DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-03-17
Baltimore, Maryland 21244-1850

State Demonstrations Group

February 1, 2018

Allison Taylor
Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington Street, Room W461, MS25
Indianapolis, IN 46204

Dear Ms. Taylor:

The State of Indiana submitted its Substance Use Disorder (SUD) Implementation Protocol as required by special term and conditions (STC) X.10 of the state's section 1115 Healthy Indiana Plan (HIP) demonstration (Project No. 11-W-00296/5). The Centers for Medicare & Medicaid Services (CMS) has reviewed the SUD Implementation Protocol and determined that it is consistent with the requirements outlined in the STCs; therefore, with this letter, the state may now begin receiving Federal Financial Participation (FFP) for Indiana Medicaid recipients residing in the Institutions for Mental Disease (IMD) under the terms of this demonstration.

As outlined in STC X.3, the SUD Health Information Technology (HIT) plan must be submitted within 90 calendar days of this letter. If the state fails to submit within this timeframe, CMS may issue a deferral, as specified in STC XII.1. Once approved by CMS, the HIT plan will be incorporated as an addendum to the SUD Implementation Protocol. CMS is available to provide technical assistance, if needed.

If you have any questions, please contact your project officer, Ms. Shanna Janu, at 410-786-1370 or by email at Shanna.Janu@cms.hhs.gov.

We appreciate your cooperation throughout the review process.

Sincerely,

/s/

Andrea J. Casart
Director
Division of Medicaid Expansion Demonstrations

Enclosure

cc: Ruth Hughes, Associate Regional Administrator, CMS Chicago Regional Office

State of Indiana
1115 SUD Waiver
Implementation Plan

Indiana Family and Social Services Administration
Office of Medicaid Policy and Planning
Updated January 2018

Contents

Introduction

Indiana is experiencing the opioid epidemic that has been devastating the United States. Nearly six times as many Hoosiers died from drug overdoses in 2014 as did in 2000, and the number of heroin overdose deaths has increased by nearly 25 times between 2000 and 2014[1]. The State's Medicaid population has been particularly impacted by the crisis: nearly 100,000 individuals were treated for a diagnosis of substance use disorder in 2016[2].

As part of a response to a recommendation laid out by the Taskforce on Drug Enforcement, Treatment, and Prevention, Indiana Medicaid is building a stronger substance use disorder (SUD) treatment infrastructure, with increased benefits, stronger provider networks, and incorporation of evidenced-based SUD program standards. Indiana will utilize a section 1115 demonstration waiver to pursue the following primary goals, as outlined by the Centers for Medicare and Medicaid Services (CMS):

1. Increased rates of identification, initiation, and engagement in treatment
2. Increased adherence to and retention in treatment
3. Reductions in overdose deaths, particularly those due to opioids
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriately through improved access to other continuum of care services
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate
6. Improved access to care for physical health conditions among beneficiaries

Indiana Medicaid believes it can accomplish these six goals by putting particular focus on three areas:

- Expanded SUD treatment options for as many of its members as possible
- Stronger, evidenced-based certification standards for its SUD providers, particularly its residential addiction providers
- Consistency with prior authorization criteria and determinations among its health plans

Organized by six key milestones that have been identified by CMS, the following implementation plan provides a vision for the direction Indiana Medicaid will go over the months and years ahead in combating the State's opioid epidemic.

Access to Critical Levels of Care for SUD Treatment

Indiana Medicaid provides coverage of SUD treatment services to its members. Throughout the waiver application process, Indiana Medicaid reviewed its options for individuals struggling with

[1] INDIANA STATE DEPARTMENT OF HEALTH, INDIANA:SPECIAL EMPHASIS REPORT, DRUG OVERDOSE DEATHS, 1999-2013 (2016), available at http://www.in.gov/isdh/files/2016_SER_Drug_Deaths_Indiana.pdf.
[2] Based on ICD-10 claims analysis for claims with a date a service between January 1 and December 31, 2016. Excludes tobacco use disorder.

SUD compared with the standards outlined through the American Society of Addiction Medicine (ASAM). Many services that align with an ASAM level of care are currently covered, but through the usage of the 1115 SUD waiver, State Plan Amendments, and other regulatory tools, Indiana will provide coverage for a more complete continuum of services. The following table provides an overview of each ASAM level of care with current Indiana Medicaid coverage along with proposed changes:

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage
OTP	Opioid Treatment Program	Pharmacological and non-pharmacological treatment in an office-based setting (methadone)	Currently covered for all (as of September 2017)	Continued oversight of new policy
0.5	Early Intervention	Services for individuals who are at risk of developing substance-related disorders	Currently covered for all	No change expected
1.0	Outpatient Services	Outpatient treatment (usually less than 9 hours a week), including counseling, evaluations, and interventions	Currently covered for all	No change expected
2.1	Intensive Outpatient Services	9-19 hours of structured programming per week (counseling and education about addiction-related and mental health programs)	Currently MRO-only	Will be covered for all individuals
2.5	Partial Hospitalization	20 or more hours of clinically intensive programming per week	Covered for all	No change expected
3.1	Clinically Managed Low-Intensity Residential	24-hour supportive living environment; at least 5 hours of low-intensity treatment per week	No coverage	Bundled daily rate for residential treatment
3.5	Clinically Managed High-Intensity Residential	24-hour living environment, more high-intensity treatment (level 3.7 without intensive medical and nursing component)	No coverage	Bundled daily rate for residential treatment
3.7	Medically Monitored Intensive Inpatient Services	24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting	Covered for all (based on medical necessity)	Align authorization criteria with ASAM
4.0	Medically Managed Intensive Inpatient	24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital	Covered for all (based on medical necessity)	Align authorization criteria with ASAM
Sub-Support	Addiction Recovery Management Services	Services to help people overcome personal and environmental obstacles to recovery, assist the newly recovering person into the recovering community, and serve as a personal guide and mentor toward the achievement of goals	No coverage	Covered for all individuals
Sub-Support	Supportive Housing Services	Services for individuals who are transitioning or sustaining housing.	No coverage	Explore options for coverage

Each of the ASAM levels of care will be addressed in more detail by providing current coverage, future coverage, and a timeline for implementation over the next 12-24 months for these proposed changes.

Level of Care: OTS (Opioid Treatment Services)

Summary of Actions Needed:

- Amendment to Indiana Administrative Code (IAC) promulgating coverage of OTP services

Current State:

Through August 2017, Indiana Medicaid did not provide coverage for opioid treatment program (OTP) services, including the daily administration of methadone. The Family and Social Services Admission (FSSA), Division of Mental Health and Addiction (DMHA) currently certifies thirteen (13) OTPs, including three that are operated through a community mental health center (CMHC). Since 2008, DMHA has been prohibited from certifying new programs; however, Indiana Senate Enrolled Act 464 (2015) allows DMHA to approve up to five new programs before June 30, 2018. As a result of this legislation, DMHA is moving forward with the certification of up to five new OTPs throughout the state. In addition, DMHA is reviewing and updating the Indiana Administrative Code to clarify sections of the code and modify outdated sections.

Indiana Senate Enrolled Act 297 (2016) required that as of July 1, 2017, all OTPs operating in Indiana must either be:

- Enrolled as an Indiana Health Coverage Programs (IHCP) provider, or
- Enrolled as an ordering, prescribing, or referring provider in accordance with Section 6401 of the Patient Protection and Affordable Care Act.

As a result of this legislation, Indiana Medicaid began pursuing conversations with several OTPs about a bundled payment for all services rendered.

Future State:

Indiana Medicaid has completed making the system changes to enroll OTPs as billing providers and reimburse these programs with a daily bundled payment that includes all services as required by federal regulations and in alignment with ASAM Patient Placement Criteria. These services include the following:

- Individualized, patient-centered assessment and treatment
- Assessing, ordering, administering, reassessing, and regulating medication and dose levels appropriate to an individual
- Monitored drug testing, to be done at a minimum of eight times a year
- A range of cognitive, behavioral, and other substance use disorder-focused therapies

- Case management, including medical monitoring and coordination of on-and off-site treatment services, provided as a needed
- Psychoeducation, including HIV/AIDS education and other health education services

BT201755 was published on August 17, 2017 finalizing all of the billing guidance and enrollment information for OTP services. Services were originally announced to begin on August 2, 2017; however, due to public comment and system specifications, the effective date was delayed until September 1, 2017. Meanwhile, the State Plan Amendment (SPA) authorizing the use of the bundled payment structure was submitted to CMS on September 8, 2017. This SPA was approved on December 4, 2017.

Indiana Medicaid has made a concerted effort at working closely with DMHA to ensure that the State's Medicaid guidance is consistently aligned with the State's non-Medicaid guidance. Representatives from Indiana Medicaid continue to participate in quarterly meetings with all of the OTP providers, and the program will closely monitor the success of this new coverage and amend policy as necessary. Finally, Indiana Medicaid will promulgate its coverage of OTP services as part of a comprehensive review of its behavioral health administrative rules.

A list of action items and expected implementation timeline regarding OTP services is provided in the table below:

Action	Implementation Timeline
Pursue Indiana Administrative Code (IAC) change for coverage and reimbursement of OTPs	Will be filed by December 31, 2018

Level of Care: 0.5 (Early Intervention)

Summary of Actions Needed:

- None anticipated

Current State:

Indiana Medicaid provides coverage for several individual services around early intervention, including smoking cessation counseling and screening, brief intervention, and referral to treatment (SBIRT). These services are available to all Indiana Medicaid members without prior authorization.

Future State:

No changes are expected at this ASAM level of care.

Level of Care: 1.0 (Outpatient Services)

Summary of Actions Needed:

- Amendment to Indiana Administrative Code (IAC) aligning outpatient services with ASAM structure

Current State:

Indiana Medicaid provides coverage for two broad categories of outpatient services: office-based addiction treatment (also known as "clinic option" services) and community-based addiction treatment (also known as "Medicaid Rehabilitation Option" services).

Office-Based Treatment

All Indiana Medicaid members have coverage for office-based behavioral health services. Individuals are covered for these services for up to twenty (20) units per member, per provider, per rolling 12-month period; additional units require prior authorization based upon medical necessity. These services must be certified by and may be provided by a physician, a Health Services Provider in Psychology (HSPP), and other providers as outlined in *405 IAC 5-20-8(2)*.

Community-Based Treatment

Indiana Medicaid also has an array of services for mental health and addiction treatment known as Medicaid Rehabilitation Option (MRO). These optional services are authorized under Section 1905(a)(13)(C) of the Social Security Act and are allowed to be rendered in an individual's home or other setting within the community. Individuals are assigned an MRO package of services based upon an approved mental health or substance use diagnosis and an appropriate level of need, as determined through a DMHA-approved assessment tool called the Child and Adolescent Needs and Strengths (CANS) or Adult Needs and Strengths Assessment (ANSA). Depending upon the automated results of the CANS or ANSA, an individual with a level of need of two or higher for youth (three or higher for adults) is assigned/authorized a package/array of service that includes a specific number of units of each MRO service that's available to the member for a six-month eligibility period. Individuals who still require services at the end of six months must undergo a redetermination and be assigned/authorized a new package of services designed to meet their needs.

Services billable through MRO include the following:

- Addiction counseling (individual and group)
- Behavioral health counseling and therapy
- Behavioral health day treatment
- Case management
- Intensive outpatient treatment (IOT)
- Medication training and support
- Peer recovery services
- Skills training and development

MRO services are further distinguished by the provider staff qualifications eligible to deliver the service. Many of the services covered under MRO can be rendered by a licensed professional, a qualified behavioral health professional (an unlicensed individual who may have professional experience or education qualifications to provide services), or any other behavioral health professional (who may have an associate or bachelor's degree, or equivalent behavioral health experience). Additionally, due to a freedom of choice waiver authorized under Section 1915(b)(4) of the Social Security Act, MRO services are only reimbursable to community mental health centers.

Future State:

Indiana Medicaid currently has a robust set of services for outpatient addiction treatment. The only explicit change that will be sought, which will be discussed further in the next section, is the removal of Intensive Outpatient Treatment (IOT) from the MRO package of services. Indiana Medicaid plans to make this service available to all individuals and reimbursable to qualifying providers beyond community mental health centers.

The State is also planning to make amendments to the Indiana Administrative Code to update provider staff qualifications, including adding licensed clinical addiction counselors, and to further align its coverage standards with the ASAM Criteria.

A list of action items and expected implementation timeline regarding outpatient services is provided in the table below:

Action	Implementation Timeline
Pursue Indiana Administrative Code (IAC) amendments to Mental Health Services Rule	Will be filed by December 31, 2018

Level of Care: 2.1 (Intensive Outpatient Services)

Summary of Actions Needed:

- State Plan Amendment
- Indiana Administrative Code change
- CoreMMIS system changes
- Provider notification

Current State:

As indicated in the previous section, Indiana Medicaid has reimbursed for intensive outpatient treatment (IOT) as a service available through the MRO benefit. IOT is a treatment program that operates at least three hours per day for at least three days in a week. The service includes group therapy, interactive education groups, skills training, random drug screenings, and counseling, all of which fall in line with ASAM Level of Care 2.1 expectations for Intensive Outpatient Services. Like all other MRO services, it is only reimbursable through CMHCs.

Over the past year, providers other than CMHCs have been trying to work with our managed care entities (MCEs) on proper payment for IOT services outside of MRO. The MCEs have adopted the usage of "intensive outpatient program" (IOP) for services billed outside of MRO. In January 2017, OMPP provided clearer reimbursement instructions directly to the MCEs on IOP services that also differentiate between substance use and psychiatric treatment. The following summarizes those instructions:

For providers billing on a UB-04 claim form:

- Must bill CPT Code 90899 -*Unlisted psychiatric service or procedure* for any IOP service with one of the following revenue codes, based on the type of service rendered:
    - 905 – psychiatric
    - 906 – chemical dependency

For providers billing on a CMS-1500 claim form:

- HCPCS code S9480 (Intensive outpatient psychiatric services) would be used for psychiatric IOP
- HCPCS code H0015 (Alcohol and/or drug services; intensive outpatient) would be used for substance use IOP
    - One unit equals three hours of IOP services

Future State:

Indiana Medicaid wants to ensure that this policy is consistent for both the managed care and fee-for-service population. As a result, Indiana Medicaid will be submitting a SPA to completely remove IOT from the MRO package of services to ensure that it is reimbursable to all appropriate entities, including community mental health centers. Indiana anticipates using the same federal authority as MRO for this separate service (Section 1905(a)(13)(C) of the Social Security Act). An updated section of the Indiana Administrative Code will be devoted to coverage of IOT services.

A list of action items and expected implementation timeline regarding intensive outpatient services is provided in the table below:

Action	Implementation Timeline
Pursue Indiana Administrative Code (IAC) change to remove IOT from MRO	Will be filed by December 31, 2018
Pursue State Plan Amendment (SPA) to move IOT coverage from MRO	Will be filed by June 30, 2018
Pursue amendment to 1915(b)(4) waiver	Will be filed by June 30, 2018
Make necessary system changes to CoreMMIS	Will be completed by June 30, 2018
Develop provider communication over new benefits	Contingent upon approval of SPA (formal notification will be delivered at least 30 days prior to launch)

Level of care: 2.5 (Partial Hospitalization)

Summary of Actions Needed:

- None anticipated

Current State:

Indiana Medicaid covers partial hospitalization for all members according to medical necessity. The following program standards apply for all individuals:

- Services must be ordered and authorized by a psychiatrist
- Face-to-face evaluation and assignment of a mental health or substance use diagnosis must take place within 24 hours following admission
- Psychiatrist must actively participate in the case review and monitoring of care
- Documentation of active oversight and monitoring of progress by a physician, psychiatrist, or HSPP must appear in the patient's clinical record
- At least one psychotherapy service (group psychotherapy service) must be delivered daily
- For those under 18 years old: active psychotherapy must appear on clinical record, and one family encounter per five business days of episode of care is required
- Must include four to six hours of active treatment per day, at least four days per week
- Authorized for up to five days; must check with each health plan for other authorization criteria.

Future State:

No immediate changes are expected at this ASAM level of care. However, Indiana Medicaid's partial hospitalization criteria will undergo a complete review against the ASAM Patient Placement Criteria, and this effort may result in changes to the Indiana Administrative Code as part of the previously mentioned comprehensive review of the behavioral health administrative rule.

Level of care: 3.1 / 3.5 (Clinically Managed Low-Intensity Residential / Clinically Managed High-Intensity Residential)

Summary of Action Items:

- CoreMMIS system modifications (including finalizing coding)
- New provider specialty
- Conversation with MCEs regarding authorization criteria
- Provider notification

Current State:

Residential treatment for substance use disorders can be provided within residential addiction treatment facilities, including institutions for mental disease (IMDs). An IMD is defined as a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. Federal law prohibits federal financial participation (FFP) from going to IMDs for individuals aged 21 through 64. One of the primary goals of the 1115 SUD waiver is to waive this restriction and allow IMDs to provide treatment to all IHCP members, including inpatient and residential treatment.

Indiana Medicaid currently has no defined methodology to pay for residential treatment for substance use disorder. As a result, neither Level 3.1 (clinically managed low-intensity residential) nor Level 3.5 (clinically managed high-intensity residential) are currently reimbursable.

Future State:

Upon approval of the 1115 waiver, Indiana Medicaid will be able to reimburse for residential stays in all settings, including IMDs, for most populations (fee-for-service and managed care). Indiana will allow members to seek authorization for residential IMD stays based on a statewide average length of stay of thirty (30) days.

The State will be pursuing a bundled per diem payment based upon the approved ASAM level of care. The funding authority will be the 1115 SUD waiver. The bundled rate methodology for both Level 3.1 and 3.5 residential services will initially be based around a mix of current MRO services that is most appropriate to that particular level of care.

Consistent with the therapies offered according to ASAM Level 3.1 and Level 3.5 treatment, the following table summarizes the individual services that will be incorporated into the bundled payment rate:

Service	Unit Type	MRO Service	Cost Per Unit
Individual/Family Therapy	Hour	H0004	$108.97
Group Therapy	Hour	H0004 (Group)	$27.23
Skills Training and Development	Hour	H2014	$104.56
Medication Training and Support	Hour	H0034	$74.48
Peer Recovery Supports	Hour	H0038	$34.20
Case Management	Hour	T1016	$58.12

Drug Testing	Encounter	80101	$19.03

Through a rigorous analysis from Milliman, the following daily bundled rates will be utilized:

- Level 3.1 (clinically managed low-intensity residential)
  - Adult - $126.46 per day
  - Child - $130.37 per day
- Level 3.5 (clinically managed high-intensity residential)
  - Adult - $361.65 per day
  - Child - $439.56 per day

Only facilities that have been designated by the Division of Mental Health and Addiction (DMHA) as an ASAM Level 3.1 or Level 3.5 residential facility will be eligible to receive reimbursement from Indiana Medicaid. The development of improved certification requirements and ASAM designation for these facilities will be addressed under a later section of the implementation plan.

Indiana Medicaid will be developing a new provider specialty for residential addiction treatment facilities that have been certified by DMHA and designated at ASAM Level 3.1 or Level 3.5. The State anticipates having this new provider specialty, along with all other necessary system changes for the fee-for-service and managed care populations, complete ahead of a March 1, 2018 implementation. To allow adequate time for facilities to complete the DMHA designation process and to separately enroll as this new provider specialty, Indiana Medicaid will give currently enrolled facilities until July 1, 2018 to complete these steps; any facility seeking reimbursement for residential services after that time will be required to complete the previous two steps ahead of reimbursement.

Indiana Medicaid will also pursue conversations with our managed care entities to ensure that each health plan is basing admission decisions for residential treatment on the six dimensions of the ASAM Patient Placement Criteria. The managed care entities, as well as Indiana Medicaid's fee-for-service prior authorization vendor, will be allowed to utilize any evidence-based clinical decision system that incorporates all six specific dimensions of life care, as articulated in the ASAM Patient Placement Criteria. These six dimensions include:

- Acute intoxication and/or withdrawal potential
- Biomedical conditions and complications
- Emotional, behavioral, or cognitive conditions and complications
- Readiness to change
- Relapse, continued use, or continued problem potential
- Recovery environment

A list of action items and expected implementation timeline regarding residential treatment is provided in the table below:

Action	Implementation Timeline
Make necessary system changes to CoreMMIS to enroll residential addiction facilities and to reimburse for residential treatment	Will be completed by March 1, 2018
Develop provider communication over new benefits	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch

Level of care: 3.7/4.0 (Medically Monitored Intensive Inpatient / Medically Managed Intensive Inpatient)

Summary of Action Items:

- Conversation with MCEs regarding authorization criteria
- Consider change in reimbursement from DRG-based payment to per diem payment

Current State:

Due to the same federal regulatory restriction, Indiana Medicaid is prohibited from seeking federal financial participation (FFP) for treatment in IMDs for individuals aged 21 through 64 for inpatient treatment. Since July 2016, our managed care entities have had the authority to reimburse for inpatient IMD stays in lieu of services or settings covered under the State Plan. Indiana Medicaid does currently reimburse for inpatient treatment for substance use and chemical dependency treatment based upon a diagnosis-related group (DRG) payment methodology. Indiana Medicaid's managed care entities, as well as the fee-for-service prior authorization vendor, utilize evidenced-based clinical criteria for admission standards to inpatient treatment.

Future State:

Upon approval of the 1115 waiver, Indiana Medicaid will be able to reimburse for inpatient stays in IMD settings for all populations (fee-for-service and managed care). Indiana will allow members to seek authorization for inpatient IMD stays for lengths of stay of up to fifteen (15) days.

During the latter part of 2018, Indiana Medicaid will consider reimbursing substance use-related inpatient stays on a per diem basis. This would allow providers to receive payment based upon the number of days, as well as the intensity of treatment, for which an individual is seeking treatment. Indiana Medicaid will review its State Plan to determine if a SPA is necessary for this change and pursue the amendment accordingly.

The managed care entities, as well as Indiana Medicaid's fee-for-service prior authorization vendor, will be allowed to utilize any evidence-based clinical decision system for inpatient stays that incorporates all six specific dimensions of life care, as articulated in the ASAM Patient Placement Criteria.

A list of action items and expected implementation timeline regarding intensive inpatient services is provided in the table below:

Action	Implementation Timeline
Determine final action and necessary system changes to CoreMMIS to allow reimbursement for inpatient SUD stays on a per diem basis	Fall 2018
Develop provider communication over changes in reimbursement structure	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch

Sub Support Service – Addiction Recovery Management Services

Summary of Action Items:

- Pursue State Plan Amendment
- CoreMMIS system changes
- Pursue amendment to IAC
- Provider communication

Current State:

Indiana currently does not have coverage for addiction recovery management services. As previously described under Outpatient Services, mental health treatment is available through a Medicaid Rehabilitation Option (MRO) package of services, but these new services will be available specifically for substance use treatment.

Future State:

Indiana will be pursuing a State Plan Amendment to use the same federal authority (Section 1905 (a)(13)(C) of the Social Security Act) that currently authorizes MRO services to reimburse for Addiction Recovery Management Services. These services include the following:

- Peer Recovery Support
- Recovery-Focused Case Management

These services will be individually reimbursable services using the following tentative criteria:

	Peer Recovery Support	Recovery-Focused Case Management
Coding	H0038 (SUD modifier)	T1016 (SUD modifier)
Provider Types	• Addiction Peer Recovery Coach Other licensed professionals will be allowed to provide this service as long as they are trained as an Addiction Peer Recovery Coach.	• Licensed professionals o Psychiatrist o Licensed Addiction Counselor (LAC) o Licensed Clinical Social Worker (LCSW) o Licensed Mental Health Counselor (LMHC) o Licensed Marriage and Family Therapist (LMFT) o Licensed Clinical Addiction Counselor (LCAC) • Qualified Behavioral Health Provider (QBHP)
Eligibility	• All Indiana Medicaid members (except for those eligible only for family planning services, emergency services, or QMB-only/SLMB-only/QI coverage)	

	• Must meet medical necessity (have a primary or secondary diagnosis of substance use disorder)

A list of action items and expected implementation timeline regarding Addiction Recovery Management Services is provided in the table below:

Action	Implementation Timeline
Make necessary system changes to allow reimbursement for Addiction Recovery Management Services	Spring 2018
Pursue State Plan Amendment (SPA) to add coverage and reimbursement of services* *coverage of services will begin upon approval of SPA	Spring 2018
Pursue Indiana Administrative Code changes to add coverage of services	Will be filed by December 31, 2018
Develop provider communication over new benefits	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch

Sub Support Service – Supportive Housing Services

Summary of Action Items:

- Create collaborative workgroup
- Develop rate methodology
- CoreMMIS system changes
- Provider communication

Current State:

Indiana Medicaid currently provides no coverage for supportive housing services.

Future State:

Using the 1115 SUD waiver as a funding mechanism, Indiana will be pursuing coverage of supportive housing services. Indiana is using *CMCS Informational Bulletin: Coverage of Housing-Related Activities and Services for Individuals with Disabilities* as a template for the services that will be offered. The services will fall under two broad categories: services for individuals transitioning to housing, and services for individuals to help sustain their housing status. Indiana envisions the following activities falling under each category:

- **Transitioning Services**

  - Identification of resources to help cover the security deposit, moving costs, environmental modifications, and other one-time expenses
  - Tenant screening and housing assessment to identify individual's preferences and barriers related to successful tenancy
  - Assistance with housing application or housing search process
  - Assistance with arranging for and supporting details of the move
  - Development of a housing support crisis plan
- **Sustaining Services**
  - Early identification and intervention for behaviors that may jeopardize housing
  - Education and training on the roles, rights, and responsibilities of a tenant and landlord
  - Coaching on key relationships with landlords and property managers
  - Assistance with resolving disputes with landlords
  - Assistance with housing recertification process
  - Training in being a good tenant and lease compliance

In May 2017, Indiana Medicaid participated in a day-long summit on the topic of supportive housing. The summit was hosted by one of Indiana Medicaid's MCEs and was attended by representatives from all four of the MCEs along with various stakeholders representing housing. This summit was used to lay the foundation for a larger commitment to exploring supportive housing opportunities throughout the remainder of 2017.

Indiana will utilize time throughout 2018 to get a better understanding of the terminology surrounding supportive housing. Indiana Medicaid will then invite representatives from each of the MCEs, the Indiana Housing and Community Development Authority (IHCDA), and other interested stakeholders to continue the efforts begun in May 2017 towards developing a supportive housing solution. Indiana Medicaid will provide ongoing updates to CMS as required to demonstrate progress towards a final solution.

Withdrawal Management Services (Inpatient Detoxification)

Summary of Action Items:

- Conversation with MCEs regarding authorization criteria

Current State

Indiana Medicaid currently reimburses for withdrawal management services (known as inpatient detoxification). Indiana does not address distinctions among the various withdrawal management levels of care according to the ASAM Patient Placement Criteria.

During the 2016 legislative session, the Indiana General Assembly passed Senate Enrolled Act 297, which required the Office of Medicaid Policy and Planning (OMPP) to establish inpatient detoxification admission criteria in accordance with either:

- The most current edition of the American Society of Addiction Medicine (ASAM) Patient Placement Criteria; or
- Other clinical criteria that are determined by the office and are evidenced based and peer reviewed.

Indiana Medicaid released BT201632 announcing that inpatient detoxification criteria may be based upon one of the following:

- Milliman Care Guidelines
- InterQual Criteria
- American Society of Addiction Medicine (ASAM) Patient Placement Criteria
- Anthem Clinical Utilization Management (UM) Guidelines

Future State:

Indiana will continue requiring the usage of the criteria outlined in BT201632. Similar to authorization requirements for residential and other inpatient treatment, the managed care entities, as well as Indiana Medicaid's fee-for-service prior authorization vendor, will be allowed to utilize any evidence-based clinical decision system that incorporates all six specific dimensions of life care, as articulated in the ASAM Patient Placement Criteria.

Use of Evidenced-Based SUD-Specific Patient Placement Criteria

In addition to newly covered addiction treatment services, Indiana is incorporating established standards of care for medical necessity criteria and provider qualifications. Specifically, Indiana will be incorporating the ASAM Criteria into both prior authorization requests for services as well as certification for residential providers. Indiana will accomplish this through administrative rule changes, policy manual updates, and contract amendments.

Patient Assessment

Individuals seeking substance use treatment for all ASAM levels of care, including residential and inpatient, will be required to undergo a psychosocial assessment that will be used for the completion of a plan of treatment. As part of the assessment, providers will be required to address all six dimensions of multidimensional assessment, including the following:

- Acute intoxication and/or withdrawal potential
- Biomedical conditions and complications
- Emotional, behavioral, or cognitive conditions and complications
- Readiness to change
- Relapse, continued use, or continued problem potential
- Recovery/living environment

Each of the six dimensions plays a critical role in assigning an individual to the most appropriate level of care, including residential or inpatient treatment. As part of any prior authorization

request, providers will be required to submit assessments that address all six dimensions. Indiana Medicaid will work with its managed care partners to develop a standard template that will be submitted with every authorization request for an SUD-specific service. The template will be organized according to the ASAM Patient Placement Criteria and will help guide providers towards the most appropriate level of care for a member.

As previously mentioned, Indiana Medicaid currently utilizes the CANS and ANSA assessment tools to determine an individual's placement with an MRO package of services. Indiana Medicaid will work closely with DMHA to review these tools and align them closer with the ASAM Criteria.

DMHA will pursue opportunities to provide education to Indiana's provider community around the appropriate use of the ASAM Criteria. This will include ongoing outreach to Indiana's ASAM chapter as well as the utilization of national ASAM resources.

Utilization Management

Once an eligible licensed professional has completed a psychosocial assessment for individuals needing substance use treatment, those findings must be confirmed by an independent third party that has the necessary competencies to use the ASAM Patient Placement Criteria. Services at ASAM Level 2 and above will require prior authorization through either Cooperative Managed Care Services (CMCS) – the fee-for-service prior authorization vendor – or one of our four managed care entities. All service level of care and length of stay requests will be authorized using the ASAM Patient Placement Criteria. Each vendor will be allowed to utilize any evidence-based system for clinical guidelines that incorporates the medical criteria required for an individual to meet an ASAM level of care.

Indiana will review each of its managed care partners' contracts and pursue amendments to formalize the usage of the ASAM Patient Placement Criteria as well as any other changes necessary as a result of the 1115 SUD demonstration waiver. These amendments will be used to ensure that members have access to SUD services at the most appropriate level of care, that interventions are appropriate for the diagnosis and level of care, and that providers receive an independent process for reviewing placement in residential treatment settings.

Each of Indiana Medicaid's managed care entities (MCEs) are contractually obligated to operate and maintain a utilization management program. This allows each MCE to place limits on coverage on the basis of medical necessity or utilization control criteria. The State requires the usage of a nationally recognized set of guidelines for its medical management criteria, which may include InterQual, Milliman Care Guidelines, or any other accepted set of evidence-based guidelines. When utilizing a set of guidelines for residential and inpatient addictions treatment, each MCE will be required to demonstrate incorporation of the six dimensions of multidimensional assessment, as outlined in the ASAM Patient Placement Criteria.

While each MCE is allowed to decide which nationally recognize set of guidelines to use for its medical management criteria, all MCEs are required to utilize the Indiana Health Coverage

Programs Prior Authorization Request Form. To help facilitate prior authorization requests for addiction treatment services in alignment with the ASAM Patient Placement Criteria, Indiana Medicaid will work with the MCEs to develop an additional form that will assist providers in requesting approval for the usage of the most appropriate level of care for an individual (as indicated in the previous section). Additionally, as discussed in the previous section, Indiana is expecting to update the ANSA assessment tool to be used by all SUD providers as the multidimensional assessment required by the ASAM Criteria to ensure that individuals are placed in the most appropriate level of care.

The MCEs are expected to use additional utilization review processes to ensure that services are medically necessary. Each MCE is required to have policies and procedures in place to review instances of over- and under-utilization of emergency room services and other health care services, identify aberrant provider practice patterns, ensure active participation of a utilization review committee, evaluate efficiency and appropriateness of service delivery, and identify quality of care issues. All of these processes are especially critical to the State's efforts around combatting substance use.

A list of action items and expected implementation timeline related to patient assessment and utilization management is provided in the table below:

Action	Implementation Timeline
Provider education on ASAM Criteria	Ongoing throughout 2018
Development of standard prior authorization SUD treatment form	Completed by July 1, 2018
Review contracts and pursue amendments where necessary	Filed by July 1, 2018
Review CANS/ANSA for alignment with ASAM Criteria	Completed by December 31, 2018

Use of Nationally Recognized SUD-Specific Program Standards for Residential Treatment

Indiana's current residential facility certification requirements are not designed to support residential facilities as treatment facilities. They do not adequately meet the standards placed by the ASAM Criteria. Rather than focus on treatment requirements for services rendered within a residential facility, current certification focuses on resident rights, physical building attributes and basic health/nutrition needs of residents. As a result of this insufficiency, Indiana does not have a definitive breakdown of providers by ASAM Criteria-approved level of care.

To remedy this problem, DMHA is developing new administrative rules that align residential facility certification with the higher standards of the ASAM Patient Placement Criteria. Providers who are wishing to receive reimbursement from Indiana Medicaid for residential services will need to be designated by DMHA as either an ASAM Level 3.1 or Level 3.5 facility.

The Indiana Administrative Code will be updated with specific requirements around the setting, provider type, treatment goals, and therapies required at the appropriate level of care.

Because the rulemaking process can take upwards of twelve to eighteen months for promulgation, DMHA is proposing to issue provisional ASAM designations until the new certification requirements have been promulgated. Between May and September 2017, DMHA and Indiana Medicaid visited each current residential facility to begin discussions on both the new coverage authorized through the 1115 SUD waiver as well as the new certification requirements. Ahead of each meeting, DMHA delivered a one-page memo along with a four-page questionnaire that providers were asked to complete ahead of the formal on-site visit with the provider. The completion of the questionnaire will assist DMHA in assigning a provisional ASAM Level of Care designation to the facility.

In late 2017, DMHA will be prepared to issue guidance to its currently certified residential facilities around the requirement of the ASAM designation. DMHA will begin accepting documentation and issuing provisional designations in early 2018. This designation will be instrumental during the implementation of a new Indiana Medicaid provider specialty, as discussed in the next section. Finally, DMHA will spend much of 2018 reworking its Indiana Administrative Code language for residential certification to incorporate all required aspects of the ASAM Criteria, including a requirement that residential facilities offer medication-assisted treatment (MAT) on-site or through facilitated access off-site.

A list of action items and expected implementation timeline related to standards for residential facilities is provided in the table below:

Action	Implementation Timeline
Finalize process for provisional ASAM designation	Will be completed by December 31, 2017
Insert permanent certification language in Indiana Administrative Code	Will be filed by December 31, 2018

Sufficient Provider Capacity at Critical Levels of Care

Network adequacy is a critical concern for the success of the 1115 SUD waiver. DMHA certifies all mental health and addiction providers in Indiana. For purposes of the 1115 SUD waiver, Indiana will address two current certifications:

- Addiction Treatment Services Provider (Regular) – an agency with eleven or more direct service staff
- Addiction Treatment Services Provider (Outpatient) – an agency with ten or fewer direct service staff/volunteers/contract workers

Addiction Treatment Services Provider (Regular)

The State has identified 80 facilities that are certified by DMHA as Addiction Treatment Services Providers (Regular). This group of facilities includes residential facilities, psychiatric

hospitals, acute care hospitals (and wings of acute care hospitals), and opioid treatment programs.

Due to the previously-mentioned 2015 state law change, nearly all of Indiana's opioid treatment programs (OTPs) are now enrolled with Indiana Medicaid. A new provider specialty for OTPs has been developed and went active in September 2017. Indiana will continue to pursue the remaining programs, as well as any new clinics that open in the coming months, for Medicaid enrollment.

The largest provider enrollment challenge facing Indiana Medicaid is the enrollment of residential facilities. Nearly all of the currently-enrolled facilities are community mental health centers (CMHCs) or outpatient mental health clinics with a limited number of residential beds; many facilities would not meet the standards of a psychiatric hospital or an outpatient clinic, and without reimbursement for residential stays, these facilities have had no incentive to enroll with Indiana Medicaid. In addition to pursuing updated certification standards that meet the ASAM Criteria, Indiana will also be creating a new provider specialty for residential addictions facilities. To enroll with Indiana Medicaid, these facilities will be required to be certified by DMHA as a residential sub-acute facility and will also be designated by DMHA as an ASAM Level 3.1 or 3.5 facility. By meeting the ASAM designation, these facilities will automatically meet the qualification to be certified as an Addiction Treatment Services Provider (Regular).

Addiction Treatment Services Provider (Outpatient)

The State has identified 161 organizations that are licensed as Addiction Treatment Services Provider (Outpatient). Many of these organizations are not enrolled as IHCP providers. Many are believed to be small office practices that are not overseen by a physician or HSPP, preventing Medicaid reimbursement. These addictions providers must have qualified staff and must perform at least outpatient treatment services and may provide intensive outpatient treatment services to those individuals with whom assessments indicate a need for those services. Indiana Medicaid may consider creating additional provider specialties for these office-based outpatient addictions providers.

Provider Enrollment

Indiana Medicaid enrolls its behavioral health providers using one of the following provider types and specialties:

- Type 01 (Hospital) – Specialty 011 (Psychiatric)
- Type 11 (Mental Health) – Specialty 110 (Outpatient Mental Health Clinic)
- Type 11 (Mental Health) – Specialty 111 (Community Mental Health Center)
- Type 11 (Mental Health) – Specialty 114 (Health Service Provider in Psychology)
- Type 31 (Physician) – Specialty 339 (Psychiatrist)
- Type 35 (Addiction Services) – Specialty 835 (Opioid Treatment Program)

As indicated above, many of the Addiction Treatment Services Providers (Outpatient) are considered mid-level practitioners and are not enrolled with Indiana Medicaid. Additionally,

some providers enrolled under one of these provider specialties may only provide mental health and not addiction treatment. Both pose a challenge towards understanding access to addiction services.

Indiana Medicaid will take several measures to ensure sufficient provider capacity:

- We will pursue stronger data analytics around our provider capacity. This will begin by determining, by provider specialty, how many providers are capable of providing each ASAM level of care. We will determine the correct system specifications to determine both who is capable of billing a specific level of care and who is actually billing a specific level of care. We will track this information over the course of the demonstration.
- We will also complete a full assessment of the availability of medication-assisted treatment (MAT) for Indiana Medicaid members. This will include identifying the number and locations of all Indiana Medicaid providers who have the appropriate buprenorphine training for prescribing MAT.
- We will also consider adding additional provider specialties to account for more mid-level practitioners, including licensed behavioral health professionals.

Overall Provider Strategy

Indiana's provider community is new to the principles of the ASAM Patient Placement Criteria. As a result, the State will take a multi-tiered approach to bring our providers closer in alignment with ASAM principles:

- From summer 2017 through the remainder of the year, the State will visit each residential addictions facility to begin a dialog around Medicaid reimbursement for residential treatment as well as the ASAM Patient Placement Criteria. This discussion will assist the State in assigning a provisional ASAM Level of Care designation, as previously discussed.
- By early 2018, Indiana Medicaid will have completed all necessary system modifications to ensure that residential addictions facilities are able to enroll and receive reimbursement for addictions service rendered. This will be communicated through Indiana Medicaid's provider website as well as an IHCP Provider Bulletin.
- Also by early 2018, Indiana Medicaid will have developed new training material on the 1115-approved services as well as provider enrollment for interested residential facilities. This material will be included as part of quarterly and annual IHCP provider workshops.
- By the end of the first quarter 2018, Indiana Medicaid will have developed the data analytics required to assess utilization of services by ASAM level. This analysis will be completed quarterly in anticipation of a full assessment of member access to all ASAM levels of care by the end of 2018. This will also include the availability of medication-assisted treatment.
- Throughout 2018, upon approval of new administrative certification rules, all residential facilities will be able to receive an ASAM designation. The finalized designation will be

parallel to an ongoing effort at educating providers on the use of the ASAM Patient Placement Criteria to ensure that individuals seeking treatment are placed at the most appropriate level of care.

A list of action items and expected implementation timeline related sufficient provider capacity is provided in the table below:

Action	Implementation Timeline
Create new provider specialty for residential addictions facilities	Will be completed by March 1, 2018
Data reporting by provider specialty and ASAM level of care	Will be completed by March 31, 2018
Assessment of ASAM providers and services	Will be completed by December 31, 2018

Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse

Governor's Task Force on Drug Enforcement, Treatment, and Prevention

On September 1, 2015, then-Governor Mike Pence issued Executive Order 15-09, establishing the Governor's Task Force on Drug Enforcement, Treatment, and Prevention to identify best practices and make informed recommendations for policy makers. The task force included membership from the Indiana General Assembly, the Governor's Office, the Indiana State Department of Health, the Indiana Department of Correction, the Indiana Department of Child Services, the Indiana Family and Social Services Administration, and other organizations and associations throughout Indiana. The group held multiple regional public meetings to hear from individuals affected by substance use disorders, local and state government officials, law enforcement, and other community leaders.

On December 5, 2016, the task force completed its work and issued a final report detailing all of their findings along with 17 actionable recommendations for lawmakers and state agencies to consider. The following list includes all recommendations identified by the group:

Enforcement Recommendations:

1. Support legislation to enhance penalties for persons dealing drugs convicted of serious and aggravated offenses.
2. Direct the Indiana Department of Correction to work with Starke and other northwest Indiana counties to pilot and adopt the Regional Therapeutic Communities program, which provides more treatment options for local officials in addressing addiction.
3. Direct the Indiana Criminal Justice Institute (CJI) and the Indiana Division of Mental Health & Addiction (DMHA) to identify a county criminal justice entity and implement a therapeutic substance use disorder treatment program for offenders awaiting adjudication and for those service sentences while in jail.

Treatment Recommendations:

4. Direct the Indiana Family and Social Services Administration (FSSA) to implement the Gold Card program, which removes administrative burdens by allowing qualified physicians the ability to prescribe medications without prior authorization (while still following the established criterion).
5. Direct the FSSA to pursue a Medicaid 1115 Demonstration Waiver for individuals with substance use disorders to broaden Indiana Medicaid benefit packages and provide a more comprehensive continuum of covered services and care.
6. Direct appropriate entities to promulgate and adopt with all expediency chronic pain prescribing rules for all prescribers.
7. Direct the Indiana State Department of Health (ISDH) to work with appropriate entities including those that represent physicians, nurses, dentists, physician assistants, podiatrists, and veterinarians to develop guidelines for prescribing acute pain medications. Endorse opioid and controlled substance prescribing guidelines for emergency departments as part of a larger strategy to combat prescription drug abuse in Indiana.
8. Direct the ISDH to convene a working group to send recommendations on improvements and best practices related to INSPECT – Indiana's Prescription Drug Monitoring Program - to the INSPECT Oversight Committee.
9. Direct the Indiana Professional Licensing Agency (PLA) to begin implementing a pilot program, the INSPECT Integration Initiative, to allow for the integration of INSPECT data with hospital patient records.
10. Direct the PLA to request that the INSPECT Oversight Committee explore possible measures to increase access to INSPECT for prescribers and dispensers.
11. Direct state agencies to raise awareness of Aaron's Law.
12. Direct the Indiana Department of Homeland Security (IDHS) to identify gaps in naloxone availability compared with overdose demographics.
13. Support legislation that would amend state law to require ISDH to issue a standing order for the dispensing of an overdose intervention drug, such as naloxone, and to expand the state's LifeLine Law to include immunity beyond alcohol offenses.
14. Direct the ISDH to implement a central repository naloxone distribution program for first responders should Indiana experience increased numbers of overdoses that would deplete local responders' supplies.
15. Support legislation that would modify the Governor's Commission for a Drug-Free Indiana in a way that maintains support for Local Coordinating Councils but brings together state agencies and stakeholders to address the drug abuse issues Indiana is facing today.
16. Direct the Indiana Department of Workforce Development to work closely with existing youth assistance programs and identify best practice models to replicate statewide.
17. Request the Commission for Improving the Status of Children make recommendations through its Educational Outcomes Task Force and Substance Abuse and Child Safety Task Force on the following: developing an age-appropriate substance abuse

curriculum for students, and finding ways to better connect affected youth with substance abuse services.

Gold Card Program

Indiana Medicaid implemented a Gold Card program in late 2015. This allows qualified Indiana Medicaid prescribers to be exempt from prior authorization document submission requirements for individual Indiana Medicaid members when prescribing buprenorphine and buprenorphine/naloxone. The Gold Card program currently has 16 prescribers. The following requirements currently apply to each prescriber:

- Must be an enrolled IHCP provider
- Must be licensed to practice medicine in the State of Indiana and be in good standing with the Indiana PLA and FSSA
- Must hold one of the following certifications:
    - A subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology (ABPN)
    - An addiction medicine certification from the American Board of Addiction Medicine (ABAM)
    - A certification of added qualification (CAQ) in addiction medicine from the American Osteopathic Association
- Must comply with all applicable Federal and State laws and regulations pertaining to the prescribing of controlled substances, including buprenorphine and buprenorphine/naloxone
- Must agree to comply with all current IHCP buprenorphine and buprenorphine/naloxone criteria as set forth by State and Federal law and the FSSA or its designee
- Must maintain complete medical records for individual IHCP members documenting criteria compliance
- Must commit to IHCP audits, occurring at the discretion of FSSA
- Must immediately inform FSSA, through its pharmacy benefit manager (PBM), of any change in qualification status
- Must agree that the FSSA reserves the right to withdraw the prescriber from participation in this program

Buprenorphine Prior Authorization Criteria

For non-Gold card members, Indiana Medicaid adopted specific prior authorization criteria for prescriptions of buprenorphine and buprenorphine/naloxone (also known as Suboxone). The criteria is now used by all of the MCEs' PBMs. These products may be approved for up to six months at a time, with a member receiving a 34-day supply at a time. The following authorization criteria applies for both fee-for-service and managed care members:

- Patient must be 16 years of age or older
- Physician must meet all qualifications to prescribe buprenorphine and buprenorphine/naloxone

- Patient must have a diagnosis of opiate dependence/addiction
- Physician must verify that the risks of using buprenorphine/naloxone with alcohol or benzodiazepines have been explained to the patient
- Physician must verify that there are not untreated or unstable psychiatric conditions that would interfere with buprenorphine/naloxone or buprenorphine compliance
- For pregnant members, physician must explain choice of buprenorphine/naloxone or buprenorphine over alternatives
- Physician must provide documentation of the patient's referral to or active involvement in formal counseling with a licensed behavioral health provider.

Indiana Attorney General's Prescription Drug Abuse Prevention Task Force

The Indiana Attorney General's Prescription Drug Abuse Prevention Task Force is a separate task force created in September 2012 by then-Indiana Attorney General Greg Zoeller to focus on five key components:

1. Providing education regarding the safe and appropriate prescribing and use of opioids for medical providers
2. Reducing drug diversion
3. Ensuring sustainability with the state's Prescription Drug Monitoring Program (INSPECT)
4. Increasing availability of disposal sites for unused controlled substances
5. Improving access to treatment and recovery for those suffering from addiction

The task force published a four-year report in December 2016. Many of the same objectives identified by the Governor's Task Force were acted upon by this task force. The four-year report detailed many legislative accomplishments, including the following:

- Obtained a long-term funding solution for INSPECT by moving 100% of the funds generated by the Controlled Substance Registrations back into the program
- Required licensing boards to establish opioid prescribing guidelines for chronic pain
- Required methadone clinics to check INSPECT before prescribing
- Required pharmacists to report dispensing data to INPSECT within 24 hours
- Created immunity for first responders and lay persons to administer naloxone
- Allowed for Syringe Exchange Programs to be implemented in counties at risk of HIV or Hep C outbreaks
- Appropriated $30 million to the Mental Health and Addiction Forensic Treatment Services account (administered by DMHA) for addiction services for those convicted of a felony

Prescribing Guidelines

In 2014, the Indiana Medical Licensing Board issued final rules establishing the standards and protocols for physicians in the prescribing of opioid controlled substances for pain management

treatment. These standards are outlined in 844 IAC 5-6. The rules apply for individuals who have been prescribed one of the following:

- More than sixty (60) opioid-containing pills a month for more than three (3) consecutive months
- A morphine equivalent dose of more than fifteen (15) milligrams per day for more than three (3) consecutive months
- A transdermal opioid patch for more than three (3) consecutive months
- A tramadol dose reaching a morphine equivalent of more than sixty (60) milligrams per day for more than three (3) consecutive months
- An extended release opioid medication that is not in an abuse deterrent form for which an FDA-approved abuse deterrent form is available

Additionally, in response to Indiana Senate Enrolled Act 297 (2016), DMHA created clinical practice guidelines for office-based opiate treatment. These guidelines have been distributed to OMPP, the Indiana Professional Licensing Agency, and each of the MCEs. The guidelines have been attached as an appendix to this implementation report.

The Indiana General Assembly also passed Indiana Senate Enrolled Act 226 (2017), which limited the prescription supply for opioids to only seven days for adults who are prescribed an opioid for the first time as well as for children under the age of 18.

Expanded Access to Naloxone

In 2015, the Indiana General Assembly passed Indiana Senate Enrolled Act 406 (2015), which significantly expanded the number of people who can have access to a prescription for Naloxone. Passage of the law allowed a person at risk for overdose or any individual who knows someone who may be at risk for overdosing to receive a prescription for the medication.

In 2016, this law was further amended through Indiana Senate Enrolled Act 187 (2016) that required the State Health Commissioner to issue a statewide standing order for the dispensing of naloxone. This further expanded access by allowing any individual to walk into a pharmacy for a prescription of naloxone without having to see a physician or other qualified prescriber first.

Naloxone (Narcan) is considered a preferred drug through Indiana Medicaid's pharmacy benefit. In determining ways of expanded access to naloxone further, Indiana Medicaid is exploring ways to allow emergency responders to receive reimbursement for the administration of naloxone. Indiana Medicaid does not currently enroll paramedics or emergency responders directly; rather, Indiana Medicaid enrolls transportation providers, including ambulances and common carrier providers. Indiana will consider releasing guidance allowing a physician to bill for the administration of naloxone on behalf of an emergency responder as well as consider enrolling emergency responders directly.

A list of action items and expected implementation timeline related to the expansion of naloxone for overdose reversal is included below:

Action	Implementation Timeline
Consider options for emergency responder reimbursement of naloxone	Will be completed in early 2018

Prescription Drug Monitoring Program

On August 24, 2017, Indiana Governor Eric Holcomb announced a major statewide initiative around incorporating the State's prescription drug monitoring program (knowing as INSPECT) directly into health care systems' electronic health records. Once fully integrated, practitioners will no longer be required to use multiple portals to access information around the prescribing and dispensing of controlled substances. Initial efforts at integration were made through Deaconness Midtown hospital in Evansville, Indiana; due to that system's success, the effort is being pushed across the entire state. Within three years, Indiana hopes to have all of its hospital systems fully integrated with INSPECT.

Taken as a whole, these efforts demonstrate the State's commitment to using all available resources (legislative changes, state regulations, certification, members within the community) for multiple strategies towards addressing both prescription drug use and opioid use disorder. All of these efforts should provide assurance to CMS that Indiana has a sufficient health IT infrastructure at every appropriate level to achieve the goals of this demonstration.

Improved Care Coordination and Transitions Between Levels of Care

Indiana Medicaid places contractual obligations on each of its managed care entities (MCEs) around case management and care coordination. The following list details each of those obligations:

- Each MCE must provide case management services for any member at risk for inpatient psychiatric or substance use hospitalization; for members discharged from an inpatient psychiatric or substance use hospitalization, case management services must be provided for at least 90 calendar days following the hospitalization.
- Each MCE must schedule an outpatient follow-up appointment to occur no later than seven calendar days following a psychiatric or substance use hospitalization discharge.
- Case managers are assigned to ensure that each new member already receiving behavioral health services is linked to an appropriate behavioral health provider.
- Case managers must also consult with both a member's physical and behavioral health provider(s) to facilities the sharing of clinical information
- With appropriate consent, case managers are required to notify all providers when a member is hospitalized or receives emergency treatment for behavioral health issues, including substance use within five calendar days of the admission or emergency treatment.
- Each MCE is required to have policies and procedures in place to facilitate the reciprocal exchange of health information between physical and behavioral providers treating a

member. This information sharing must include primary and secondary diagnoses, findings from assessments, medication prescribed, psychotherapy prescribed, and other relevant information.

- Each MCE is required to send a behavioral health profile to a member's primary medical provider (PMP) on a quarterly basis. Information about substance use treatment may only be released only with a member's consent, per *42 CFR Part 2* standards.

The MCEs also use advanced data analytics to help identify who may be at risk for substance use. The MCEs utilize ER claims, pharmacy claims, diagnosis codes, health needs assessments, and other tools to help predict individuals who may be high risk and high cost in a given year. Depending upon the level of risk assigned to an individual, a person may be given 1:1 care coordination.

Another idea that some of Indiana Medicaid's MCEs utilize is having points of contact housed within state's community mental health centers. These points of contact work with their members to facilitate the transition among the various levels of behavioral health services.

Indiana believes it can take additional steps to ensure a smooth transition for individuals moving between levels of care:

- While our current contracts with our MCEs require case management services for individuals transitioning from inpatient hospital stays, Indiana will pursue conversations and additional contract amendments to ensure that this obligation extends to individuals transitioning from residential treatment facilities.
- Upon release from an inpatient or residential level of treatment, Indiana believes individuals gain strength on the road to recovery through their relationships with others who have experienced the same difficulties. Indiana Medicaid is choosing to expand its coverage of peer recovery coaches as a way of helping individuals connect with professional and nonprofessional services and resources that are available in their community. This will be especially important for Traditional Medicaid members who do not have the resources available through the MCEs.

Appendix: Best Practice Guidelines for the Treatment of Opioid Use Disorders

These best practice guidelines were developed in response to Indiana Senate Enrolled Act (SEA) 297 & SEA 214 (2016). The intent of the guidelines is to provide a standard of care for the treatment of opioid use disorders (OUDs) in the State of Indiana and will be sent to the Indiana Professional Licensing Agency, the Office of Medicaid Policy and Planning, and the managed care organizations contracted with the Office for implementation. Practice standards were determined through a review of existing guidelines and research base. The Indiana guidelines are intended to quickly assist providers in locating up to date, accurate and useful information. Leslie Hulvershorn, MD, Medical Director at the Indiana Division of Mental Health and Addiction (DMHA), was the primary author. Information was then reviewed within DMHA and was circulated for review to stakeholders, such as Mental Health America of Indiana, Addiction Psychiatry faculty and fellows from the Indiana University School of Medicine, and CleanSlate Centers. This guide applies to inpatient and office-based opioid treatment (OBOT) providers and Opioid Treatment Providers (OTPs; i.e., "methadone clinics") in their use of buprenorphine and naltrexone. Sections within quoted material marked by "[text in italics]" should be interpreted as additional text provided by the authors of the Indiana guidelines, not a part of the originally published material (e.g., American Society of Addiction Medicine guidelines). These guidelines are not intended to be a substitute for formal medical training in the treatment of substance use disorders. The definition of 'physician' in these guidelines includes all DATA-waved clinicians who prescribe buprenorphine for addiction treatment legally under their license in Indiana.

Abbreviations

American Psychiatric Association = APA American Society of Addiction Medicine = ASAM Medication assisted treatment= MAT

Opioid use disorders= OUDs

Office-based opioid treatment = OBOT (e.g., DATA waived physicians)

Opioid treatment programs=OTPs (Require particular license from DEA; Offer daily supervised dosing of methadone, and other medications)

Guideline Summary:

Comprehensive treatment, including medication assisted treatment (MAT), is an effective response to opioid use disorder (OUD). The use of medications, in combination with behavioral therapies, provides a whole-patient approach to the treatment of substance use disorders. Individuals receiving MAT often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning.

The opioid use disorder treatment protocol shall have the goal of opioid abstinence when appropriate or, if not possible, the minimal clinically necessary dose of medication. Treatment providers shall provide themselves, or through referral, comprehensive treatment options, including:

1. Opioid maintenance;
2. Opioid detox;
3. Overdose reversal;
4. Relapse prevention;
5. Long acting, nonaddictive medication assisted treatment medications.

Treatment for opioid use disorders shall be comprehensive and include:

1. Initial and periodic behavioral health assessments for each patient;
2. Informed consent from a concerning all available opioid treatment options, including each option's potential benefits and risks, before prescribing medication;
3. Appropriate use of providing overdose reversal medication, relapse prevention, counseling and ancillary services;
4. Transitioning off agonist and partial agonist therapies, when appropriate, with the goal of opioid abstinence.

Section 1. Assessment and Diagnosis of opioid use disorders for Office-based opioid treatment (OBOT) providers

Introduction:

In order to appropriately assess for opioid use disorders, as well as co-occurring mental health, other substance use disorders and physical health, best practices have been reviewed. Essential information about these best practices is as follows: .

For any provider treating opioid use disorders (OUDs), the following practices are recommended for assessment and diagnosis.

Assessment & Diagnosis Recommendations (excerpted from American Society of Addiction Medicine (ASAM) Guidelines [1]):

"(1) First clinical priority should be given to identifying and making appropriate referral for any urgent or emergent medical or psychiatric problem(s), including drug related impairment or overdose.

(2) Completion of the patient's medical history should include screening for concomitant medical conditions including infectious diseases (hepatitis, HIV, and TB), acute trauma, and pregnancy. [If the provider does not provide this type of medical screening, the patient should be referred to a provider who does and any findings (if not readily identifiable in the medical record) should be reported to the provider treating the OUDs.]

(3) A physical examination should be completed as a component of the comprehensive assessment process. The prescriber (the clinician authorizing the use of a medication for the treatment of opioid use disorder) may conduct this physical examination him/herself, or, in accordance with the ASAM Standards, [refer to another provider to] ensure that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction.

(4) Initial laboratory testing should include a complete blood count, liver function tests, and tests for hepatitis C and HIV. Testing for TB and sexually transmitted infections should also be considered. Hepatitis B vaccination should be offered, if appropriate.

(5) The assessment of women presents special considerations regarding their reproductive health. Women of childbearing age should be tested for pregnancy, and all women of childbearing potential and age should be queried regarding methods of contraception, given the increase in fertility that results from effective opioid use disorder treatment.

(6) Patients being evaluated for addiction involving opioid use, and/or for possible medication use in the treatment of opioid use disorder, should undergo (or have completed) an assessment of mental health status and possible psychiatric disorders (as outlined in the ASAM Standards). [Any psychiatric disorders that are identified warrant treatment, either by referral or treatment directly by the OBOT provider. Periodic mental health screens (and subsequent treatment) should be completed by the OBOT provider every 3 months, or with the emergence of psychiatric symptoms (e.g., depression, psychosis), whichever occurs first.]

(7) Opioid use is often co-occurring with other substance related disorders. An evaluation of past and current substance use and a determination of the totality of substances that surround the addiction should be conducted.

(8) The use of marijuana, stimulants, or other addictive drugs should not be a reason to suspend opioid use disorder treatment. However, evidence demonstrates that patients who are actively using substances during opioid use disorder treatment have a poorer prognosis. [The use of benzodiazepines and other sedative hypnotics is a reason to suspend agonist treatment because of safety concerns related to respiratory depression. A

thirty day benzodiazepine taper should be initiated at the onset of treatment or whenever the benzodiazepine use is discovered. On occasion, if ongoing withdrawal is clearly present and documented, a ninety day benzodiazepine taper may be warranted.]

(9) A tobacco use query and counseling on cessation of tobacco products and electronic nicotine delivery devices should be completed routinely for all patients, including those who present for evaluation and treatment of opioid use disorder.

(10) An assessment of social and environmental factors should be conducted… Addiction should be considered a bio-psycho-social-spiritual illness, for which the use of medication(s) is but only one component of overall treatment."

Diagnostic Recommendations (excerpted from ASAM Guidelines [1]):

"(1) Other clinicians may diagnose opioid use disorder, but confirmation of the diagnosis by the provider with prescribing authority and who recommends medication use must be obtained before pharmacotherapy for opioid use disorder commences.

(2) Opioid use disorder is primarily diagnosed on the basis of the history provided by the patient and a comprehensive assessment that includes a physical examination.

(3) Validated clinical scales that measure withdrawal symptoms, for example, the Objective Opiate Withdrawal Scale (OOWS), Subjective Opiate Withdrawal Scale (SOWS), and the Clinical Opiate Withdrawal Scale (COWS), may be used to assist in the evaluation of patients with opioid use disorder.

(4) Urine drug testing during the comprehensive assessment process, and frequently during treatment, is recommended. The frequency of drug testing is determined by a number of factors, including the stability of the patient, the type of treatment, and the treatment setting."

Section 2. Appropriate use of medications for the treatment of Opioid Use Disorders by OBOT Providers

Introduction:

Medications with a substantial evidence base supporting their efficacy in various stages of the treatment of opioid use disorders are reviewed in this section.

Specifically, evidence supporting detoxification, maintenance treatment, dosing recommendations and overdose reversal are reviewed. In addition, practices lacking an evidence base are also covered here.

(i) Opioid maintenance treatment options:

Buprenorphine (excerpted from ASAM Guidelines [1]): "Treatment with buprenorphine for opioid addiction consists of three phases: (1) induction, (2) stabilization, and (3) maintenance. Induction is the first stage of buprenorphine treatment and involves helping patients begin the process of switching from the opioid of abuse to buprenorphine. The goal of the induction phase is to find the minimum dose of buprenorphine at which the patient discontinues or markedly diminishes use of other opioids and experiences no withdrawal symptoms, minimal or no side effects, and no craving for the drug of abuse. The consensus panel recommends that the buprenorphine/naloxone combination be used for induction treatment (and for stabilization and maintenance) for most patients. The consensus panel further recommends that initial induction doses be administered as observed treatment; further doses may be provided via prescription thereafter... Pregnant women who are deemed to be appropriate candidates for buprenorphine treatment should be inducted and maintained on buprenorphine monotherapy. The stabilization phase has begun when a patient is experiencing no withdrawal symptoms, is experiencing minimal or no side effects, and [cravings have been significantly reduced]. Dosage adjustments may be necessary during early stabilization, and frequent contact with the patient increases the likelihood of compliance. The longest period that a patient is on buprenorphine is the maintenance phase. This period may be indefinite. During the maintenance phase, attention must be focused on the psychosocial and family issues that have been identified during the course of treatment as contributing to a patient's addiction[, rather than on buprenorphine dose escalation.]"

Minimum clinically necessary dosing (excerpted from ASAM Guidelines [1]):

> "(1) Opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal. Generally, buprenorphine initiation should occur at least 6–12 hours after the last use of heroin or other short-acting opioids, or 24–72 hours [or more for individuals taking high doses of opioids] after their last use of long-acting opioids such as methadone.
>
> (2) Induction of buprenorphine should start with a dose of 2–4 mg, [with 8mg inductions being appropriate for a greater degree of physiologic dependence]. Dosages [are often] increased in increments of 2–4mg.
>
> (3) Clinicians should observe patients in their offices during induction.
>
> (4) Buprenorphine doses after induction and titration should be, on average, at least 8mg per day. However, if patients are continuing to use opioids, consideration should be given to increasing the dose by 4–8mg (daily doses of 12–16mg). [While the US FDA approves dosing to a limit of 24mg per day, there is little evidence for clinical benefit beyond 16mg. Dosing beyond 24 mg is not recommended.] In addition, the use of higher doses may increase the risk of diversion.

(5) Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder. [Buprenorphine prescribers should be in regular contact with the psychosocial treatment team in order to be aware clinical progress. Preferably, the psychosocial and prescribing providers are co-located and on the same treatment team.]

(6) Clinicians should take steps to reduce the chance of buprenorphine diversion. Recommended strategies include frequent office visits (weekly in early treatment), drug testing, including testing for buprenorphine and [metabolites (e.g., norbuprenorphine)], and recall visits for pill counts. [In the case of diversion, the opioid treatment provider must determine that the benefit to the patient in receiving the medication outweighs the potential risk of diversion resulting from the take home medication.]

(7) Patients should be tested frequently for buprenorphine, other substances, and prescription medications. Accessing Prescription Drug Monitoring Program (PDMP) data [(INSPECT) is] useful for monitoring. [See Section V.2. below. If a patient tests positive for a controlled substance other than the buprenorphine prescribed, the clinician shall review the treatment plan and consider changes with the goal of opioid abstinence.

(8) Patients should be seen frequently at the beginning of their treatment. Weekly visits (at least) are recommended until patients are determined to be stable. There is no recommended time limit for treatment. [Provider must determine and document that the benefit of the receiving a supply of medication to treat an opioid use disorder would outweigh the potential risk of diversion.]

(9) Buprenorphine taper and discontinuation is [generally] a slow process and close monitoring is recommended… Patients should be encouraged to remain in treatment for ongoing monitoring past the point of discontinuation.

(10) When considering a switch from buprenorphine to naltrexone, 7–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the patient is not physically dependent on opioids before starting naltrexone.

(11) When considering a switch from buprenorphine to methadone, there is no required time delay because the addition of a full mu-opioid agonist to a partial agonist does not typically result in any type of adverse reaction.

(12) Patients who discontinue agonist therapy and resume opioid use should be made aware of the risks associated with an opioid overdose, and especially the increased risk of death."

(ii) Detoxification:

A. Buprenorphine detoxification (excerpted from ASAM Guidelines [1]): "Buprenorphine can be used for the medically supervised withdrawal of patients from both self-administered opioids and from opioid agonist treatment with methadone.... The goal of using buprenorphine for medically supervised withdrawal from opioids is to provide a transition from the state of physical dependence on opioids to an opioid-free state, while minimizing withdrawal symptoms. Medically supervised withdrawal with buprenorphine consists of an induction phase and a dose-reduction phase. The consensus panel recommends that patients dependent on short acting opioids (e.g., hydromorphone, oxycodone, heroin) who will be receiving medically supervised withdrawal be inducted directly onto buprenorphine/naloxone tablets. The use of buprenorphine (either as buprenorphine monotherapy or buprenorphine/naloxone combination treatment) to taper off long acting opioids should be considered only for those patients who have evidence of sustained medical and psychosocial stability, and should be undertaken in conjunction and in coordination with patients' OTPs."

B. Clonidine detoxification (excerpted from the APA guidelines [2]): "Clonidine is a [non-addictive] centrally acting α2-adrenergic antihypertensive medication that effectively decreases the noradrenergic hyperactivity associated with opioid withdrawal. Clonidine is not approved for opioid withdrawal in the United States but has been extensively studied and used for this indication elsewhere. Clonidine reduces withdrawal symptoms such as nausea, vomiting, diarrhea, cramps, and sweating but, unlike methadone, does little to reduce other symptoms such as muscle aches, insomnia, distress, and drug craving [3, 4]. As a non-opioid medication, clonidine has some advantages over methadone for withdrawal. For example, clonidine does not produce opioid-like tolerance or dependence or the post-methadone rebound in withdrawal symptoms [5]. In addition, patients completing a course of clonidine-assisted withdrawal can immediately be given an opioid antagonist (e.g., naltrexone) if indicated. The disadvantages of clonidine include its aforementioned inability to improve certain opioid withdrawal symptoms, associated hypotension that can be profound despite the use of low doses of this medication, and its possible sedative effects. Contraindications to the use of clonidine include acute or chronic cardiac disorders, renal or metabolic disease, and moderate to severe hypotension [6]. On the first day of clonidine-aided detoxification, a clonidine dose of 0.1 mg three times daily (totaling 0.3 mg per 24 hours) is usually sufficient to suppress signs of opioid withdrawal; inpatients can generally receive higher doses to block withdrawal symptoms because of the availability of medical staff to monitor the patient for hypotension and sedation. The dose is adjusted until withdrawal symptoms are reduced. If the patient's blood pressure falls below 90/60 mm Hg, the next dose should be withheld, after which tapering can be resumed while the patient is monitored for signs of withdrawal. In the case of short-acting opioids such as heroin, clonidine-aided withdrawal usually takes 4–6 days. Other medications may be used along with clonidine to treat withdrawal symptoms. In general, clonidine-assisted detoxification is easier to carry out and monitor in inpatient settings. Clonidine-induced sedation is also less of a problem for inpatients."

C. Clonidine-Naltrexone (Excerpted from APA [2]): "The combined use of clonidine and naltrexone for rapidly withdrawing patients from an opioid has been demonstrated to be safe and effective. Essentially, naltrexone-precipitated withdrawal is avoided by pretreating the patient with clonidine. This technique is most useful for opioid dependent patients who are in transition to narcotic antagonist treatment [e.g., naltrexone]. The limitations of this method include the need to monitor patients for 8 hours on the first day because of the potential severity of naltrexone-induced withdrawal and the need for careful blood pressure monitoring during the entire detoxification procedure."

D. Supplementary Medications (Excerpted from APA [2]): "Some clinicians and treatment programs have used medications targeting the symptoms of opioid withdrawal as the primary means for treating this condition. For example,…, antiemetics are prescribed to treat nausea and vomiting, NSAIDs are provided for muscle cramps, and antispasmodics [(e.g., dicyclomine)] are used to treat gastrointestinal cramping. There are limited controlled data about the use of such medications for the treatment of opioid withdrawal [8]…Diphenhydramine, hydroxyzine, and sedating antidepressants (e.g., doxepin, amitriptyline, trazodone) have been used for [insomnia and anxiety.] It should be noted that these medications have also been abused, although much less often than benzodiazepines [9]. Other medications such as NSAIDs and antispasmodics may be safely provided but appear to be less effective than mu agonist opioids for symptom relief."

(iii) Overdose Reversal (Excerpted from APA Guidelines [2]):

"The syndrome of acute opioid overdose is recognizable by respiratory depression, extreme miosis, and stupor or coma [10]. Pulmonary edema may also be observed. Naloxone is a competitive antagonist at all three types of opiate receptors (mu, kappa, and sigma) and has no intrinsic agonist activity [11]. It is clinically indicated to rapidly reverse a known or suspected opioid overdose [10, 12]…Because naloxone is rapidly absorbed by the brain and then quickly redistributed and eliminated from the body, its activity in the brain is short-lived [10, 13]. Thus, further monitoring and infusion of additional naloxone are needed to continue antagonizing the effects of severe opioid overdose, particularly if longer-acting opioids have been ingested [12, 14]. Monitoring for opioid withdrawal symptoms is also indicated because patients may experience significant distress that can last for several hours after reversal of an opioid overdose with an antagonist [9]." [Currently, in the State of Indiana, naloxone is available without a prescription from individual prescribers, as pharmacies have a written order to prescribe from the State Health Commissioner. At the time of assessment, OBOT providers should provide education about naloxone's role in overdose reversal to all patients in treatment for OUDs, as well as any involved family, caregivers or friends.

OBOT providers should recommend that patients in treatment obtain a supply of naloxone to use in case of an overdose, but provide education that not all overdoses can be rescued.]

(iv) Relapse prevention:

Relapse prevention is the use of pharmacologic and psychotherapeutic techniques that have been shown to decrease the risk of relapse in individuals in treatment for substance use disorders. See section 4 for psychotherapeutic techniques. FDA approved pharmacological treatments shown to reduce relapse in persons with OUDs include naltrexone, buprenorphine containing products and methadone.

Naltrexone (ASAM guidelines [1]):

"(1) Naltrexone is a recommended treatment for preventing relapse in opioid use disorder [and is generally well tolerated]. Oral formula naltrexone may be considered for patients in whom adherence can be supervised or enforced [e.g., individuals who are incarcerated, adolescents supervised by parents, inpatients]. Extended-release injectable naltrexone [Vivitrol TM] may be more suitable for patients who have issues with adherence, [particularly individuals living in the community, receiving outpatient treatment.]

(2) [Oral naltrexone should usually be taken daily in 50-mg doses.]

(3) Extended-release injectable naltrexone [Vivitrol TM] should be administered every 4 weeks by deep IM injection in the gluteal muscle at a set dosage of 380 mg per injection.

(4) Psychosocial treatment, [in conjunction with treatment with naltrexone, is required.] The efficacy of naltrexone use in conjunction with psychosocial treatment has been established, whereas the efficacy of extended release injectable naltrexone without psychosocial treatment ''has not'' been established.

(5) There is no recommended length of treatment with oral naltrexone or extended-release injectable naltrexone. Duration depends on clinical judgment and the patient's individual circumstances. Because there is no physical dependence associated with naltrexone, it can be stopped abruptly without withdrawal symptoms.

(6) Switching from naltrexone to methadone or buprenorphine should be planned, considered, and monitored. Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist because there is no physical dependence associated with antagonist treatment and thus no possibility of precipitated withdrawal. Patients being switched from naltrexone to buprenorphine or methadone will not have physical dependence on opioids and thus the initial doses of methadone or

buprenorphine used should be low. Patients should not be switched until a significant amount of the naltrexone is no longer in their system, about 1 day for oral naltrexone or 30 days for extended-release injectable naltrexone.

(7) Patients who discontinue antagonist therapy and resume opioid use should be made aware of the increased risks associated with an opioid overdose, and especially the increased risk of death.

(8) Naltrexone should be used with ‘‘caution’’ under the following conditions:

(a) All patients should be warned of the risk of hepatic injury and advised to seek medical attention if they experience symptoms of acute hepatitis. Hepatic injury is a concern if very high doses are used, for example, 200–300 mg per day. Use of naltrexone should be discontinued in the event of symptoms and/or signs of acute hepatitis. Cases of hepatitis and clinically significant liver dysfunction were observed in association with naltrexone exposure during the clinical development program and in the post marketing period. Transient, asymptomatic hepatic transaminase elevations were also observed in the clinical trials and post marketing period.

(b) Patients with [clinically significant] liver impairment should complete liver enzyme tests before and during treatment with naltrexone to check for additional liver impairment.

(c) Patients who experience injection site reactions should be monitored for pain, redness, or swelling. Incorrect administration may increase the risk of injection site reactions. Reactions have occurred with extended-release injectable naltrexone. To reduce injection site reactions in obese patients, a longer needle size may be used.

(d) [Patients with co-occurring psychiatric disorders should be monitored for [psychiatric] adverse events. Suicidal thoughts, attempted suicide, and depression have been reported [with naltrexone]].

(9) Significant ‘‘medication interactions’’ with naltrexone are as follows:

(a) Naltrexone should not be used with methylnaltrexone or naloxegol.

(b) Naltrexone blocks the effects of opioid analgesics because it is an opioid antagonist.

(c) Glyburide may increase serum concentration of naltrexone. Monitor for increased toxicity effects of naltrexone.”

Section 3. Switching between medications that treat OUDs

Introduction:

In order to assist providers with the process of switching between medications, detailed, current evidence is provided. Switching may be needed for the following reasons, including but not limited to: patient preference, side effects, difficulty accessing a particular medication, etc.

(Excerpted from ASAM guidelines [1]):

"(I) Switching from methadone to other opioid treatment medications may be appropriate in the following cases:

(1) Patient experiences intolerable methadone side effects.

(2) Patient has not experienced a successful course of treatment on methadone.

(3) Patient wants to change and is a candidate for the alternative treatment. Transfer of medications should be planned, considered, and monitored. Particular care should be taken in reducing methadone dosing before transfer to avoid precipitating a relapse. If the patient becomes unstable and appears at risk for relapse during the transfer of medications, reinstating methadone may be the best option.

(II) Switching from methadone to buprenorphine:

[This medication switch should be referred or closely supervised by an experienced addictionologist.] Patients on low doses of methadone (30–40mg per day or less) generally tolerate the transition to buprenorphine with minimal discomfort; whereas patients on higher doses of methadone may find that switching causes significant discomfort. Patients should be closely monitored during such a switch because there is a risk that stable methadone patients may become unstable when changing to buprenorphine...

Patients should be experiencing mild to moderate opioid withdrawal before the switch. This would typically occur at least 24 hours after the last dose of methadone, and indicates that sufficient time has elapsed for there to be minimal risk that the first dose of buprenorphine will precipitate significant withdrawal.

Moderate withdrawal would equate to a score greater than 12 on the COWS. An initial dose of 2–[8] mg of buprenorphine should be given and the patient should be observed for 1 hour. If withdrawal symptoms improve, the patient can be dispensed two additional 2–4-mg doses to be taken as needed.

(III) Switching from Methadone to Naltrexone

[This medication switch should be referred or closely supervised by an experienced addictionologist. This process often takes place in inpatient settings.] Patients switching from methadone to oral naltrexone or extended- release injectable naltrexone need to be completely withdrawn from methadone and other opioids before they can receive naltrexone. This may take up to 14 days, but can typically be achieved in 7 days. A naloxone challenge (administration of 0.4–0.8 mg naloxone and observation for precipitated withdrawal) may be useful before initiating treatment with naltrexone to document the absence of physiological dependence and to minimize the risk for precipitated withdrawal.

(IV) Switching from Buprenorphine to Naltrexone

Buprenorphine has a long half-life; 7–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the patient is not physically dependent on opioids before starting naltrexone. It may be useful to conduct a naloxone challenge before starting naltrexone to demonstrate an absence of physical dependence. Recently, investigators have begun to evaluate newer methods of rapidly transitioning patients from buprenorphine to naltrexone using repeated dosing over several days with very low doses of naltrexone along with ancillary medications. Although the results are promising, it is too early to recommend these techniques for general practice, and the doses of naltrexone used may not be readily available to most clinicians. [However, for physicians with addiction expertise, the American Academy of Addiction Psychiatry in partnership with the American Psychiatric Association, the American Society of Addiction Medicine, and the American Osteopathic Academy of Addiction Medicine provides the Columbia Rapid Naltrexone Induction Protocol at: http://pcssmat.org/wp-content/uploads/2015/02/PCSSMAT-Implementing- Antagonist-with-Case.Bisaga.CME_.pdf]

(V) Switching to Methadone

Transitioning from buprenorphine to methadone is less problematic because the addition of a full mu-opioid agonist to a partial agonist does not typically result in any type of adverse reaction. There is no time delay required in transitioning a patient from buprenorphine to treatment with methadone.”

Section 4. Counseling and Ancillary services for OBOT providers

Introduction:

The combination of behavioral interventions and medications to treat substance use disorder is commonly referred to as MAT. While prescribing health care professionals can provide some or all of these interventions, some patients will require additional professionals to care for their medical, psychiatric, and addictive conditions. Best practice requires ensuring evidence-based interventions can be accessed as available, treatment should be individualized to the needs of the specific patient.

Excerpted from APA Guidelines [2]:

"When considering psychosocial treatments for treating opioid-related disorders, it is essential to note that all clinical trials of psychosocial interventions for opioid abusers have taken place in programs that also provide either opioid agonist maintenance (e.g., methadone) or treatment with opioid antagonists. Although some follow-up studies of naturalistic treatment have found equivalent efficacy for methadone maintenance and outpatient drug-free programs for heroin users [10, 15-18], early attempts at providing psychotherapy alone yielded unacceptably high attrition rates [19]."

Evidence based treatments which should be used to supplement medication assisted treatment for OUDs (excerpted from APA guidelines [2]):

"1. Cognitive-behavioral therapies

> In individuals who are receiving methadone maintenance, CBT is efficacious in reducing illicit substance use and achieving a wide range of other treatment goals. The benefits of CBT in combination with drug counseling are equivalent to those of drug counseling alone or drug counseling plus supportive-expressive psychotherapy in patients with low levels of psychiatric symptoms; however, in the presence of higher degrees of depression or other psychiatric symptoms, supportive-expressive therapy or CBT has been shown to be much more effective than drug counseling alone [19-24]. CBT may also help reduce other target symptoms or behaviors (e.g., HIV risk behaviors) in opioid-using individuals [25]. Group based relapse prevention therapy, when combined with self-help group participation, may also help recently detoxified patients reduce opioid use and criminal activities and decrease unemployment rates [26].

2. Behavioral therapies

Contingency management approaches are beneficial in reducing the use of illicit substances in opioid-dependent individuals who are maintained on methadone [27- 29]. Although other reinforcers or rewards (e.g., vouchers for movie tickets or sporting goods) may be provided to patients who demonstrate specified target behaviors (e.g., providing drug-free urine specimens, accomplishing specific treatment goals, attending treatment sessions), methadone take-home privileges are a commonly offered and effective incentive that is made contingent on reduced drug use [30-33]. Furthermore, contingency management, either alone or in conjunction with family therapies, can also be used to enhance adherence with unpopular treatments such as naltrexone and has been shown to result in diminutions in drug use among recently detoxified opioid-dependent individuals [34-40].

3. *Psychodynamic and interpersonal therapies*

The utility of adding a psychodynamic therapy to a program of methadone maintenance has been investigated. The provision of supportive-expressive therapy, a specific approach to such treatment, may be particularly helpful for patients with high levels of other psychiatric symptoms [20, 23]. However, in terms of individual IPT, the potential benefits of treatment are unclear, as it is very difficult to engage opioid-dependent patients in such approaches. Psychodynamically oriented group therapy, modified for substance-dependent patients, appears to be effective in promoting abstinence when combined with behavioral monitoring and individual supportive psychotherapy [41].

4. *Family therapies*

Family therapy has been demonstrated to enhance treatment adherence and facilitate implementation and monitoring of contingency contracts with opioid- dependent patients [42, 43]. [Family therapies are particularly beneficial for adolescents with OUDs].

5. *Self-help groups and 12-step-oriented treatments*

Self-help groups, such as Narcotics Anonymous, are beneficial for some individuals in providing peer support for continued participation in treatment, avoiding substance-using peers and high-risk environments, confronting denial, and intervening early in patterns of thinking and behavior that often lead to relapse.

Because of the emphasis on abstinence in the 12-step treatment philosophy, patients maintained on methadone or other opioid agonists may encounter disapproval for this type of pharmacotherapy at Narcotics Anonymous meetings."

Section 5. Transitioning off agonist and partial agonist therapies, with the goal, when appropriate of opioid abstinence

Introduction:

For many individuals, agonist treatments may be necessary until they have reached a point in their treatment where taper and discontinuation can be considered with their treatment providers.

Excerpted from ASAM guidelines [1]:

"There is no recommended time limit for treatment with buprenorphine. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended…Patients and clinicians should not take the decision to terminate treatment with buprenorphine lightly. Factors associated with successful termination of treatment with buprenorphine are not well described, but may include the following:

(1) Employment, engagement in mutual help programs, or involvement in other meaningful activities.

(2) Sustained abstinence from opioid and other drugs during treatment.

(3) Positive changes in the psychosocial environment.

(4) Evidence of additional psychosocial supports.

(5) Persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation.

Patients who relapse after treatment has been terminated should be returned to treatment with buprenorphine."

Section 6. Training and experience requirements for providers who treat and manage individuals with OUDs

(1) Minimal Prescriber Requirements for Buprenorphine Prescribing

Excerpted from ASAM Guidelines [1]: "To practice office-based treatment of opioid addiction under the auspices of DATA 2000, physicians must first obtain a waiver from the special registration requirements established in the Narcotic Addict Treatment Act of 1974 and its enabling regulations. To obtain a DATA 2000 waiver, a physician must submit notification to SAMHSA of his or her intent to begin dispensing and/or prescribing this treatment. The Notification of Intent form must contain information on the physician's qualifying credentials

and must contain additional certifications, including that the physician (or the physician's group practice) will not treat more than 30 patients for addiction at any one time.

Notification of Intent forms can be filled out and submitted online at the SAMHSA Buprenorphine Web site at http://www.buprenorphine.samhsa.gov.

Physicians who meet the qualifications defined in DATA 2000 are issued a waiver by SAMHSA and a special identification number by DEA. To qualify for a DATA 2000 waiver, physicians must have completed at least 8 hours of approved training in the treatment of opioid addiction or have certain other qualifications as defined in the legislation (e.g., clinical research experience with the treatment medication, certification in addiction medicine) and must attest that they can provide or refer patients to the necessary, concurrent psychosocial services. The consensus panel recommends that all physicians who plan to practice opioid addiction treatment with buprenorphine attend a DATA 2000-qualifying 8-hour training program on buprenorphine. SAMHSA maintains a list of upcoming DATA 2000- qualifying buprenorphine training sessions on the SAMHSA Buprenorphine Web site. Additional information about DATA 2000 and buprenorphine also can be obtained by contacting the SAMHSA Buprenorphine Information Center by phone at 866-BUP-CSAT (866-287-2728) or via e-mail at info@buprenorphine.samhsa.gov."

(2) It is recommended that physicians obtain advanced training such as formal ASAM certification or addiction psychiatry fellowship training.

(3) Requirements for INSPECT reviews when prescribing opioids

At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient under and document in the patient's chart whether the INSPECT report is consistent with the physician's knowledge of the patient's controlled substance use history.

Section 7. Addressing benzodiazepine use

Introduction:

Given the potential lethality of opioids and benzodiazepines, special attention needs to be given to patients taking both classes.

Excerpted from Management of Benzodiazepines in Medication-Assisted Treatment

[44]:

"Generally:

1. Individuals must be agreeable to engage in a plan to address their benzodiazepine use before beginning MAT.

2. [The evidence base does not support the use of chronic] benzodiazepines in a person presenting for MAT with methadone or buprenorphine is contraindicated. It presents an extremely high risk for adverse drug reaction involving overdose and/or death during the induction process. [A closely supervised, short-term benzodiazepine taper is indicated in this instance.]

3. CNS [central nervous system] depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression. Serious overdose and death may occur if MAT is administered in conjunction with benzodiazepines, sedatives, tranquilizers, anti- depressants, or alcohol.

4. Individuals who use benzodiazepines, even if used as a part of long-term therapy, should be considered at risk for adverse drug reactions including overdose and death….

6. If a person presenting for MAT will not allow a clinician to coordinate care, he or she [is not] appropriate for methadone and/or buprenorphine

Section 8. Managing Relapse

Introduction:

Relapse is an anticipated event in the process of recovery. . Nonetheless, there are practices that prescribers can adopt that are more likely to promote recovery than others. Best practices to address relapse are detailed here.

Excerpted from APA guidelines [2]:

"Because individuals with substance use disorders are often ambivalent about giving up their substance use, it can be useful to monitor their attitudes about participating in treatment and adhering to specific recommendations. These patients often deny or minimize the negative consequences attributable to their substance use; this tendency is often erroneously interpreted by clinicians and significant others as evidence of dishonesty. Even patients entering treatment with high motivation to achieve abstinence will struggle with the reemergence of craving for a substance or preoccupation with thoughts about attaining or using a substance. Moreover, social influences (e.g., substance- using family or friends), economic influences (e.g., unemployment), medical conditions (e.g., chronic pain, fatigue), and psychological influences (e.g., hopelessness, despair) may make an individual more vulnerable to a relapse episode even when he or she adheres to prescribed treatment. For these reasons, it can be helpful for clinicians and patients to anticipate the possibility that the patient may return to substance use and to agree on a corrective

plan of action should this occur. If the patient is willing, it can be helpful to involve significant others in preventing the patient's relapse and prepare significant others to manage relapses should they occur.

Supporting patients in their efforts to reduce or abstain from substance use positively reinforces their progress. Overt recognition of patient efforts and successes helps to motivate patients to remain in treatment despite setbacks. Clinicians can optimize patient engagement and retention in treatment through the use of motivational enhancement strategies [45, 46] and by encouraging patients to actively partake in self-help strategies. Monitoring programs, such as EAPs and impaired-physician programs [47-49], can sometimes help patients adhere to treatment.

Early in treatment a clinician may educate patients about cue-, stress-, and substance-induced relapse triggers [50, 51]. Patients benefit from being educated in a supportive manner about relapse risk situations, thoughts, or emotions; they must learn to recognize these as triggers for relapse and learn to manage unavoidable triggers without resorting to substance-using behaviors. Participation in AA or similar self-help group meetings can also support patients' sobriety and help them avoid relapse. Many other strategies can also help prevent relapse. Social skills training is targeted at improving individual responsibility within family relationships, work related interactions, and social relationships. During the early recovery phase, it can be helpful to encourage patients to seek new experiences and roles consistent with a substance-free existence (e.g., greater involvement in vocational, social, or religious activities) and to discourage them from instituting major life changes that might increase the risk of relapse. Facilitating treatment of co-occurring psychiatric and medical conditions that significantly interact with substance relapse is a long- term intervention for maintaining sobriety [52-54]. Therapeutic strategies to prevent relapse have been well studied and include teaching individuals to anticipate and avoid substance-related cues (e.g., assessing individual capacity to avoid relapse in the presence of substance-using peers), training individuals how to monitor their affective or cognitive states associated with increased craving and substance use, behavioral contingency contracting, training individuals in cue extinction and relaxation therapies to reduce the potency of substance-related stimuli and modulate craving intensity, and supporting patients in the development of coping skills and lifestyle changes that support sobriety [55, 56]. Behavioral techniques that enhance the availability and perceived value of social reinforcement as an alternative to substance use or reward for remaining abstinent have also been used [57]. If relapse does occur, individuals should be praised for even limited success and encouraged to continue in or resume treatment. Clinicians may help patients analyze relapses as well as periods of sobriety from a functional and behavioral standpoint and use what is learned to adjust the treatment plan to fit the individual's present needs. For chronically relapsing substance users, medication therapies may be necessary adjuncts to treatment."

Section 9. Obtaining informed consent concerning all available opioid use disorder treatment options, including risks and benefits of each option.

Introduction:

The informed consent process should ensure that each patient voluntarily chooses their treatment and that relevant facts concerning the use of the medications (including non-opioid medication treatment options) are clearly and adequately explained, such as follows :

Opioids are drugs that stimulate mu-receptors in the brain to produce a wide range of effects including pain relief, sedation, euphoria, addiction, and, with high enough doses, death. Opioids include heroin, morphine, methadone, oxycodone, hydrocodone, buprenorphine, tramadol and others. An opioid use disorder (i.e. addiction) is diagnosed when opioids are used in a compulsive, uncontrolled way producing negative physical, mental and social consequences. Treatment options for opioid addictions are compared below.

Behavioral Interventions: Behavioral interventions are recommended to accompany any addiction treatment.

Benefits and advantages

- Capable of addressing a host of contexts associated with addiction (e.g., depression or pain)
- No medication costs or side effects, except in the case of adolescents, where groups have been shown to worsen prognosis

Risks and downsides

- The long-term chance of quitting opioids is low without taking medication like those listed below.
- Group therapies involve some compromise of confidentiality and can be time consuming.

Methadone: Methadone is an opioid dispensed by a government regulated Opiate Treatment Provider (OTP).

Benefits and advantages

- Scientifically proven to reduce withdrawal, illicit opioid relapse, psychiatric, legal, medical, social and financial consequences of opioid addiction.
- Clients are monitored closely for progress.

Risks and downsides

- Requires ongoing use of opioids
- Requires daily, often early morning visits to the OTP in the first months.
- OTPs typically focus on only opioid addiction and do not treat other co-occurring addictions and mental illnesses.
- OTP/Methadone treatment is generally not covered by public/private insurance. Only 13 OTP clinics and the Veteran's Administration in Indiana--so may need to drive long distances.
- Methadone can cause serious side effects with high doses, or when mixed with alcohol, benzodiazepines, barbiturates or certain muscle relaxants; Can cause irregular heartbeat, cessation of breathing and death.
- Stopping methadone, as with any opioid, causes opioid withdrawal sickness. Accidental ingestion by children can be fatal.

Buprenorphine (Suboxone, Subutex, Zubsolv, Bunavail): Buprenorphine is an opioid prescribed by an OTP or a doctor with a special prescribing certification. It has many of the same benefits and risks as methadone. However there are several key differences listed as follows.

Benefits and advantages

- Buprenorphine treatment (outside of an OTP) typically requires fewer treatment appointments than methadone to receive medication.
- Buprenorphine treatment is more often covered by public and private insurance. Risk of lethal over dose is much less than with methadone or other opioids.
- Babies born to mothers maintained on Buprenorphine have less risk of experiencing NAS.

Risks and downsides

- May not work as well as methadone in certain patients with severe opioid addiction. Lack of highly structured treatment programming with buprenorphine does not serve some people well.

Naltrexone (Revia, Vivitrol): Naltrexone is a prescription drug that blocks the effects of opioids in the brain. Naltrexone comes as a pill that is taken one or two times a day or as a shot given by a nurse once a month. You can not take opioids for about two weeks before starting naltrexone. Naltrexone is also used to treat alcohol addiction.

Benefits and advantages

- Does not require the use of an opioid to facilitate recovery Increases adherence to psycho-social treatment.
- Significantly reduces cravings for opioids.

- Will not result in respiratory depression if taken in excess Covered by most insurance plans.
- Treats alcohol addiction too.

Risks and downsides

- Naltrexone may cause opioid withdrawal symptoms if started before someone has detoxed from opioids.
- Can cause serious liver problems, although this is more likely when taking high doses of the oral form. Opioid pain medications will not work as well when taking naltrexone. The injection can cause some discomfort, rarely could become infected. Individuals can still overdose on opioids, while taking naltrexone.
- Should not be started during pregnancy.

This information has been reviewed with the client, by the signing physician. Signature of

Client: date:

Signature of

Physician: date:

Section 10. Drug Testing

Introduction:

Testing biological samples for the presence of drugs of abuse is an essential part of the treatment of OUDs. Best practices of drug screening are detailed here.

Excerpted from APA[2]:

"Urine drug testing, or other reliable biological tests for the presence of drugs, during the initial evaluation and frequently throughout treatment, is highly recommended. Results from some studies have indicated that more intensive monitoring of substance use may increase recovery rates from a substance use disorder…There are a variety of toxicology tests available, some with greater and lesser reliability and validity. Urine testing is useful for detecting substance use over the preceding 5-day period for common substances of abuse (cocaine, opiates, cannabis, amphetamines, benzodiazepines, and PCP); however, certain opioids (buprenorphine, oxycodone, hydrocodone, and fentanyl) cannot be detected with routine methods and require special assays. [It is important to screen for the metabolites of the prescribed opioid agonist (e.g. norbuprenorphine), to ensure compliance with the treatment. Point of care testing (e.g., urine testing) is needed to make rapid clinical decisions, supplemented by "send out," confirmatory

laboratory values.] The person who is interpreting these labs should be very familiar with the methodology and the reliability.

There is little research on the optimal frequency of testing, [however, random drug testing is optimal.]….The frequency of drug testing will be determined by a number of factors, including the stability of the patient, the type of treatment, the treatment setting, and the half-life of drugs in the matrix being tested. Patients will likely require more testing early in treatment or during periods of relapse. Patients participating in office based treatment with buprenorphine may be tested at each office visit.

Opioids are detectable in the urine for 1–3 days after use. A negative urine test combined with no history of withdrawal may indicate a lack of physical dependence.

However, a negative urine test does not rule out opioid use, disorder, or physical dependence. Urine testing is also helpful to identify

> (1) Use of other psychoactive substances.
>
> (2) If a patient tests positive for an illegal drug…or a controlled substance that the patient is not taking as part of the treatment plan, then the provider needs to review the treatment plan and consider changes with the goal of opioid abstinence."

Section 11. Pregnant Women with OUDs

Introduction:

Pregnant women have unique needs and require treatment customized to their situation. Best practices for their treatment are highlighted here.

(Excerpted from ASAM guidelines [1]

> "(1) The first priority in "treating" pregnant women for opioid use disorder should be to identify emergent or urgent medical conditions that require immediate referral for clinical evaluation.
>
> (2) A medical examination and psychosocial assessment is recommended when evaluating pregnant women for opioid use disorder.
>
> (3) Obstetricians and gynecologists should be alert to signs and symptoms of opioid use disorder. Pregnant women with opioid use disorder are more likely to seek prenatal care late in pregnancy, miss appointments, experience poor weight gain, or exhibit signs of withdrawal or intoxication.

(4) [As with all patients with OUDs,] psychosocial treatment is [strongly] recommended in the treatment of pregnant women with opioid use disorder.

(5) Counseling and testing for HIV should be provided in accordance with state law. Tests for hepatitis B and C and liver function are also suggested. Hepatitis A and B vaccination is recommended for those whose hepatitis serology is negative.

(6) Urine drug testing may be used to detect or confirm suspected opioid and other drug use with informed consent from the mother, realizing that there may be adverse legal and social consequences of her use. State laws differ on reporting substance use during pregnancy. Laws that penalize women for use and for obtaining treatment serve to prevent women from obtaining prenatal care and worsen outcomes.

(7) Pregnant women who are physically dependent on opioids should receive treatment using methadone or buprenorphine mono-product rather than withdrawal management or abstinence.

(8) Care for pregnant women with opioid use disorder should be co-managed by an obstetrician and an addiction specialist physician. Release of information forms need to be completed to ensure communication among healthcare providers.

(9) Treatment with [buprenorphine or] methadone [(within a licensed Opioid Treatment Program)] should be initiated as early as possible during pregnancy.

(10) Hospitalization during initiation of methadone and treatment with buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester.

(14) Clinicians should be aware that the pharmacokinetics of [buprenorphine] are affected by pregnancy….Increased or split doses may be needed as pregnancy progresses. After child birth, doses may need to be adjusted.

(15) Buprenorphine monoproduct is a reasonable and recommended alternative to methadone for pregnant women. Whereas there is evidence of safety, there is insufficient evidence to recommend the combination buprenorphine/ naloxone formulation.

(16) If a woman becomes pregnant while she is receiving naltrexone, it is appropriate to discontinue the medication if the patient and doctor agree that the risk of relapse is low. If the patient is highly concerned about relapse and wishes to continue naltrexone, she should be informed about the risks of staying on naltrexone and provide her consent for ongoing treatment. If the patient wishes to discontinue naltrexone, but then reports relapse to opioid use, it may be appropriate to consider treatment with methadone or treatment with buprenorphine.

(17) Naloxone is not recommended for use in pregnant women with opioid use disorder except in situations of life-threatening overdose.

(18) Mothers receiving methadone and buprenorphine monoproduct for the treatment of opioid use disorders should be encouraged to breastfeed.

(19) [Naltrexone may be appropriate for a mother after delivery who is capable of detoxification and at risk of relapse.]

Methadone Versus Buprenorphine

The discussion and decision for medication should be reviewed with the patient and documented in her chart. For women who are pregnant or breastfeeding, opioid agonist treatment with methadone or buprenorphine is seen as the most appropriate treatment, taking into consideration effects on the fetus, neonatal abstinence syndrome, and impacts on perinatal care and parenting of young children. Methadone is the accepted standard of care for use during pregnancy; however, buprenorphine monoproduct is a reasonable alternative and also has some advantages over methadone. Infants born to mothers treated with buprenorphine had shorter hospital stays (10 vs. 17.5 days), had shorter treatment durations for neonatal abstinence syndrome (NAS) (4.1 vs. 9.9 days), and required a lower cumulative dose of morphine (1.1 vs. 10.4 mg) compared to infants born to mothers on treatment with methadone.

Combination Buprenorphine/Naloxone

There is some evidence suggesting that buprenorphine/ naloxone is equivalent in safety and efficacy to the monoproduct for pregnant women…At present, however, this evidence is insufficient to recommend the combination buprenorphine/naloxone formulation in this population."

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