect which warrants the coordinated use of several professional services. These teams shall participate and cooperate with the local special investigation unit in compliance with 13 [Vermont Statutes Annotated] § 5415.

¹ Lund Family Center is a comprehensive residential and community treatment program for women with substance use disorders and their children who also participated in Round I of the Regional Partnership Grants (RPG-I) program administered by Children's Bureau, Administration for Children and Families, Department of Health and Human Services. More information about Lund's participation in the RPG-I program can be found at <https://www.ncsacw.samhsa.gov/technical/rpg-i.aspx?id=101>.

a comprehensive, multiagency release-of-information form² (see *Attachment B: CHARM Collaborative Release of Information*) for clients to sign that would allow members to appropriately share information for care-coordination purposes. Collaborative members and their agencies' attorneys spent two years negotiating the terms of the MOU and release-of-information form. Skilled facilitation provided by KidSafe and the ongoing commitment of all members to effectively serve pregnant women with opioid use disorders and their families were critical factors in the eventual success of this effort.

Another part of the solution to the information-sharing challenge came from a state statute that provides for the development of child protection teams that may share client information under certain circumstances. Similar statutes exist in other states and might offer policy opportunities to communities interested in creating a model similar to the CHARM Collaborative. The Vermont statute (Title 33, Section 4917) allows a group of empaneled professionals to share relevant, client-specific information with one another for the purpose of ensuring child safety. Establishing an empaneled group required approval for each member from the commissioner of the VDCF. Once each CHARM Collaborative member received this approval, the group became a designated child protection team. Effective information sharing allowed the group to coordinate services for families with child safety concerns successfully.

Another significant early challenge for CHARM was the limited availability of MAT in Vermont. Initially, the State Opioid Treatment Authority required physicians to obtain a one-time waiver to prescribe methadone for each pregnant woman. In 2002, the State Opioid Treatment Authority established the first state-approved OTP at Fletcher Allen Hospital in Burlington. This OTP dispensed methadone from the hospital pharmacy to women who arrived daily for their prescribed dose. Later, the methadone program moved to a community-based clinic. In 2004, buprenorphine became a second option for MAT during pregnancy in Vermont. In Burlington, buprenorphine prescriptions and dosing became available at the Fletcher Allen Hospital's COGS, where many CHARM women received prenatal care. State approval for the first OTP and for buprenorphine use effectively increased access to MAT for pregnant women in Vermont.³

² The release-of-information form provided in this document is a sample and is not endorsed by SAMHSA or HHS.

³ At the writing of this report, state-approved OTPs exist in all states, except for Wyoming and North Dakota. For more information on OTPs, including a state directory, certification requirements, and a list of opioid treatment authorities, see <http://dpt2.samhsa.gov/treatment/directory.aspx>.

CHARM Today

Today, the CHARM Collaborative includes 10 organizations that collectively provide comprehensive care coordination for pregnant women with opioid use disorders and consultation for child welfare, medical, and addiction professionals across Vermont. Several members have been involved in CHARM since the group's inception. The following table lists the CHARM Collaborative members.

Member Organization	Services Provided
Comprehensive Obstetric and Gynecological Services (COGS), Fletcher Allen Health Care Hospital	<ul style="list-style-type: none"> ▪ Prenatal care ▪ MAT assessment ▪ Buprenorphine treatment ▪ Care coordination
NeoMed Clinic, Vermont Children's Hospital at Fletcher Allen Health Care Hospital	<ul style="list-style-type: none"> ▪ Neonatal assessment and treatment ▪ Parent education on neonatal abstinence syndrome ▪ Developmental assessment
Howard Center/Chittenden Clinic	<ul style="list-style-type: none"> ▪ MAT assessment ▪ Methadone and buprenorphine treatment ▪ Individual and group substance abuse treatment
Lund	<ul style="list-style-type: none"> ▪ Residential care for mothers and infants ▪ Substance abuse treatment ▪ Parent and family support
Vermont Department for Children and Families	<ul style="list-style-type: none"> ▪ Child safety assessments ▪ Child welfare services
Vermont Department of Corrections/Correct Care Solutions	<ul style="list-style-type: none"> ▪ Health care for women in the corrections system
Alcohol and Drug Abuse Programs, Vermont Department of Health	<ul style="list-style-type: none"> ▪ Substance abuse treatment ▪ Opioid Treatment Authority

Member Organization	Services Provided
Maternal and Child Health Programs (Chittenden, Franklin, and Grand Isle Counties), Vermont Department of Health	<ul style="list-style-type: none"> ▪ Public health services ▪ Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) ▪ Home-visiting referrals
Vermont Department of Health Access	<ul style="list-style-type: none"> ▪ Medicaid coverage
Visiting Nurse Association of Chittenden and Grand Isle	<ul style="list-style-type: none"> ▪ Nurse home-visiting services

At any given time, approximately 100 women receive coordinated care through the CHARM Collaborative. Each month, about 20 pregnant women are added to the client list and about 10 newborns are delivered. Annually, the collaborative serves 200–250 families.

Members of the CHARM Collaborative meet once a month for two hours to discuss the needs of client families and how to address these needs. Decisions about solutions and follow-up tasks are made for each family before the next family is discussed. To support these discussions, the facilitator distributes a list of client families at each meeting. These lists are divided into four categories of families: (1) new to CHARM, (2) with a woman expected to give birth within 30 days, (3) with a woman who recently gave birth, and (4) about whom a collaborative member has concerns. Within each category, the names are listed alphabetically, and families are discussed in that order. Typically, about 40 families are discussed at each meeting. Periodically, the first 15 minutes are used for providing cross-disciplinary training, sharing outcomes, and discussing related projects and other process issues that are not case specific.

With 40 families to discuss in less than two hours, the meeting process needs to be quick and effective. CHARM's many years of experience working as a collaborative is one of the key factors that helps them use their time effectively. Other key factors include having a skilled facilitator at each meeting and having immediate access to current client files. Many members have remote access to their case files while participating in the meetings.

Decisions about follow-up with client families made during meetings might include increasing care coordination, intensity of services, and social supports as well as formally submitting a report to VDCF or requesting a VDCF safety assessment.

Critical Facilitator Competencies

An effective facilitator is:

- Organized
- Objective (not partial to certain members)
- Effective at oral and written communication
- Aware of relationships among group members and political influences on the group
- Adept at conflict resolution

Organizing and maintaining the CHARM Collaborative process requires the efforts of several key individuals, including the facilitator, a NeoMed nurse, and COGS and NeoMed caseworkers. Each individual plays a key role in sustaining the overall effort.

The facilitator (who is from KidSafe Collaborative) guides the CHARM Collaborative. She is responsible for developing the CHARM meeting agendas, facilitating CHARM Collaborative meetings, managing conflicts among CHARM members, monitoring the empanelment process for the child protection teams, managing the budget of the CHARM Collaborative, developing resources, and managing communication among collaborative members. Along with other CHARM Collaborative members, the facilitator gives presentations at conferences throughout the country on the CHARM process and lessons learned. Her knowledge of child welfare issues and policies and her communication and facilitation skills allow her to objectively and effectively assist the CHARM Collaborative in addressing the needs of each family, while protecting client rights and respecting the mandates of each member organization. The facilitator spends about four hours per week on CHARM, and her time is supported financially by a combination of small grants from private foundations, United Way, and the Vermont Division of Alcohol and Drug Abuse Programs. The state funding for the facilitator is discretionary, and the amount varies from year to year.

The neonatal nurse monitors the release-of-information forms and maintains the list of CHARM families. Her efforts for CHARM require about one hour per week, and Fletcher Allen Health Care Hospital provides her services on an in-kind basis.

The social worker at the COGS clinic works primarily with CHARM families, taking on most of the care coordination responsibilities for these families during pregnancy. The medical assistant and the nurse in the NeoMed clinic provide most of the care coordination for families during infancy. They work with CHARM families in addition to other families who receive neonatal services. Fletcher Allen Health Care Hospital supports these three positions. If the CHARM Collaborative did not exist, COGS and the NeoMed clinics would still provide care coordination services for these families, but the CHARM Collaborative improves the efficiency of this care coordination and decreases the amount of time it requires.

Benefits of CHARM

The CHARM Collaborative benefits families, organizations, the community, and the State of Vermont. This collaborative has resulted in a full range of services for the families of pregnant women with opioid use disorders in the northern half of the state. Collaborative members have shared the CHARM process throughout the state, and other counties are now implementing similar models. For the organizations involved in CHARM, the time saved by coordinating services for 40 families in one 2-hour meeting a month (compared with the time required to coordinate services by telephone and e-mail) is substantial, and members believe that the quality of care they provide to families is better as a result. The CHARM process avoids problems resulting from conflicting information about patient health, progress in recovery, and behavior. Family needs are identified sooner and addressed more quickly, and fewer families “fall through the cracks” than if the services these families received were not coordinated among providers.

“With CHARM, there is a time and space set aside so we can tie up loose ends and make sure families are doing okay. If they are not, we can act quickly and prevent or address child safety concerns.”

-CHARM Collaborative member

The benefits of CHARM to families include healthier pregnancies, healthier children, and a greater chance of remaining together or being reunified. Since CHARM began, access to MAT for pregnant women has increased, and women are receiving treatment earlier in their pregnancies. There is a trend toward increased birth weight and fewer newborns requiring pharmacological treatment for withdrawal symptoms after discharge from the hospital. Newborns who do require treatment after discharge are able to complete their treatment at home.

In 2012, a study led by one of the COGS obstetricians and published in the *Journal of Addiction Medicine* identified some outcomes of the CHARM Collaborative (Meyer, Benvenuto, Howard, Johnston, Plante, Metayer, & Mandell, 2012). The authors investigated the impact that increased access to MAT had for women and infants served by CHARM from 2000 to 2006. Of the 106 CHARM infants who underwent developmental screening at eight months, 96 (94 percent) were within normal limits on all developmental parameters, six (5.6 percent) had mild delays, two (1.8 percent) had more severe delays, and two (1.8 percent) died after discharge from the hospital.⁴ Of 134 CHARM newborns delivered between 2003 and 2006, 116 (86 percent) were discharged from the hospital in the custody of the mother. This percentage increased from 83.3 percent in 2003 to 91.8 percent in 2006.

Over the last several years, CHARM members have identified factors that seem to predict infant health in CHARM families. Healthy outcomes in infants are more likely when women obtain prenatal care early during pregnancy, consistently complete their prenatal visits, receive MAT, participate in counseling, and/or attend at least one prenatal appointment with a neonatologist. Conversely, poor health outcomes for the baby are more likely when women miss prenatal and neonatal appointments, continue their illicit use of opioids, lack stable housing, and/or do not continue to obtain substance abuse counseling (even if they continue to undergo MAT).

B. Engaging Mothers during Pregnancy

This section describes the decision-making process and services of the CHARM Collaborative across three time frames: pregnancy, birth, and after birth.

Members of the CHARM Collaborative have identified four goals for each family during pregnancy: (1) engage each woman in prenatal care as early in the pregnancy as possible, (2) reduce opioid cravings and withdrawal symptoms using MAT, (3) engage each woman (and her partner if possible) in substance abuse counseling, and (4) provide social support and meet basic needs for the family.

Factors Resulting in Healthier Infants

- Access to early prenatal care
- Consistent attendance of prenatal visits
- Receipt of MAT and counseling
- Completion of at least one prenatal or neonatal visit

Factors Resulting in *Less Healthy* Infants

- Missed prenatal and neonatal appointments
- Continued use of illicit opiates
- Lack of stable housing
- Discontinuation of counseling (even if the woman continues to receive MAT)

⁴ Neither of the infants who died required treatment for neonatal abstinence syndrome. The mothers of both infants were actively receiving substance abuse treatment, with no indication of relapse. The causes of death were suffocation from co-sleeping and sudden infant death syndrome.

Prenatal Care

Most pregnant women enrolled in CHARM are referred to COGS for prenatal care by another CHARM Collaborative member. They can also be referred by a hospital emergency department staff, community obstetrician, primary care provider, or substance abuse counselor. Women can also refer themselves to COGS for prenatal care. If a woman is referred by an emergency department, COGS will schedule an appointment for her for the next business day. COGS staff regard this situation as urgent but not as an emergency requiring immediate action.

The goals for a CHARM woman's first visit to COGS for prenatal care are to confirm the pregnancy; assess the woman's opioid use disorder and whether she needs MAT; assess her nutrition status and refer her to WIC for nutrition support, if needed; and begin assessing her social support needs. Most CHARM women receive referrals for home-based well-baby services. If the pregnancy and/or opioid use disorder is not confirmed, the woman is referred to other services based on her needs, and the family is not added to the CHARM client list.

CHARM women can also receive prenatal care from community-based obstetricians or primary care providers. The number of CHARM women receiving prenatal services from non-COGS providers is growing, as the number of providers receiving training and improving their competency in using MAT during pregnancy increases. In some cases, women receive early prenatal care from community providers and transfer to COGS later in the pregnancy for closer monitoring and coordinated care.

Prenatal Care at COGS

The COGS Team

Four staff members provide services to CHARM women at COGS: a physician, a registered nurse, a medical assistant, and a medical social worker. All four staff members work to engage and retain the pregnant women with opioid use disorders in prenatal care and substance abuse treatment, including MAT. Two of the four COGS staff members attend CHARM meetings every month.

The physician has in-depth knowledge of addiction through years of experience and a close association with a physician who has specialized in addiction medicine. The physician attends relevant conferences and continuing education events. In the early days of the CHARM Collaborative, all CHARM women received a consultation with the addiction medicine specialist. Currently, the obstetrician requests consultations with the addiction medicine specialist only for complicated or unusual situations.

The nurse communicates regularly with the CHARM facilitator. The nurse also coordinates information dissemination and services for CHARM families with the physician, medical assistant, and social worker.

The medical assistant generates lists of new patients for the facilitator each month and identifies families to be discussed by the COGS team at monthly CHARM meetings.

The medical social worker coordinates medical care, substance abuse treatment, social supports, and nutrition services for CHARM families. She also educates parents about CHARM and requests a signed release-of-information form from families that enroll in the program. She relies on the CHARM meetings to efficiently coordinate services with other providers for CHARM clients.

CHARM Services Provided at COGS

CHARM women receive prenatal care services at COGS, and the frequency of these visits depends on gestational age and whether the women have complications that need monitoring. In addition to standard prenatal care, each visit includes giving a urine drug test; monitoring the attendance of

prior prenatal visits; offering substance abuse counseling; scheduling NeoMed and home-visiting appointments; and assessing social support needs regularly, including housing, transportation, and mental health services. All CHARM women are tested for HIV, gonorrhea, chlamydia, and hepatitis B and C at their first visit to COGS. COGS offers CHARM women hepatitis B immunizations after the first trimester. The women are tested again for gonorrhea and chlamydia at 28 weeks of gestation and for hepatitis C during the third trimester. The women are also given a group B streptococcus test at 35 weeks.

COGS team members also encourage the partners of CHARM mothers to seek substance abuse treatment when needed and can assist in coordinating referrals and assessments for them. The COGS team refers CHARM women to services and supports as needed or documents these needs to discuss at the next CHARM meeting.

At each prenatal visit, the physician, nurse practitioner, medical assistant, and social worker monitor the woman's behavior for indications of a relapse or a need to adjust the MAT dosage. The COGS team can adjust MAT doses immediately, when needed, for women receiving MAT at COGS. For women receiving MAT from another provider, COGS staff contact that provider immediately, without waiting for the next CHARM meeting.

Women receive an ultrasound during an early prenatal care visit. Seeing the baby is often a significant motivator for women to protect their health and stay engaged in substance abuse treatment. The ultrasounds also allow the physician to identify any anomalies in the fetus. Additional ultrasounds are done each trimester.

MAT

CHARM women have several options for receiving MAT during pregnancy. If a pregnant woman is already stable on MAT, she is likely to stay with the same MAT provider throughout her pregnancy. However, most pregnant women are not stable on MAT when they come to the attention of the CHARM Collaborative.

A MAT assessment is typically completed at COGS or a methadone clinic in accordance with the Vermont MAT guidelines for pregnant women. For providers who are determining whether to prescribe buprenorphine or methadone, the Vermont guidelines recommend basing the decision on the answers to several questions, such as:

- Is the woman able to take medication consistently on her own?
- Is she able to follow safety procedures?
- Does she need a high level of structure to be successful in complying with the medication prescription (and is it helpful to require her to go to the clinic every day to receive methadone)?
- What is her living situation?
- Which medication does she prefer?

Treatment of Opioid Dependence in Pregnancy, Vermont Guidelines

A consolidated set of recommendations for the management of opioid use disorders during pregnancy. Developed by the Vermont Child Health Improvement Program. Available at: <https://www.uvm.edu/medicine/vchip/?Page=perinataltools.html>

Methodone

Burlington and the surrounding areas have one primary methadone provider. This methadone clinic was the first to open in Vermont, and its medical director is the addiction-certified physician who advocated for MAT for pregnant women prior to the existence of CHARM.

Induction on methadone can be provided to CHARM women on an outpatient basis at this clinic or at the hospital over a 2- or 3-day admission, if needed for medical reasons. The dosage is adjusted frequently, until the women are stable and relatively symptom free. After the induction period, the provider adjusts the dosage as needed, based on patient reports and observed behavior. At first, patients must visit the clinic daily for dosing. As of January 2013, in accordance with federal regulations, women can receive their doses on a weekly basis, once their condition is stable.

Buprenorphine

Most CHARM women with a buprenorphine prescription receive the medication from the COGS clinic on a weekly basis. Due to a statewide initiative implemented in 2013, known as the Hub and Spoke Initiative (see *Attachment C: Hub and Spoke Initiative*), CHARM women can also receive buprenorphine from the state's methadone clinic or other community-based providers. Buprenorphine induction by COGs takes place during a 24-hour hospital admission.

CHARM Release-of-Information Form

Following a woman's induction and initial stabilization with MAT, a CHARM member (at COGs or the methadone clinic) informs her about the CHARM Collaborative and requests her signature on a comprehensive release-of-information form. By signing this form, the woman becomes a CHARM client. The vast majority of eligible women sign the information-release form.

The small number of women who choose to not participate in CHARM receive the same care from most of the same providers as CHARM participants but with only standard care coordination. The service needs, health, and recovery progress of non-CHARM women are not discussed at CHARM meetings until 30 days before their expected due date. At that time, if any group member has concerns about the safety of a patient's baby, that group member submits a report to VDCF, and the group operates under its authority as an empaneled child protection team, in compliance with all relevant information-sharing protocols. As providers develop relationships and build trust with women not enrolled in CHARM and their families, the providers continue sharing information about the CHARM Collaborative, and many of the pregnant women with opioid use disorders ultimately agree to participate.

The Hub and Spoke Initiative

(<http://healthvermont.gov/adap/documents/HUBSPOKEBriefingDocV122112.pdf>) is a coordinated, systemic response to the complex issues of opioid and other substance abuse disorders in Vermont. The Vermont Agency of Human Services and community providers developed this initiative jointly.

Substance Use Disorder Counseling

All CHARM women who receive MAT must also receive substance use disorder counseling and nonpharmacological substance use disorder treatment. Both group and individual treatment are

provided to CHARM women through programs at the Chittenden Clinic, Fletcher Allen Health Care Hospital, Lund's residential care program, and other community-based treatment providers. CHARM Collaborative members treat lack of engagement in substance use disorder counseling as a risk factor for poor birth outcomes for CHARM women, even if the woman continues receiving MAT. Collaborative members emphasize the importance of substance use disorder counseling with families and make every effort to keep women engaged and actively participating in this component of their treatment.

Lund is a comprehensive treatment center and family-support agency that offers an array of integrated services in response to the needs of pregnant or parenting teens and women, adoptive families, and children. Lund is an active member of the CHARM Collaborative, providing residential care for women and their babies when that level of treatment is indicated and providing outpatient substance use disorder counseling to many CHARM women.

Neonatal Consultation

An important component of the CHARM process consists of prenatal visits to NeoMed, where providers focus on educating women about the health and safety of their newborn; on building a relationship; and on establishing trust among NeoMed staff, the woman, and her family. The COGS clinic staff refer CHARM women for one or two prenatal consultations with the NeoMed providers. COGS clinic staff strongly encourage the women to complete these visits, including sometimes accompanying CHARM women to NeoMed to schedule the appointment.

The NeoMed provider meets with each expectant CHARM woman to discuss the importance of prenatal care, what to expect from a newborn, optimal care of the newborn, the potential for neonatal abstinence syndrome (NAS), and what NAS assessment and treatment for the woman's infant might require. When discussing care for the infant, the provider and expectant mother talk about the importance of skin-to-skin contact, breastfeeding, and a low-stimulus environment, with low lighting and noise levels and few visitors. The provider and client also discuss the woman's fears, concerns, strengths, and goals.

Each family receives an "Our Care Notebook," with resources, information, personal stories, and encouragement. A quality improvement project at the University of Vermont, called Improving Care for Opioid-Exposed Newborns (ICON), created the Our Care Notebook, with the help of several women who had been served by the CHARM Collaborative. The ICON team also included previous COGS staff and NeoMed staff.

Collaborative members consider participation in one or more prenatal NeoMed consultations to be a protective factor for infant well-being. Women receiving prenatal care from the COGS clinic are more likely to attend prenatal visits than those who receive prenatal care elsewhere.

Our Care Notebook

This notebook for mothers of opiate-exposed newborns provides information, lists of resources, stories, and encouragement. It is available for other communities to customize at <https://www.uvm.edu/medicine/vchip/?Page=perinataltools.html>

Involvement of the Child Welfare System During Pregnancy

If CHARM women are stable, their pregnancy has no complications, and no concerns exist about the safety of the baby, the family is discussed at only two CHARM Collaborative meetings—when the family first enters the program and again within 30 days of the woman’s due date. A woman is considered stable when she is taking the prescribed MAT with no problems and is attending counseling and prenatal visits. The brief discussion of the woman and her family at the second CHARM Collaborative meeting (within 30 days of due date) is to confirm the lack of safety concerns. At that point, if no safety concerns have been identified, the labor and delivery team is alerted and no further actions are taken. VDCF is aware of all families served by the CHARM Collaborative. If no concerns have arisen regarding a CHARM woman’s infant, VDCF does not conduct a safety risk assessment of that woman and her family.

If a CHARM woman is not stable on MAT, continues to use illegal substances during her pregnancy, is not attending substance use disorder counseling or prenatal visits, and/or does not have a safe and stable living situation, the safety of her baby becomes a concern. Depending on the level of concern, CHARM Collaborative members might refer the case to VDCF prior to the baby’s birth and/or refer the woman and her child(ren) to a residential care facility for more intensive treatment and greater structure and safety.

In Vermont, unlike most other states, the child welfare system can initiate a safety and risk assessment prior to a woman’s due date. If VDCF receives a report of prenatal substance exposure or a pregnant woman admits using illegal drugs or nonprescribed medications during the third trimester, the agency places the report on a “high-risk” calendar. At 30 days prior to the expected due date, VDCF initiates a risk and safety assessment, and if indicated, a caseworker begins providing supportive services to the family.

Women served by the CHARM Collaborative receive frequent drug tests. If a woman has had multiple positive test results, a collaborative member typically submits a report to VDCF before the third trimester.

Collaborative members consider the implementation of the state policy of allowing early safety and risk assessments to be conducted to be one of the most significant and beneficial system-level changes that have resulted from CHARM. VDCF workers can create safety plans, provide services, and when necessary, arrange alternative placements well in advance of hospital discharge for new mothers. This minimizes the need for emergency custody orders and improves service planning with families and providers.

The child safety assessments of families affected by prenatal substance exposure are completed using the same protocol as that used for all families reported to VDCF for any reason. Similarly, the individualized child safety interventions provided to CHARM families of infants with prenatal substance exposure or parental prescriptions for MAT are the same as those provided to other families. CHARM Collaborative members may share the results of safety assessments and intervention plans with other collaborative members, and all members who are working with a family share their observations regarding the family’s progress, success, concerns, and needs.

Early Intervention

CHARM Collaborative members consider the provision of services by the child welfare system 30 days prior to the child’s birth to be one of the most significant and beneficial system-level changes that the collaborative has made.

C. During Birth and the Hospital Stay

Services Provided at Birth

CHARM women may give birth in any hospital, but most deliver at Fletcher Allen Health Care Hospital in Burlington. The CHARM facilitator alerts all collaborative members of expected deliveries within the next 30 days. The hospital social worker contacts VDCF if any child safety concerns arise at the time of birth. In most cases, the identification and planning of the needs for alternative placements for the baby or additional supports for families to adequately care for the baby take place prior to labor and delivery.

Labor and delivery protocols are the same for all women giving birth at this hospital, except that the focus on pain control increases, because women taking buprenorphine or methadone often experience higher levels of pain during childbirth. Medical providers report no evidence of drug-seeking behavior during labor and delivery for CHARM women.

Hospital staff do not screen all CHARM mothers or newborns at birth for illegal substance use or exposure. CHARM women undergo regular drug tests, so screening at birth would not provide any new information. Toxicology screening for women and newborns who are not part of the CHARM Collaborative is ordered by the attending pediatrician or neonatologist, based on observed behavior in the mother and/or withdrawal symptoms in the baby.

If hospital staff suspect substance use in a mother and exposure in a baby who are not part of CHARM, they speak with the mother about their concerns. Depending on the response, staff might order a toxicology screen of the mother. If her results are positive for an illegal or nonprescribed substance, hospital staff submit a report to VDCF, who completes a child safety assessment. If the mother denies use of illicit or nonprescribed substances during pregnancy and concerns about the baby remain, a toxicology screen may be ordered for the baby. Parental permission is not required in this situation. If the results are positive, a report is submitted to VDCF, and the hospital social worker meets with the mother to discuss the toxicology test results and the implications of the report to VDCF. The social worker describes the CHARM Collaborative and asks the woman to sign the comprehensive release-of-information form and enroll in the CHARM program.

Infant Care, NAS Assessments, and Treatments

All CHARM newborns stay in their mother's room after birth. CHARM mothers are encouraged to use nonpharmacological treatments for their infants' withdrawal symptoms, including skin-to-skin contact, breastfeeding, and a low-stimulus environment (i.e., low levels of light and noise and few visitors).

CHARM infants typically stay in the hospital for 4–6 days and are cared for by hospital pediatricians or the mother's own pediatrician, if that individual has hospital privileges. A nurse or medical assistant from NeoMed visits each CHARM mother in the hospital to hand deliver a NeoMed appointment slip for one or two weeks after discharge. These staff also mail an appointment reminder to the woman's home. The NeoMed medical professional does not meet the baby until the woman's first visit to the clinic, unless the baby has complications.

Toxicology Screening at Birth

Eliminating duplicative and unnecessary drug tests reduces stigma, improves collaborative practice, and decreases costs.

Hospital nurses assess all CHARM newborns for NAS, using a scoring tool based on the Finnegan Neonatal Abstinence Scoring System (Finnegan, Connaughton, Kron, & Emich, 1975). Assessments begin at two hours after birth and continue every three to four hours for the first 96 hours until discharge, or if the infant receives a NAS diagnosis, until treatment begins and the infant's condition is stable on medication. Through a quality-improvement project led by ICON, nurses teach parents to observe and monitor symptoms of withdrawal in their infants and encourage the parents to participate in the NAS assessments during the hospital stay.

Between June 2009 and December 2012, 76.7 percent of CHARM babies (365 of 476) did not require pharmacological treatment for withdrawal symptoms (Borden, 2013).

Newborns diagnosed with NAS are treated with methadone and remain in the hospital until their withdrawal symptoms are safely managed. Their average length of stay is the same as for newborns with no need for methadone treatment (4–6 days). Some newborns complete methadone treatment and are weaned from it by the time they leave the hospital. Most parents in stable recovery for whom there are no child safety concerns and who have infants needing treatment after discharge continue administering treatment at home. Parents are trained to administer methadone to their infants and must demonstrate the ability to measure the correct dosage before leaving the hospital and at each NeoMed appointment. Parents continue to monitor their baby for withdrawal symptoms, and the NeoMed provider gives the family a weaning schedule to follow at home.

Parents may call NeoMed staff with questions or concerns at any time. CHARM Collaborative members believe that this high level of support is a critical component of the success of the collaborative. NeoMed staff do not recommend that other hospitals give parents responsibility for administering methadone to a newborn at home unless a similar mechanism is in place to provide immediate support by telephone at all times.

Involvement of VDCF and Courts at Birth

The VDCF directs caseworkers to assess mothers when any of the following circumstances occur before, at, or shortly after birth:

- An infant has been born with a positive toxicology screen for illegal substances or prescription medication not prescribed to the patient or administered by a physician;
- A physician certifies or the mother admits to using illegal substances or nonprescribed prescription medication during the last trimester of her pregnancy; or
- Using NAS scoring, a medical professional has deemed an infant has NAS as the result of maternal use of illegal substances or nonprescribed prescription medication (VDCF, 2011).

Reports to VDCF under these circumstances lead to safety assessments, and the results are used to determine whether a case is opened for ongoing child welfare services. The Federal Child Abuse Prevention and Treatment Act requires states to implement policies and procedures to notify child protective services agencies of newborns with prenatal substance exposure. In accordance with the Child Abuse Prevention and Treatment Act of 2010, VDCF develops a plan to provide safe care for these newborns. In Burlington, the plan of safe care is collaboratively developed with VDCF and medical staff and social workers at the hospital.

VDCF may open a case for ongoing services, without court involvement, based on the results of the safety and risk assessment. As soon as a case is opened, VDCF begins providing services to the family. Services might include linkages to home-visiting services; substance use disorder treatment, if the mother is not already receiving treatment; residential placement for the mother and baby; or

alternative placement for the baby, if needed. The VDCF worker also informs the family about the CHARM Collaborative and encourages the mother to sign the comprehensive release-of-information form to obtain access to coordinated care. If VDCF seeks custody of the child or a protective order, the courts become involved and standard child welfare and legal practice is followed. In this situation, the VDCF worker may convey relevant updates, progress, and concerns from CHARM Collaborative members to the judge.

D. Infant, Postpartum, and Ongoing Services

Services for Children After Hospital Discharge

All CHARM women are expected to bring their infant for regular visits to NeoMed until the child is 12–18 months old. The first appointment takes place one or two weeks after the baby's discharge from the hospital. Newborns receiving methadone treatment are scheduled for visits every two weeks, visits are less frequent for newborns not on methadone treatment. During these appointments, a health care provider measures the baby's weight and size; conducts a physical examination; monitors the infant's growth and development; and reviews the mother's MAT dose, receipt of substance abuse counseling, and needs for other family supports. In addition, the provider delivers parenting education. The parents of newborns receiving methadone treatment at home must bring the methadone to each appointment so that health care providers can measure the remaining amount. Parents must also demonstrate the ability to measure the correct dosage for their baby.

A community-based pediatrician or primary care provider is responsible for well-baby visits and illnesses not related to prenatal exposure. If safety concerns for the baby arise at any time, NeoMed staff and/or the pediatrician report the concerns to VDCF. NeoMed staff also share their concerns at CHARM meetings.

Services for Women and Families

The COGS clinic provides services to CHARM women for eight weeks after delivery for follow-up care. After that time, the women receive ongoing care from a community-based obstetrics and gynecology clinic or a primary care provider. Women who received buprenorphine from the COGS clinic also need to transfer to a new MAT provider. The COGS clinic helps women to find new providers and make appointments.

A current challenge for the CHARM Collaborative is finding a new provider who will accept women transitioning from the COGS clinic as clients. Vermont's MAT capacity is limited, and the state requires MAT providers to give priority to pregnant women needing MAT. Once a woman has given birth, she loses priority access. CHARM women who received MAT from clinics other than COGS can usually continue doing so without changing their provider after the neonatal period.

Involvement of Child Welfare System and Courts

VDCF does not contact CHARM families who are stable and providing safe care for their infant. If safety concerns are reported to VDCF about a CHARM family, the department conducts safety assessments, opens child welfare cases for these families when appropriate, and creates treatment plans, using the same protocols it uses for families not enrolled in CHARM.

CHARM families have more contact with more providers than typical VDCF families. As a result, providers serving CHARM families and the CHARM Collaborative team give VDCF more information about CHARM families than is typically available for non-CHARM families on which to base case planning and permanency decisions. Court proceedings for CHARM families, when needed, also follow standard practices. Judges benefit from having more complete information on women involved with CHARM, as it is more than they typically receive on women not involved with CHARM.

E. Elements of System Linkages

An intensive collaborative effort like CHARM is necessary to address the complex needs of women with opioid use disorders during pregnancy and their families. Developing a successful and sustainable collaborative requires commitment from multiple agencies and a coordinated multiyear effort. The CHARM Collaborative is an example of a highly successful collaborative that has developed and implemented multiple elements of system linkages. The practice elements of screening and assessment, engagement and retention in care, services to infants, and collaboration with related agencies are described throughout this report.

The CHARM Collaborative also implemented some of the other 10 elements of system linkages described earlier in this report, including the underlying values and principles of collaboration, joint accountability and shared outcomes, information sharing and data systems, budgeting and program sustainability, and training and staff development. This section discusses the importance of each of these elements and how the CHARM Collaborative has addressed them. More information on establishing successful collaborative efforts and technical assistance is available through the publication *Screening and Assessment for Family Engagement, Retention, and Recovery (SAFERR)* from the National Center on Substance Abuse and Child Welfare.

Underlying Values and Principles of Collaboration

CHARM Collaborative members have gained an understanding of the missions and mandates of each partner agency. The values and principles that guide their collaborative efforts are reflected in their MOU (see *Attachment A: CHARM Collaborative Memorandum of Understanding*) and articulated in presentations and training programs provided by members. These values include the common goal of a healthy family, recognition that the formal charge of the collaborative is to ensure child safety, and a commitment to comprehensively support families and ensure the safety of their children.

An important principle of the CHARM Collaborative is acceptance of disagreement without disrupting the process or relationships among members. The group usually agrees on recommendations regarding whether a child will remain at or be removed from the home. However, when one or more members disagree with a group decision about removal of a child, they use an agreed upon process for expressing their dissenting views. According to this process, the disagreement is made known to the group, and the members can write their opinion in a letter to the judge, which becomes part of the family's case file. When CHARM Collaborative members disagree about the need to open a VDCF case, the process is different. The group recognizes that VDCF operates independently from the CHARM Collaborative and is ultimately responsible for child safety. When VDCF representatives decide to open a case based on information shared at a CHARM Collaborative meeting, they inform collaborative members. In the past, VDCF representatives did not always share their decisions with the CHARM Collaborative, a practice that damaged

Collaborative Practice Tool

The Screening and Assessment for Family Engagement, Retention, and Recovery is a collaborative model to help child welfare, substance abuse treatment, and family court professionals make better-informed decisions for children and families affected by substance use disorders: <http://store.samhsa.gov/product/Screening-and-Assessment-for-Family-Engagement-Retention-and-Recovery-SAFERR-/SMA08-4261>.

trust among CHARM Collaborative members. Agreement about how to communicate differing views on significant decisions has enhanced the trust and effectiveness of the CHARM Collaborative.

Joint Accountability and Shared Outcomes

Each CHARM provider monitors and reports the results of outcome measures within his or her agency or institution, but most do not analyze or report data on the subset of women that their agency or institution serves who are enrolled in CHARM. Members share information on outcomes that are relevant to other members of the CHARM Collaborative.

At present, the CHARM Collaborative has no mechanism for consistently monitoring shared outcome measures. If this group is able to identify and monitor shared outcomes in the future, its members might be in a better position to quantify their effectiveness; identify areas that need improvement; and communicate with stakeholders about the ability of the collaborative to achieve efficiencies, save money, or prevent costs. Shared outcome measures for a group like the CHARM Collaborative could include indicators of child well-being and safety, infant health and development, and parental engagement in treatment and maintenance of recovery.

Examples of relevant outcome measures come from a study led by a COGs obstetrician (Meyer, et. al., 2012). This study found that increased access to MAT for pregnant women improved infant health outcomes and allowed more infants to remain with their mothers.

Information Sharing and Data Systems

Shared information is a prerequisite for joint accountability. Joint information systems form the basis for communicating across systems and are necessary to track progress toward shared goals. Effective communication and information sharing provide the guideposts to gauge the effectiveness of the programs in the CHARM Collaborative.

The ubiquity of electronic medical records provides communities that are developing a new collaborative with more opportunities to create secure information sharing systems than the CHARM Collaborative founders had a decade ago. Groups can determine early in their development which information each partner needs and when. Establishing a secure and efficient mechanism to share, monitor, and protect client information then becomes possible. A formal MOU and/or information-sharing agreement signed by all members is necessary for effective and appropriate exchange of client information.

CHARM Collaborative members share information on clients who have signed a comprehensive release-of-information form. For clients who have not signed the form, collaborative members share information as an empaneled child protection team in compliance with state statute. The release-of-information authorization allows collaborative members to discuss the needs of each family during their monthly meetings and to exchange health and safety information in between

“As we [VDCF] learned more about medication-assisted treatment, about all the support these women were getting, like case management through the visiting nurses association, medical follow-up, and medication management, and about the benefits of all this support to the child, it led to a shift in our thinking. Understanding that the CHARM Collaborative provided a comprehensive approach and these women were pretty well monitored helped me feel comfortable that child safety was being attended to.”

- CHARM Collaborative member

meetings. Collaborative members do not share any data electronically because not all members can do so securely. The facilitator records the information that collaborative members share and the decisions members make during their monthly meetings, and members receive paper copies of these notes at the next meeting. The facilitator also shares paper copies of the list of families to be discussed each month at the beginning of each meeting. Each CHARM Collaborative member follows his or her agency's protocols to manage and protect the hard-copy information shared during meetings.

The MOU and the comprehensive release-of-information form that the CHARM Collaborative created effectively address the requirements and restrictions of federal information-sharing regulations. Federal regulations governing the protection of patient records concerning alcohol and drug abuse (Title 42 of the Code of Federal Regulations, Part 2,⁵ and the Health Insurance Portability and Accountability Act of 1996) are often seen as barriers to effective information sharing by community collaboratives. By working across systems and using the services of legal professionals, the CHARM Collaborative was successful in creating protocols and documents that allow members to share information in ways that are effective, legally permissible, and respectful of individual and family privacy and confidentiality. (See *Attachment A: CHARM Collaborative Memorandum of Understanding* and *Attachment B: CHARM Release of Information*.)

Budgeting and Program Sustainability

Cost of the Collaborative

Although no cost studies on the impact of the CHARM Collaborative have been conducted, the staff providing the case management believe that the model allows them to provide higher quality services in less time than would be possible without the collaborative. For example, the program avoids costs by coordinating services for 20 or more families in each 2-hour monthly CHARM Collaborative meeting. Without these monthly meetings, coordinating services for each family would take 15 minutes to several hours each month, so the total case management time required for all of these families would be much greater than two hours. Based on a rough estimate of one hour of coordination time per family per month, the CHARM Collaborative saves 18 staff hours per month. A cost analysis is needed to determine the actual costs of the CHARM Collaborative and how much money it avoids or saves.

About 15 professionals attend each monthly CHARM Collaborative meeting, for a total of 30 staff hours. With the exception of the facilitator, agencies contribute the time of each member to attend the meetings in kind. Some agencies bill the time to third-party payers as case management or case coordination. Others categorize the time as an administrative cost. All participating agencies believe that attendance at these meetings is a cost-effective use of staff time.

Funding for Services

Most CHARM women are eligible for Medicaid during pregnancy. Medicaid covers prenatal care through labor and delivery and for 60 days postpartum. Medicaid eligibility rules vary by state. Most states provide Medicaid benefits to pregnant women, earning up to 185 percent of the federal poverty level. Most CHARM women continue to be eligible for Medicaid as long as the baby remains in their home. If a child is removed from its mother's care, Medicaid continues to cover the medical costs of the baby but not necessarily those of the mother. Loss of Medicaid coverage results in barriers to continued medical care and family planning. In Burlington, women without Medicaid or other health insurance coverage can receive medical care from federally qualified health centers.

⁵ More information on substance abuse confidentiality regulations is available on the SAMHSA website at <http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs> (accessed November 13, 2015)

Funding for MAT and substance abuse treatment services in Vermont has recently changed. In January 2014, the State of Vermont implemented the Hub and Spoke initiative, a new system for the integrated treatment of substance use disorders. The “hubs” are five regional specialty treatment centers, and the “spokes” are more than 150 physician offices around the state, including primary care providers, obstetricians and gynecologists, outpatient substance use treatment providers, and federally qualified health centers. Hubs provide comprehensive assessments and treatment protocols, methadone treatment and supports, initiation of buprenorphine, care coordination and referrals for ongoing care, consultation to physician offices (spokes), and ongoing care for clinically complex patients. The hubs are funded by the state’s Division of Alcohol and Drug Abuse Programs and they provide buprenorphine prescriptions, administration, and monitoring; substance use disorder treatment services, including counseling, contingency management, and access to recovery support; and care coordination. The spokes receive funding from the Vermont Department of Health Access on a fee-for-service basis.

Two CHARM partners are directly involved in the Hub and Spoke initiative. The Howard Center, where many CHARM women receive MAT and substance use disorder treatment, is a designated hub. The COGS clinic, where many CHARM women receive prenatal care and MAT (buprenorphine only), also is a designated spoke. Additional details on the Hub and Spoke initiative are provided in *Attachment C: Hub and Spoke Initiative*.

Sustainability

Staff from member organizations participate in the CHARM Collaborative on an in-kind basis. The only exception is the facilitator from KidSafe. A combination of funding from the state and small local grants supports her role in the CHARM Collaborative. The amount and source of these funds vary from year to year.

Training and Staff Development

Cross-training for CHARM Collaborative staff members is essential at all levels—administrative, management, and line level—to ensure cooperation between key players in the systems. Training needs to be ongoing, and a combination of formal and informal training opportunities works well.

When the CHARM Collaborative began, members provided formal and informal cross-system training for each other as they discussed each family. Founding members of CHARM also attended conferences to broaden their knowledge of practices within their respective fields and across disciplines. CHARM Collaborative members continue to participate in cross-training, typically in the form of 15- to 30-minute sessions before the regular monthly meetings. Training topics are driven by the needs of the group. For example, after an infant death, the state medical examiner gave a presentation to the CHARM Collaborative on the process of investigating a child’s death, and the Department for Children and Families provided CHARM members with training about the requirements for reporting prenatal substance exposure. In addition, ICON annual conferences on care for infants with prenatal opioid exposure are open to all CHARM members. These conferences typically address prevention and best practices for treatment of NAS as well as new research findings on the long-term impact of prenatal exposure to opioids.

F. Summary

Over a 16-year period, the extraordinary commitment of the CHARM Collaborative to a cross-system approach in working with pregnant women with opioid use disorders and their infants has resulted in improvements in practice and better outcomes for clients. The initiative has made possible the provision of a full range of services to families in half of the State of Vermont. The full service array will become available to more families as additional communities replicate the model. The quality of care of these services has improved through collaborative practice, with pregnant women gaining access to MAT and additional services earlier in their pregnancies. At the client level, outcomes have included healthier pregnancies, healthier children, and a greater likelihood that families will remain together or be reunified safely. The lessons learned from the CHARM Collaborative about overcoming barriers to collaborative practice can guide other communities seeking to help pregnant women with opioid use disorders.

Attachment A: CHARM Collaborative Memorandum of Understanding

This Memorandum of Understanding is effective immediately following obtainment of the final signature of the parties listed on Attachment A [hereinafter referred to collectively as the "Parties," or for any one of the Parties, as a "Party"] but no later than the first day of December 2012 excluding any unsigned Parties.

Whereas, the Children and Recovering Mothers Program [hereinafter "CHARM" or the "Program"] is a coalition of service providers serving women with chemical dependency and their children. It is not a separate legal entity.

Whereas, the purposes of CHARM are to coordinate services to meet the needs of pregnant and parenting women with chemical dependency and their children, improve the delivery of services to these women and their children, and identify gaps in services that need to be addressed.

Whereas, an individual participating in CHARM [hereinafter "client participant"] may be provided direct services by any or all of the Parties, in which case that individual becomes a client of each Party that provides such a service.

Whereas, the Parties desire to set forth their understandings with respect to the way in which they will comply with the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 [hereinafter "HIPAA"], federal confidentiality provisions governing substance abuse treatment, and State confidentiality provisions.

Now, therefore, the Parties, acting by and through the undersigned duly authorized agents, hereby agree as follows:

- (1) With respect to all information related to client participants in the Program, each Party agrees to fully abide by the terms and conditions set out in HIPAA, 42 C.F.R. Part 2, 7 C.F.R. § 246.26, and state confidentiality provisions.
- (2) Each Party that is currently subject to HIPAA will continue its practice of being individually responsible for providing HIPAA Privacy Rule protections (including, without limitation, a Notice of Privacy Practices) and state privacy protections to each client participant to whom it provides direct services.
- (3) In order to facilitate the internal case coordination, referral and assessment needs of client participants, each such participant in the Program will be requested to sign a Client Consent for release and sharing of information among the Parties in the form attached to this Memorandum of Understanding as Attachment B (hereinafter the "Client Consent"). The Client Consent, when signed by the client participant, is intended solely for the uses described in it and is not intended to serve as a consent for release of information with respect to any other matter, including, without limitation, treatment, payment, or health care operations, or for disclosure of confidential information to any third party, except as expressly so authorized by that Client Consent.
- (4) Except as otherwise required by state or federal law, each Party specifically agrees to restrict access to and use of any and all information regarding client participants only to those personnel who require access to such information for the purposes set forth in the Client Consent.
- (5) The Parties further agree that, unless otherwise provided by law, any and all information regarding client participants shall not be used or disclosed for any purpose except those specified in the Client Consent.

(6) The Parties recognize that as mandated reporters of suspected child abuse and neglect under the provisions of 33 V.S.A. § 4913, they are required to report any and all incidences where there is reasonable cause to believe that a child has been abused or neglected or is at significant risk of harm to the Family Services Division of the Vermont Department for Children and Families.

(7) This Memorandum of Understanding inures to the benefit of and is binding on the Parties and is intended for the sole and exclusive benefit of the Parties. Nothing in this Memorandum of Understanding shall give rise to or be deemed to give rise to any third party beneficiary rights to any third party, and in particular, but without limitation, this Memorandum of Understanding does not give rise to any third party rights to any client participant.

So entered into by,

<p>Fletcher Allen Health Care</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	<p>Howard Center for Human Services, Inc.</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>
<p>KidSafe Collaborative, Inc.</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	<p>Lund Family Center</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>
<p>Vermont Department for Children and Families</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	<p>Vermont Department of Corrections</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>

<p>Vermont Department of Health</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	<p>Visiting Nurse Association, Inc.</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>
<p>Franklin County Home Health Agency, Inc.</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	<p>Northwestern Medical Center, Inc.</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>
<p>Northwest Counseling and Support Services, Inc.</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	<p>Department of Vermont Health Access</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>
<p>Vermont Agency of Human Services, Field Services Division</p> <p>By _____ Duly Authorized Agent</p> <p>Date _____</p>	

Attachment B: CHARM Collaborative Release of Information

CHILDREN AND RECOVERING MOTHERS (CHARM) PROGRAM CONSENT TO USE AND DISCLOSURE OF HEALTH INFORMATION FOR TREATMENT AND SOCIAL SERVICES

I, _____, date of birth _____, authorize the use and disclosure of my health and treatment information by and among each of the team members of the Children and Recovering Mothers (CHARM) Team, including any individual(s) involved in the direct service or service coordination within each organization. The Children and Recovering Mothers (CHARM) Team members participate from the following organizations:

- Fletcher Allen Health Care
- Northwestern Medical Center
- Visiting Nurse Association, Inc.
- Franklin County Home Health Agency, Inc.
- Lund Family Center
- Northwest Counseling and Support Services, Inc.
- Howard Center (including the Chittenden Clinic and Rocking Horse Program)
- KidSafe Collaborative
- Vermont Agency of Human Services: Department of Health, Department for Children and Families (including Children's Integrated Services), Department of Corrections, Department of Vermont Health Access, and Agency of Human Services Field Services Division

The means of this use of disclosure may be written, verbal or electronic.

I understand that the purposes of the CHARM Team are to evaluate the need for and facilitate the coordination of medical services, substance abuse treatment services, and social support services in order to best provide for the safety of my child and to support my successful treatment during pregnancy and post-partum.

I authorize the use and disclosure of my health and treatment information and that of my child by and among the participating organizations of the Children and Recovering Mothers (CHARM) Team solely for these stated purposes.

The health and treatment information that will be shared may include the following:

- Name, date of birth
- Address, phone number(s)
- Antenatal and post-partum medical care and treatment provided to me and my child(ren)
- Pregnancy and delivery
- Psycho-social history
- Current living situation
- History and attendance at alcohol/drug treatment, including methadone maintenance, and mental health services
- Lab test results, including drug testing
- Mental health and/or drug and alcohol assessment, diagnosis, treatment, progress and discharge summary (if applicable)
- Children's health and safety assessments
- WIC program participation history
- Department for Children and Families history of involvement
- Criminal history and/or current involvement with Department of Corrections
- Other (specify) _____ .

ADDITIONAL PROVISIONS CONCERNING YOUR CONSENT:

I understand that my alcohol and/or drug treatment records are protected under federal statutes and regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, including 42 C.F.R. Part 2, and my personal health information is protected by the Health Insurance Portability and Accountability Act of 1996 ["HIPAA"], 45 C.F.R. Pts. 160 & 164, and in some cases by 7 C.F.R. § 246.26, and such information cannot be disclosed without my written consent unless otherwise provided for in these provisions.

I also understand that my decision to use the services of the Children and Recovering Mothers (CHARM) Team is voluntary. My signature indicates that I understand the important information provided in this Consent. I may end CHARM Team services at any time.

I understand that if I want members of the CHARM Team to disclose information about me or my child to someone other than the members of the CHARM Team, I will need to sign a separate Consent or Authorization to release such health and treatment information for each party to whom such information is disclosed, except as specifically described below.

I further understand that if any of the members of the CHARM Team or the participating organizations want to use or disclose any information regarding me or my child for a purpose other than that described in this Consent form, except information required by law pertaining to the mandatory reporting of suspected child abuse or neglect, that member or participating organization must obtain my written permission, stating the purpose of the consent, prior to using or disclosing that information.

I also understand that I may request restrictions on the use or disclosure of treatment records. I understand that the CHARM Team will consider my request but is not bound to agree to it in

which case I may decline to participate with the CHARM Team. However, my refusal to be involved with the CHARM Team will not affect my ability to receive services from the individual participating organizations.

I further understand that generally the participating organizations may not condition my treatment with them on whether I sign a consent form, but that in certain limited circumstances, I may be denied treatment with them if I do not sign such a form.

I may revoke this Consent at any time by notifying any member of the Children and Recovering Mothers (CHARM) Team, but revoking this Consent will not affect any actions that were taken by the CHARM Team or its participating organizations before I revoked it.

This Consent will remain in effect for the period while I receive services and for thirty (30) days after the termination of services by the last participating organization on the CHARM Team providing services to me unless I choose to terminate it on the following date, or as a result of the following event or condition: _____ .

I understand that the Vermont Department for Children and Families [DCF] may currently have opened, or in the future may open, a child protection case that involves me or my child. If so, I specifically authorize the DCF representative on the CHARM Team to disclose and/or re-disclose health and treatment information about me: (1) to other employees of DCF who have a need to know such information; and (2) to the Vermont Family Court and any party to a juvenile proceeding which involves me or my child brought under Chapters 51–53 of Title 33 of the Vermont Statutes.

I have read all of the above information, and I understand its contents and consent to the disclosure and/or re-disclosure of the confidential information identified above to the participating organizations and staff members of the CHARM Team for the purposes specified.

_____ Name of Patient (Please Print)	_____ Date
_____ Signature of Patient (18 and over or Emancipated Minor) or Signature of Parent/Guardian or Legal Representative	_____ Date
_____ Witness: Name and Title	_____ Date

This Consent to Release Information will be kept on file by the KidSafe Collaborative (Community Network for Children, Youth and Families, Inc.) or by another authorized organization on behalf of the CHARM team, unless revoked by the client or terminated as specified in this agreement.

Rev.: <input type="checkbox"/>	Date: _____
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Attachment C: Hub and Spoke Initiative



VERMONT
AGENCY OF HUMAN SERVICES

January 2012

Integrated Treatment Continuum for Substance Use Dependence “Hub/Spoke” Initiative—Phase 1: Opiate Dependence

Current State of Prescription Drug Abuse and Treatment in Vermont

Prescription drug abuse is the nation’s fastest-growing drug problem. While Vermont is consistently ranked the “healthiest state” by many measures, it ranked 34th worst of all the states in the non-medical use of pain relievers. Other opiates overtook heroin in 2006 as the primary source of opiate addiction. In addition, drug diversion continues to be a problem for many reasons, including illegal sale and distribution, “doctor shopping,” forged prescriptions, employee theft, pharmacy theft, and obtaining prescriptions over the internet.

The Agency of Human Services (AHS) is collaborating with community providers to create a coordinated, systemic response to the complex issues of opiate and other addictions in Vermont. Medication assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Research shows that when treating substance-use disorders, a combination of medication and behavioral therapies is most successful.

Although this initiative initially focuses on medication assisted treatment for individuals with opiate addictions, it creates a framework for integrating treatment services for other substance abuse issues and co-occurring mental health disorders into the medical home through a managed approach to care. In addition, this treatment approach will help reduce recidivism in corrections and enhance outcomes for families where addiction is an identified problem for child welfare.

Each year, more Vermonters seek treatment for opiate addiction. (Figure 1) The majority of MAT patients receive buprenorphine as prescribed by a physician in a medical office setting. Methadone, unlike buprenorphine, is a highly regulated treatment provided in specialty clinics.

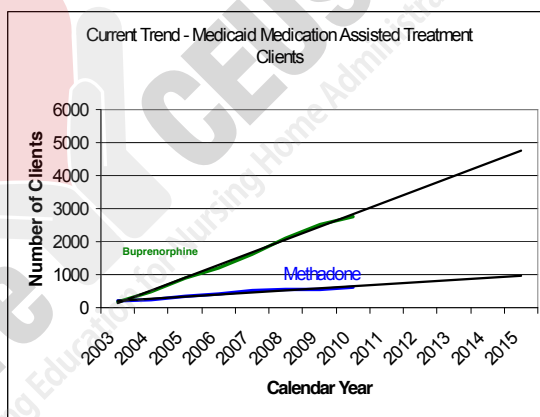


Figure 1

Waiting lists for methadone indicate insufficient treatment capacity and fewer providers are willing to prescribe buprenorphine for new patients.

Overall health care costs are approximately three times higher among MAT patients than within the general Medicaid population. In addition to the costs directly associated with medication assisted therapy, these individuals have high rates of co-occurring mental health and other health issues and are high users of emergency rooms, pharmacy benefits, and other health care services.

	<u>Medicaid Population*</u>	<u>Buprenorphine Clients</u>	<u>Methadone Clients</u>
Total People Served	146,030	2801	614
Annual Per Capita Cost	\$4,553	\$12,985	\$13,523
Total Expenditures	\$561,221,169	\$36,372,106	\$8,303,369

*less top 5% high cost, maternity and neonate

Opiate Addiction Treatment

Medication assisted therapy (MAT), such as methadone and buprenorphine in combination with counseling, has long been recognized as the most effective treatment for opiate addiction. These medications suppress the craving for opiates, thereby reducing relapse. Effective MAT programs also provide services such as mental and physical healthcare, case management, life skills training, employment, and self-help. The length of the course of treatment is individually determined according to patient need and criteria. MAT services are cost effective over time because they help stabilize the health of patients, increase their rate of employment and decrease involvement in the criminal justice system.

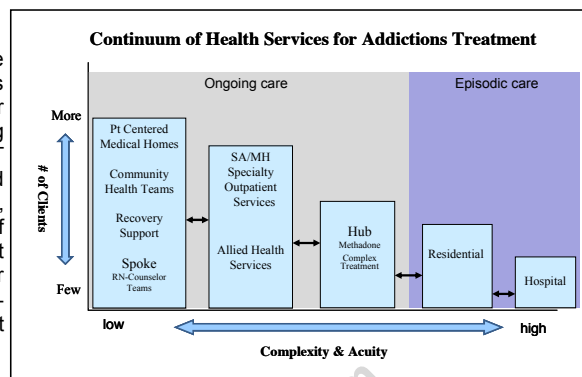


Figure 2 illustrates how opiate addiction treatment is integrated into the current health and substance abuse treatment continuum of care.

Figure 2

Solution: Implement a “Hub and Spoke” System to Provide Appropriate Care

“HUB”

A *Hub* is a specialty treatment center responsible for coordinating the care of individuals with complex addictions and co-occurring substance abuse and mental health conditions across the health and substance abuse treatment systems of care. A *Hub* is designed to do the following:

- ◆ Provide comprehensive assessments and treatment protocols.
- ◆ Provide methadone treatment and supports.
- ◆ For clinically complex clients, initiate buprenorphine treatment and provide care for initial stabilization period.
- ◆ Coordinate referral to ongoing care.
- ◆ Provide specialty addictions consultation and support to ongoing care.
- ◆ Provide ongoing coordination of care for clinically complex clients.

“SPOKE”

A *Spoke* is the ongoing care system comprised of a prescribing physician and collaborating health and addictions professionals who monitor adherence to treatment, coordinate access to recovery supports, and provide counseling, contingency management, and case management services. *Spokes* can be:

- ◆ Blueprint Advanced Practice Medical Homes
- ◆ Outpatient substance abuse treatment providers
- ◆ Primary care providers
- ◆ Federally Qualified Health Centers
- ◆ Independent psychiatrists

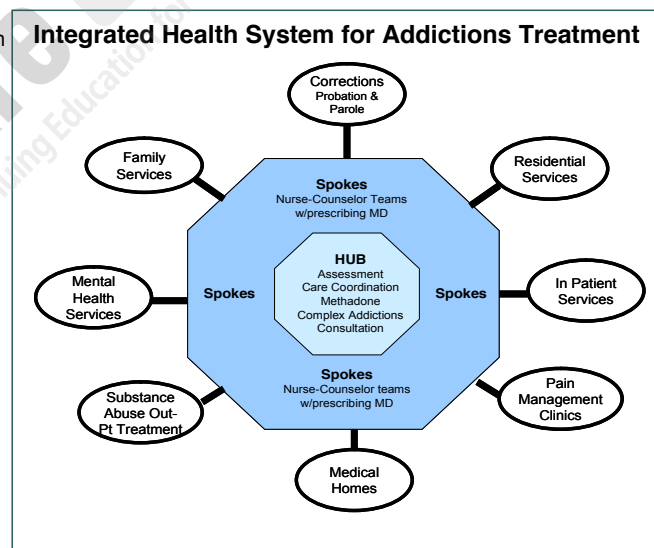


Figure 3 outlines the components of the system.

Figure 3

Caseload and Cost Model, Phase 1: Opiate Dependence - SFY 2013 & 2014

Projected Caseloads. To help determine the growing demand for treatment, caseload projections for SFY 2013 and SFY 2014 were based on actual buprenorphine growth trends from 2003-2010. Using risk stratification, 65% of cases are apportioned to the “spokes” and 35% to the “hubs.” Estimated caseloads are:

- ◆ SFY 2013: 4,753
- ◆ SFY 2014: 5,323

This represent significant growth over the SFY2011 case load of 3,415 Vermonters receiving medication assisted treatment.

Cost Modeling.

(1) Statewide system investments:

- ◆ Expand methadone treatment capacity statewide.
- ◆ Support five geographically distributed specialty addiction treatment centers.
- ◆ Support buprenorphine prescribers by augmenting Community Health Teams with nurses and substance abuse/mental health counselors.

(2) Staffing and operating expenses determined with provider and other stakeholder involvement:

- ◆ HUB: 21.7 FTE (clinical, lab, support staff, facility, security, etc.) per 400 patients served.
- ◆ SPOKE: Two FTE licensed clinicians (1 RN and 1 licensed mental health/substance abuse clinician) per 100 patients.

(3) Initial system offsets and sustainability:

- ◆ New system costs are offset by ADAP’s existing appropriation and DVHA’s current spending on the MAT population.
- ◆ DVHA will reinvest savings from improved care coordination and an enhanced federal match to sustain the new system.
 - ACA 2703 enhanced federal match: 90/10 for eight quarters where new initiative is implemented.
- ◆ Estimated reductions in health care savings in select high cost / high use categories such as pharmacy, inpatient, emergency room, lab, and residential treatment.
- ◆ Additional societal impacts and savings anticipated in areas such as corrections, employment, and children in custody (will be identified as part of evaluation design).

Total Costs. New system is cost neutral for first two years (SFY 2013-2014).*

* Assumes approved State Plan Amendment under ACA Section 2703 for Health Homes and SFY 2013 ADAP appropriation request.

	<u>2013</u>	<u>2014</u>
<i>HUB & SPOKE TOTAL:</i>	\$11,411,052	\$ 18,364,691
ADAP net of appropriation:	\$ 2,886,749	\$ 6,368,371
DVHA Investment net of new costs:	<u>\$ 1,249,311</u>	<u>\$ 1,704,907</u>
TOTAL NEW SYSTEM COSTS:	\$ 4,136,059	\$ 8,073,278
State Share:	\$ 35,411	\$ 13,239
Federal Share:	\$ 4,100,649	\$ 8,060,039

Caseload and Cost Model, Phase 1: Opiate Dependence - SFY 2013 & 2014

Blueprint Health Care Reform Integration: New system approach aligns with Blueprint Advanced Primary Care Practices and Community Health Teams (Figure 4).

VERMONT Agency of Human Services
Proposed Integrated Health System for Addictions Treatment

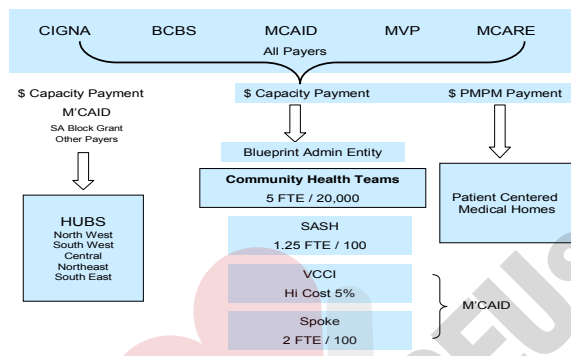


Figure 4

Evaluation:

- ◆ Design evaluation before implementation begins.
- ◆ Flag participants of “Hub and Spoke” services in VHCURES all payer data base.
- ◆ Create an addictions measure set in DocSite for care and evaluation.
- ◆ Include AHS partners and subject matter experts in building evaluation model.
- ◆ Include required ACA 2703 evaluation components (utilization, savings, outcomes, ROI, etc.).

VERMONT Agency of Human Services
Proposed Integrated Health System for Addictions Treatment
 Information & Evaluation

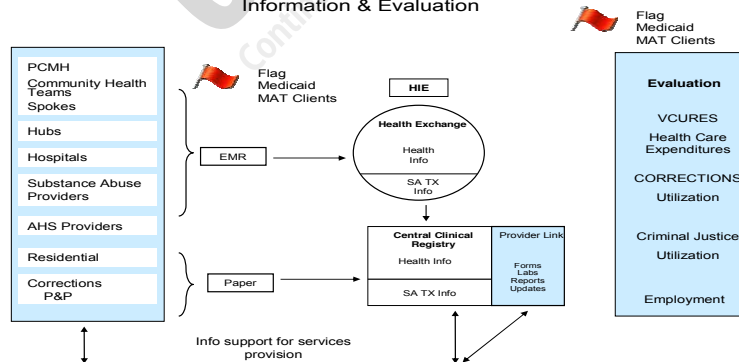


Figure 5



“This course was developed from the public domain document: Substance Abuse and Mental Health Services Administration. A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders. HHS Publication No. (SMA) 16-4978. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2016. Available at: <http://store.samhsa.gov/>.”