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Before You Write Your First Buprenorphine Prescription; A Readiness-Assessment for Prenatal Care Providers

Melinda A Ramage[1], Emma H Blake[2*], Casey R Tak[3,4], Margaret H Sullivan[1,6], Sylvia V Kauffman[5], Shelley L Galvin[1,7] and Hendrée E Jones[7]

[1]Department of Obstetrics and Gynecology, Mountain Area Heath Education Center, Asheville, NC, United States
[2]Davidson College, Davidson, NC, United States
[3]Eshelman School of Pharmacy, The University of North Carolina at Chapel Hill, Chapel Hill, NC, United States
[4]UNC Health Sciences at MAHEC, Asheville, NC, United States
[5]Department of Family Medicine, Mountain Area Health Education Center, Asheville, NC, United States
[6]Mission Hospital McDowell, Marion, NC, United States
[7]Department of Obstetrics and Gynecology, School of Medicine, The University of North Carolina at Chapel Hill, Chapel Hill, NC, United States

***Corresponding author:** Emma H Blake, Davidson College, Davidson, Opioid Response Team at MAHEC, 123 Hendersonville Road, Asheville, NC 28803, United States, Tel: 8043473515, E-mail: emma.blake@mahec.net

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Abstract

As the prevalence of opioid use disorders has increased in the general population, it has also increased among pregnant patients. The standard of care for opioid use disorder in pregnancy is a combination of obstetrical care and treatment with medications for opioid use disorder (MOUD), ideally in one clinic. This article introduces a toolkit to serve as a readiness-assessment for prenatal care providers to identify their practice's service gaps in perinatal buprenorphine prescribing and to guide the development of comprehensive services, interprofessional partnerships, and community collaboration in order to best serve pregnant patients. The three sections of the toolkit stimulate conversation and collaboration to increase access to MOUD, enhance screening and access to behavioral health, and optimize clinical operations. The utility and limitations of this toolkit are exemplified across organizations.

Keywords: Buprenorphine; Opioid use Disorder; Perinatal; OB/GYN

Introduction

The opioid epidemic is a national health problem in the United States (US). In 2017, more than 72,000 people in the US died from a drug overdose, more than 60% of which involved opioids [1]. Pregnant and parenting patients are also negatively impacted by the opioid epidemic. The incidence of childbirth by a parent with opioid use disorder (OUD), defined as a clinically significant problematic use of opioids, more than quadrupled between 1999 and 2014 (1.5/1000 deliveries in 1999 to 6.5/1000 deliveries in 2014) [2]. Untreated OUD in pregnancy is associated with adverse health outcomes, such as preterm delivery, low birth weight, and in some cases infant mortality before hospital discharge [2].

A Call to Action for OB/GYNs

The Substance Abuse and Mental Health Services Administration (SAMHSA) called obstetricians and gynecologists (OB/GYN) to help reduce the opioid epidemic [3]. This call encouraged OB/GYNs to screen for OUD among patients who are pregnant and refer these patients to treatment [4]. The message aimed to raise awareness about the evidence-based approach to treat OUD with medications for opioid use disorder (MOUD). SAMHSA recommends MOUD for the treatment of OUD in pregnancy for improved maternal and neonatal outcomes [5]. The standard of care for MOUD treatment in pregnant patients, like in the general population, includes methadone and buprenorphine pharmacotherapy. The 2018 SAMHSA guidelines, *The Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*, recommend comprehensive treatment which includes obstetrical care and access to MOUD in the same clinic [6].

To prescribe buprenorphine, providers must have a Drug Addiction Treatment Act (DATA) 2000 waiver. Data collected from a recent national survey of OB/GYNs suggest that although 77% of obstetrical providers cared for patients with OUD, only 14% had a waiver [7]. Further, of those with a waiver, only 47% had prescribed buprenorphine [7]. In a cross-sectional study looking at Medicaid-claimant OB/GYNs, fewer than 2% were DATA 2000 waivered to prescribe buprenorphine [8]. Among family practice physicians, who provide care to over 34% of pregnant women in the US [9], including providing the majority of maternity services in rural areas [10], approximately 3.6% are waivered to prescribe buprenorphine [11].

Although historically only physicians were permitted to obtain waiver training, recent legislation, such as the 2016 Comprehensive Addiction and Recovery Act (CARA) and the 2018 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, has enabled nurse practitioners (NP), physician assistants (PA), and certified nurse midwives (CNM) to be waivered [12]. This is important as CNMs attended over 9% of all births in 2017 [13]. Furthermore, an increasing number of women receive maternity services from NPs and PAs [14]. These trends indicate that CNMs, NPs, and PAs are well-positioned to assist with OUD treatment in perinatal populations [12]. However, nationally, just 3.2% of NPs and 1.7% of PAs are waivered [15].

Given the ever-growing number of patients affected by OUD, the increasingly precarious access to obstetric (OB) services in rural areas [16], and the effectiveness of current treatment on patient outcomes [17], increasing the number of providers trained in OUD treatment will enable more patients to have their healthcare needs fulfilled. This article summarizes a toolkit that identifies the gaps between obtaining a DATA 2000 waiver and providing the best patient care for the pregnant and parenting population. This toolkit aims to serve as a readiness-assessment for prenatal providers to identify the service gaps within their practices and to start developing the comprehensive services, interprofessional partnerships, and community collaboration needed to address multi-system patient care needs.

Creating the Toolkit at Project CARA

Started in 2014, Project CARA (Care that Advocates Respect/Resilience/Recovery for All) is an outpatient perinatal substance use treatment program that was created to address a growing number of consults for OUD in our maternal-fetal medicine (MFM) division. Our program was created with technical assistance from The University of North Carolina at Chapel Hill (UNC) Horizons program, a residential program dedicated to the treatment and recovery of pregnant and parenting patients with substance use disorders (SUD) [18]. In the last six years, we have expanded comprehensive services to include onsite substance use behavioral health counseling, MOUD with buprenorphine, complex care management, and direct engagement with community resources for patients during their obstetrical visits. The Project CARA team delivers services with a gender-specific trauma informed approach.

When our team began providing technical assistance to other obstetrical partners who wanted to implement buprenorphine prescribing in pregnancy in their clinic, we discovered conversation alone was insufficient. We found that obtaining a buprenorphine waiver did not always equate with being a buprenorphine prescriber, especially not a buprenorphine pre-

scriber for pregnant patients. In our experience, prenatal care providers were eager to participate in OUD care but had concerns about the bandwidth to build collaborative partnerships as well as the ability to provide the best care for patients. Their concerns sometimes prevented them from taking the necessary steps to start prescribing buprenorphine during the perinatal period.

Through our own implementation process at Project CARA, we discovered the importance of creating time and space for incorporating interprofessional communication strategies and new operational pathways into our workflows. We recognized the need to create pathways between medical, behavioral health, substance use, and community systems in order to streamline all of our referral and intake processes. We began sharing this experience with our regional obstetrical "champions," physician and/or advanced practice professional leaders responsible for mobilizing MOUD resources at their own organizations. Insight from our conversations with these champions prompted our team to create a guide or a "toolkit," based on SAMHSA's guidelines, to help our partners implement MOUD in their own prenatal care offices [6]. The toolkit provides a starting platform for guiding the discussion of clinic workflow, development of consent forms, enhancing already existing clinic systems, and identifying potential pitfalls particular to the setting.

The original intent of the toolkit was to serve as an additional "to-do" list for the prenatal care buprenorphine prescriber, but it evolved to a larger scope. It also speaks to widening the role of a champion in practice. Clearly, there is a medical team lead needed to participate in prescribing. However, the medical champion's success is contingent upon other supports like a developed behavioral health integrated practice or established partnerships with community resources. This tool is also intended to prompt the question: "Who is in the position to lead this work?" Use of this tool leads to natural discussion of what additional training is needed for other staff in the healthcare system that will interface with families affected by perinatal OUD.

The Toolkit in Action

The toolkit is broken down into three sections. See Figure 1 for each element of the toolkit. To understand the multitude of ways the toolkit can be implemented in clinical settings, we have included examples of the toolkit in action from two different sets of teams – four medical agencies (Tables 1 and 2), and one hospital-based OB/GYN practice (Table 3). These two sets of teams had previously established technical assistance relationships with Project CARA, and were selected for inclusion because they had reached out for help with building a system of perinatal substance use care in their respective counties. Project CARA used this toolkit to support them in achieving their goals. Each section of the toolkit is detailed below, with information about the overall objectives, example questions, and team implementation strategies.

Table 1: Section 1 of the toolkit; an example of a community approach to using this toolkit with multiple stakeholders across the care spectrum

	Federally Qualified Health Center (FQHC)	**Private OB/GYN Practice**	**County Health Department**	**Hospital-Affiliated Family Practice**
Do you have DATA 2000 waiver provider?	Yes	Yes	Yes	Yes
How many providers?	4	1	2	3
How many on each license?	4 providers can prescribe for 30 patients per year	1 provider can prescribe for 100 patients per year	2 providers can prescribe for 30 patients per year	2 providers can prescribe for 30 patients per year; 1 provider can prescribe for 100 patients per year
Serve pregnant patients?	Yes	Yes	No	Yes
Can treat infants with NOWS (Neonatal Opioid Withdrawal Syndrome)?	Yes	No	No	Yes
Can see patients affected by OUD after delivery?	Yes	Yes	Yes	Yes
Identified OTP for methadone?	Yes – 2 OTPs within 30 miles	Yes – 2 OTPs within 30 miles	Yes – 2 OTPs within 30 miles	Yes – 2 OTPs within 30 miles

Section 1: Data 2000 Waiver Providers.

Abbreviations: Opioid Use Disorder (OUD), Opioid Treatment Program (OTP)

Table 2: Section 2 of the toolkit; an example of a community approach to using this toolkit with multiple stakeholders across the care spectrum

	Federally Qualified Health Center (FQHC)	**Private OB/GYN Practice**	**County Health Department**	**Hospital-Affiliated Family Practice**
How do you ID a patient who may be an MOUD candidate?	4 Ps and SBIRT recommended by provider or LCSW	Social history, self-report, or UDS	4 Ps	Outside referral, self-report, UDS
How do you refer a patient for SU specific BH intake (comprehensive assessment)?	In-house referral – integrated behavioral health	Referred to outside community behavioral health clinic	Referred to outside community behavioral health clinic	Referred to outside community behavioral health clinic
Have you created a patient registry for buprenorphine prescribing and who maintains it?	Yes	No	Yes	Yes
Who determines and how is it determined that a patient needs higher level of SUDs services?	Integrated behavioral health clinician at intake and as needed: ASAM criteria	Outside clinician or (if patient refuses) referral to services/ multiple unexpected UDS	Clinical staff: discussion	Medical provider determined through UDS or pill counts
What services are available for ongoing BH support?	Onsite: 1 on 1 and group	Outside services: 1 on 1, group, and Intensive Outpatient	Outside services: 1 on 1, group, and Intensive Outpatient	Outside services: 1 on 1, group, and Intensive Outpatient
What are the tools your team is using to determine level of SUDs severity?	ASAM	None	ASAM-10	Provider determines tools

Section 2: Planning Patient Flow.

Abbreviations: Medication for Opioid Use Disorder (MOUD); Pregnancy, Past, Partner, Parents (4 Ps); Screening, Brief Intervention, and Referral to Treatment (SBIRT); Licensed Clinical Social Worker (LCSW); American Society of Addiction Medicine (ASAM); Urine Drug Screen (UDS); Behavioral Health (BH), Substance Use Disorder (SUD)

Table 3: Section 3 of the toolkit; an example of a hospital-based OB/GYN practice evaluating patient and clinical expectations

	Hospital-Based OB/GYN Clinic
Will providers with DATA 2000 waivers be available multiple clinics of the week or just one?	Once a week
Who will cover for buprenorphine provider during vacation/after hours?	1 provider as primary OBOT with 2 providers as back-up
How often should patients come?	Weekly – either with medical clinician or behavioral health clinician
What is your policy for missed appointments/need Rx/ refills?	Case by case – warrants treatment team discussion
What is your policy for illicit use? Which substance?	Case by case – warrants treatment team discussion
Can you create dot phrases or quick charts to include: CSRS Requirements	Yes - done and already embedded in the electronic medical record
Can you create a decision tree for sending out urine drug screen for confirmatory testing?	Yes – if unexpected result, perform routinely once per trimester. If positive, do not send UDS with patient self-report
What substances does your PoC urine test for?	Tests for opiates and methadone
What does it not test for?	Buprenorphine, tramadol, fentanyl, and some opioids
Common false positives/false negatives?	Methamphetamines are the most common false positive
Do you have access to confirmatory testing? Turnaround time?	Yes – 48 hours
How frequently will you see patients postpartum?	Q2-4 weeks
For how long will your team write the buprenorphine Rx?	6-9 months post-partum
How will you assist your patients in the transition to a new provider?	LCSW support
Induction: Home	Primary induction location
Induction: Office	
Induction: Hospital	

Section 3: Clinical Operations.

Abbreviations: Medical Prescription (Rx); Office Based Opioid Treatment (OBOT); Controlled Substance Reporting System (CSRS); Urine Drug Screen (UDS); Point of Care (PoC); Once every 2–4 weeks (Q2-4); Licensed Clinical Social Worker (LCSW);

Section 1: Data 2000 Waiver Providers

The first section focuses on the basics around having a DATA 2000/buprenorphine waivered provider. It provides an overview of the medical continuum of care specific to MOUD that addresses questions about access to methadone treatment, and medical care for the infant who has been exposed to opioids in utero, an expected risk of MOUD (Table 1). The main objective of Section 1 is to optimize MOUD access to perinatal patients.

Table 1 illustrates a particular example of using the toolkit. In this instance, four different medical agencies all had buprenorphine waivers. However, these agencies had different medical care services. Section 1 of the toolkit prompted these medical agencies to discuss questions like: Does one agency have easier access to new obstetrical appointments, and therefore, a shorter wait time to access buprenorphine? Should multiple agencies reserve a certain number of buprenorphine waiver spots for pregnant patients? Is there room for new collaboration for some agencies to prioritize MOUD in pregnancy and others to prioritize outside of pregnancy and post-partum therefore creating a graduated system for post-partum patients? Did some

perinatal practices offer more comprehensive behavioral health support than others, and did this influence what level of acuity of perinatal OUD they would be able to treat effectively? As demonstrated by the responses in Table 1, the toolkit facilitated conversations within these four medical agencies that might not have previously occurred. Ultimately, the toolkit propelled their decision about who would be the lead practice for perinatal buprenorphine prescribing in the region.

Section 2: Planning Patient Flow

The second section focuses on identifying access to behavioral health services for perinatal patients. Behavioral health services represent an integral part of a comprehensive treatment program that offers MOUD, and this particular group of services may be difficult to access in certain obstetrical practices. This section asks potential MOUD providers to consider who will perform initial behavioral health intakes, and to identify what tools will be used to evaluate acuity and severity of the patient's opioid use disorder (Table 2). The main objective of Section 2 is to advise agencies to either integrate behavioral health services into their programs or enhance referral to existing behavioral health services.

Table 2 highlights conversations from the same four medical agencies used in Table 1. There are often discrepancies in the ways different practices identify patients with OUD; without standardized screening techniques, it is impossible for agencies to accurately refer patients to behavioral health services. Section 2 of the toolkit prompted these four agencies to discuss related questions like: How do you identify a patient who may be a MOUD candidate? What services are available for behavioral health support? What are the tools your team is using to determine level of SUDs severity? As demonstrated by the responses in Table 2, this toolkit allowed the medical agencies to evaluate and update their current screening processes for OUD.

Section 3: Clinical Operations

The third section focuses on the details of clinical operations. When unanswered, these seemingly small details can accumulate and derail a busy prenatal care clinic flow. This section asks questions related to practice guidelines and policies such as who will perform urine drug screens and who will schedule patients for follow up with a buprenorphine waivered provider (Table 3). The main objective of Section 3 is to prompt agencies to create their own procedures and processes to most efficiently execute a perinatal clinic that offers MOUD.

Unlike Tables 1 and 2, Table 3 outlines the responses from one hospital-based OB/GYN practice. Section 3 prompted this practice to consider the additional details added to a patient encounter that involves MOUD. These include guiding questions like: What is your policy for missed appointments? What substances does your point-of-care (POC) urine drug test screen for, and what is the response to an unexpected positive? How frequently will you see patients postpartum? The responses in Table 3 show that the toolkit helped this practice develop a stronger clinical work-flow and plan to implement ongoing team training. This practice also used these beginning questions as a launch pad to develop which pieces of quality improvement they would track in perinatal substance use comprehensive care.

Discussion

The Before You Write toolkit was created from evidence-based guidelines and lessons learned from establishing a hub-and-spokes model of perinatal substance use disorders (PSUDs) in Western North Carolina. It is intended as a facilitative tool to prompt conversation about the gaps and barriers to incorporating perinatal MOUD care into existing obstetrical services. For example, the toolkit has been utilized to assess readiness and identify the needs within practices for additional education and training about policies for screening, testing, and writing prescriptions in order to best deliver comprehensive care.

Dr. Margaret Sullivan, the Women's Service Line Leader at a rural hospital in western North Carolina, is an example of a medical champion who utilized the toolkit prompts to strategically identify resources in her own community. Dr. Sullivan was able to identify pre-existing resources, both in the community and within her institution, by surveying her co-workers, as well as community leaders and physicians, in order to tailor the best combination of services for her practice. Dr. Sullivan protected the time of her team members, including another prescriber and the nurse lead of her practice, so they could carry out toolkit tasks such as attending a pre-existing regional substance use task force meeting, connecting with the director of behavioral health at their institution, and creating a relationship with the local methadone clinic. This led to new communication strategies and referral pathways between medical, substance use, and mental health services that would otherwise be siloed. This method of implementation enabled her practice to connect with community stakeholders, and her practice's participation in the toolkit tasks even led her team to advocate for integrated behavioral healthcare services in their office.

Dr. Sullivan's case exemplifies how the toolkit highlights the importance of connecting with community services and navigating the larger SUD system of care. However, every region has access to different resources, and while the toolkit can act as a guide, it is ultimately the role of the provider champion to identify and build connections with community and behavioral health services. The toolkit can prompt clinicians to identify this need for synergy, but, as Dr. Sullivan demonstrated, it is up to the champions to create the time and space to foster these connections in the way that makes most sense for their practice. Other teams might need to identify resources by reaching out to local agencies and community leaders. Teams could even utilize telehealth support, depending on the availability in their specific region. The common denominator is that everyone who participates in perinatal substance use care must be willing to collaborate outside of their own system. The toolkit cannot do this for champions, but it provides a neutral set of questions that can be used to facilitate conversations between these teams.

This toolkit is a readiness-assessment, not step-by-step guidance, for perinatal buprenorphine prescribing. While it offers conversational prompts regarding possible barriers, it does not provide solutions; quality improvement processes are needed to address implementation. So far, the toolkit has only been utilized in the context of PSUD technical support to assist newly waivered obstetrical care providers to expand their services. It is unknown if this toolkit would be equally as effective without the technical assistance and support from the existing PSUD program. Quality improvement studies might include surveys of these obstetrical providers, as well as future providers that implement the toolkit without technical assistance, in order to assess the general utility of the toolkit and its impact on substance use disorder treatment uptake by providers.

The primary purpose of the toolkit is to facilitate the collaborative relationships and internal processes necessary to make buprenorphine prescribing successful. But patient success depends on more than medication. It is clear that trauma-informed gender responsive comprehensive SUD care is best practice. Through both feedback from practices that have utilized the toolkit, as well as internal reflection from continued work in the PSUD field, we have identified topics that could be added to the toolkit to facilitate conversation around additional components of comprehensive care. New editions of the toolkit could include questions related to the workflow around neonatal abstinence syndrome, the multi-system coordination that occurs post-delivery, and the linkage to hospital post-partum pain management for patients prescribed buprenorphine. Future toolkits could also include a section focused on care coordination, prompting teams to consider needs that are frequently observed among patients such as housing, legal aid, employment, child care, and transportation.

Additionally, this toolkit does not address the systematic silos and barriers that impact access to perinatal substance use care. From our own experience working with PSUDs, we understand that barriers will persist such as prior authorization for medication, gaps in insurance coverage, transportation to clinic appointments, and childcare. Additionally, the legal and judicial systems, as well as the Department of Social Services impact access to treatment. Lastly, this toolkit was initially implemented in the predominantly white and rural region of Western North Carolina, and does not address the social and cultural stigmas, biases, and gender and racial stereotypes surrounding PSUD, specifically OUD. These biases can greatly affect patients' perception of safe treatment access. Further research is needed to identify key facilitators to help providers assist their patients to overcome these barriers.

Conclusion

Pregnant patients with OUD urgently need more widespread access to MOUD. The health impact of untreated SUD on the parent-baby dyad is clear, and it is obvious that not all patients with SUDs are receiving the care they need. While there are numerous barriers to accessing MOUD from a patient perspective, obstetrical providers have a responsibility to reduce barriers from a health care systems perspective. With only 14% of obstetrical providers currently prescribing MOUD, the prenatal care provider community has an opportunity to make great strides. The Before You Write toolkit offers evidence-based readiness assessment strategies and conversation prompts for provider teams that want to care for pregnant and parenting patients. The questions within this toolkit will help provider teams to think through critical steps of preparing for and continuing to treat patients with OUD during the perinatal period. Through careful planning, collaboration, and communication, the goal is to dramatically increase the number of prenatal care providers actively prescribing MOUD and improve maternal and neonatal outcomes for patients.

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Before You Write Your First Buprenorphine Prescription

What you need to know

Section 1: Data 2000 Waiver Providers

Do you have a DATA 2000 waivered provider?

- ☐ Yes
- ☐ No
- ☐ Pending

How many providers? _____

How many on each license? _____
Ex: 2 providers with 30 waiver; 1 provider with 100 waiver

Do your providers serve pregnant patients?

- ☐ Yes
- ☐ No
- ☐ Pending

Do you have pediatric providers in your community who treat infants affected by neonatal opioid withdrawal syndrome (NOWS)?

- ☐ Yes
- ☐ No
- ☐ Pending

Do you have a DATA 2000 waivered provider who can see women affected by opioid use disorder (OUD) who are on buprenorphine after delivery?

- ☐ Yes
- ☐ No
- ☐ Pending

Do you have an identified opioid treatment program (OTP) to refer for methadone treatment?

- ☐ Yes
- ☐ No
- ☐ Pending

Section 2: Planning Patient Flow

How will you identify a patient who may be a candidate for medication for opioid use disorder (MOUD)? Check all that apply.

- ☐ Self-report
- ☐ Verbal screening tool
- ☐ Outside referral
- Other: _____

How do you refer a patient for substance use-specific behavioral health (BH) intake (comprehensive assessment)? Check all that apply.

- ☐ Internal referral
- ☐ Refer to outside therapist/community behavioral health clinic
- ☐ Other: _____

Have you created a patient registry for buprenorphine prescribing?

- ☐ Yes
  Maintained by: _____
- ☐ No
  Will be maintained by: _____

Which team members will determine that a patient needs a higher level of substance use disorder (SUD) services? Check all that apply.

- ☐ Integrated behavioral health clinician
- ☐ Outside clinician
- ☐ Clinical staff
- ☐ Medical provider

Which tools will be used to make this decision? Check all that apply.

- ☐ ASAM Criteria
- ☐ Discussion
- ☐ Unexpected UDS
- ☐ Pill counts
- Other: _____

What services are available for ongoing BH support?
Check all that apply.

- ☐ One-on-one
- ☐ Group
- ☐ Intensive outpatient therapy
- ☐ Substance abuse comprehensive outpatient treatment
- Other: _____

PROJECT CARA of Western North Carolina

PR%F Alliance NC Promoting Alcohol-Free Pregnancies.

MotherToBaby North Carolina
Medications & More During Pregnancy & Breastfeeding
Ask The Experts

PSEED Toolkit
Perinatal Substance Exposure Educator Document

Section 3: Clinical Operations

Will providers with DATA 2000 waivers be available at multiple clinics during the week or just one?

- ☐ Multiple
- ☐ One
- Other:

Who will cover for a buprenorphine provider during vacation/after hours? Please specify:

What will be your preferred setting of buprenorphine induction? Check all that apply.

- ☐ Home
- ☐ Office
- ☐ Hospital

How frequently will patients visit the office?

- ☐ Weekly
- ☐ Bi-weekly
- ☐ Case-by-case
- Other:

What is your policy for missed appointments/need Rx/refills? Please specify:

What is your policy for illicit use? Please specify:

Who will create dot phrases or quick charts to include required documentation? Please specify:

Which substances does your point of care urine drug screen test for? Check all that apply.

- ☐ Opiates
- ☐ Buprenorphine
- ☐ Fentanyl
- ☐ THC
- ☐ Methadone
- ☐ Methamphetamines
- ☐ Amphetamines
- ☐ Cocaine
- Other:

What does it not test for? Check all that apply.

- ☐ Opiates
- ☐ Buprenorphine
- ☐ Fentanyl
- ☐ THC
- ☐ Methadone
- ☐ Methamphetamines
- ☐ Amphetamines
- ☐ Cocaine
- Other:

What are the most common false negatives and false positives for your point of care cup? Please specify:

Do you have access to confirmatory testing? If yes, what is the turnaround time?

- ☐ No
- ☐ Pending
- ☐ Yes

Turnaround time:

Create a decision tree for sending out urine drug screens for confirmatory testing. Write in your decision tree below:

How frequently will you see patients postpartum?

- ☐ Every 2 weeks
- ☐ Every 4 weeks
- Other:

For how long will your team write the buprenorphine Rx?

- ☐ 6-9 months postpartum
- ☐ Up to 12 months postpartum
- Other:

How will you assist your patients in the transition to a new provider? Please specify: