



SUBJECT: CONTROLLED MEDICATION GUIDELINES
 DEPARTMENT: AMBULATORY CARE SVS – AMB ALL (PRIMARY CARE)
 AUTHOR: ADDICTION MEDICINE WORKGROUP COMMITTEE, PRIMARY CARE

POLICY / PURPOSE:

To establish safe and supportive prescribing of controlled substances for providers and patients consistent with best practices.

DEFINITIONS:

Controlled substances include but are not limited to the following medications:

Schedule	Generic (Brand)
Schedule CII	<ul style="list-style-type: none"> Codeine (not combination product) Dextroamphetamine & Amphetamine (Adderall) Fentanyl (Duragesic) Hydromorphone (Dilaudid) Hydrocodone or Hydrocodone combination products (ex. Vicodin, Norco) Methadone Methylphenidate (Concerta, Ritalin) Morphine (ex. MS Contin, Roxanol, etc.) Oxycodone (OxyContin) or Oxycodone combination products (ex. Percocet)
Schedule CIII	<ul style="list-style-type: none"> Buprenorphine (Butrans, Suboxone, etc.) Ketamine
Schedule CIV	<ul style="list-style-type: none"> Benzodiazepines (ex. alprazolam, diazepam, etc.) Carisoprodol (Soma) Codeine containing products 90mg/du (ex. Tylenol #3) Tramadol (Ultram) Zolpidem (Ambien)
Schedule CV	<ul style="list-style-type: none"> Codeine preparations 200mg/100mL (ex. Robitussin AC) Diphenoxylate less than 2.5mg combination products (Lomotil) Pregabalin (Lyrica)

Schedule classification is organized by highest (schedule I) to lowest (schedule V) potential to cause a substance use or addiction disorder.

1. Controlled Substance Utilization Review and Evaluation System (CURES): Report that provides a history of dispensed medication for a specific person. CURES is managed by the California Prescription Drug Monitoring Program (PDMP).
2. Controlled Medication Agreement: An agreement between a provider and patient about the use of controlled substances.
3. Chronic use of CII Medication: Any number of pills written for more than three months.
4. Chronic use of CIII and CIV Medication: More than 15 pills per month for more than 3 consecutive months.¹
5. Morphine Equivalent Dose (MED): A morphine equivalent dose (MED) is the amount of opioid prescription drugs, converted to a common unit (milligrams of morphine), that a patient currently has access based on the information reported by prescribers and pharmacies. Morphine is widely regarded as the “standard” for the treatment of moderate to severe pain and is commonly used as the reference point. As MED increases, the likelihood of an adverse effect increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety.
 - a. Morphine equivalent dose calculators:
 - i. [Oregon Pain Guidance, Opioid Conversion Calculator](#)
 - ii. [Ohio Automated RX Reporting System, Med Calculator Prescription History](#)
6. Patients: Neither the Centers for Disease Control nor the Medical Board of California define a lower age limit for CURES reporting.
7. Substance use disorder (DSM-V): a problematic pattern of substance use leading to clinically significant impairment or distress, as manifested by at least two of the following, within a 12-month period:
 - a. Substance taken larger amounts or over a longer period than was intended.
 - b. A persistent desire or unsuccessful efforts to cut down or control use.
 - c. A great deal of time is spent in activities necessary to obtain the substance, use, or recover from its effects.
 - d. Craving or strong desire or urge to use substance.
 - e. Recurrent use resulting in a failure to fulfill major role obligations at work, school, or home.
 - f. Continued use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of substance.
 - g. Important social, occupational, or recreational activities are given up or reduced because of the substance use.

¹<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm#:~:text=Primary%20Clinical%20Questions,most%20days%20for%20%3E3%20months>

- h. Recurrent use in situations in which it is physically hazardous.
 - i. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
8. Tolerance: defined by either of the following:
- a. A need for markedly increased amounts of the substance to achieve intoxication or desired effect.
 - b. A markedly diminished effect with continued use of the same amount of the substance.
 - c.
9. Withdrawal: manifested by either of the following:
- a. The characteristic withdrawal syndrome of the substance
 - b. The substance is taken to relieve or avoid withdrawal symptoms
- Note: tolerance and withdrawal are not considered to be met for those individuals taking the substance under appropriate medical supervision.
10. Physical Dependence: Adaptation to a drug that produces symptoms of withdrawal when the drug is stopped

PROCEDURAL GUIDELINES:

- A. Does not apply to prescriptions provided for \leq five days.²
- B. Does not apply to controlled substances used for ADHD, cancer, palliative, or end of life care.
- C. Short Term CII or Benzodiazepines (> 5 days to < 90 days)
 - 1. Before prescribing
 - a. Required:
 - 1) Drug Urine Test
This is used to determine if patient is using other substances. The urine drug test can be obtained at the first appointment and the prescription for controlled medication can be written prior to receiving results. If result is inconsistent with expected result, provider can consult the pain clinic for support. An inconsistent result does not necessitate withholding or discontinuing controlled substances.
 - 2) CURES report
 - i. Run and review within 24 hours of writing prescription

² <https://www.mbc.ca.gov/Download/Fact-Sheets/CURES-Mandatory-Use.pdf>

- ii. Can be run by a delegate and sent to prescriber dashboard for review
- 3) Offer Narcan³ – required IF
 - i. Prescribing morphine equivalent $\geq 90\text{mg/day}$
 - ii. Prescribing both benzodiazepine and opioid
 - iii. Patient is at increased risk for overdose
 - iv. History of overdose, history of substance use disorder, or if patient is at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.
 - v. The law requires that all prescribers, consistent with the existing standard of care, provide education to patients, persons designated by the patient, or for minor patients, to their parent or guardian, regarding overdose prevention and the use of naloxone for the reversal of opioid depression.
- b. Recommended:
 - 1) Document review of CURES report: The Medical Board of California does not have specific documentation requirements. However, the Board recommends that the provider document review by either writing in chart or printing report and placing it in patient's chart.
 - 2) Offer Naloxone if morphine equivalent $\geq 50\text{mg/day}$

D. Chronic Use CII – CIV Medications

1. Chronic CII defined as any amount of medication written for more than three months
2. Chronic CIII and CIV defined as more than 15 pills per month for more than 3 continuous months
3. May be inherited or initiated by the provider
4. Before prescribing
 - a. Required
 - 1) Drug urine test
 - 2) CURES report
 - 3) Offer Narcan and provide education IF
 - i. Prescribing morphine equivalent $\geq 90\text{mg/day}$
 - ii. Prescribing both benzodiazepine and opioid
 - iii. Patient is at increased risk for overdose

³ This is the standard of care, however there may be some barriers due to supply chain and insurance coverage. Naloxone is on the Medi-Cal formulary at the time of this policy review.

- 4) Controlled Medication Agreement
 - i. Give to patient at or prior to first prescription
 - ii. Must be signed within 30 days of starting medication
- b. Recommended
 - 1) Document review of CURES
 - 2) Screen for risk for opioid abuse.
 - i. SOAPP-R⁴ can be a useful tool to assess for possible opioid abuse in chronic pain patients. If a patient scores four or more, the patient is at high risk for dependence and other treatment options should be considered (e.g., buprenorphine, methadone).
5. Ongoing prescriptions
 - a. Required
 - 1) CURES report every six months⁵
 - 2) New controlled medication IF
 - i. Controlled medication agreement is broken. If agreement is broken, provider can consult with Pain Management Clinic or IMAT via P1 or formal referral for suggestions.
 - ii. Medication regimen changes
 - iii. New provider takes over care
 - b. Recommended
 - 1) Drug urine test every year
 - 2) CURES report every three months
 - 3) In person evaluation every three months⁶ to determine need for ongoing controlled medication prescription and to assess if medication should be adjusted based on the patient's function. Telehealth appointments can be used on a case-by-case basis for ongoing care.

⁴ <https://www.helpisherede.com/Content/Documents/SOAPP-Tool.pdf>

⁵ <https://www.mbc.ca.gov/Download/Documents/CURES-FAQ.pdf>

⁶ https://www.cdc.gov/drugoverdose/pdf/Guidelines_At-A-Glance-a.pdf

ATTACHMENTS:

1. Controlled Medication Safe Use Agreement:

- a. FORM Rev 2022-05: MRF#12111 ([English](#)) [Controlled Medication Safe Use Agreement.pdf](#)
- b. FORM Rev 2022-05: MRF # 12157 S ([Spanish](#)) [Controlled Medication Safe Use Agreement.pdf](#) is attached now (once form is published in Medical Record Form Library it will be linked here as well.
Note: Both a., and b. above are currently set for use in eCW but not in Soarian, in order to change this – please contact SMMC Compliance-Policy Coordinator/HIM Dept

2. Flow Charts:

- a. Short Term CII or Benzodiazepines (< 5 days to <90 Days)
- b. Chronic CII-CIV Use

SMMC Policy Review &Approval Grid	
Origination Date: 2014-11	Last Review Date: 2021-08
Reviewed and approved by:	Date:
Ambulatory Nurse Educator	05/23
Medical Director, Primary Care	05/23
Addiction Medicine Workgroup Committee	05/23
Ambulatory Deputy Director of Nursing	05/23
Primary Care Department	06/23
Medical Executive Committee	06/23, FINAL
Date & Submission By: 2022-02, Dr. Mithu Tharayil-Supervising Physician Primary Care	
NOTE(s):	



SAN MATEO COUNTY HEALTH
**SAN MATEO
MEDICAL CENTER**



Controlled Medication Safe Use Agreement

Controlled medications may be used to increase your ability to participate meaningfully in your daily activities, but they have serious safety risks. The purpose of this agreement is to review how to use these medications safely and to make sure ethical and legal standards of care are followed.

Some examples of controlled medications may include:

- Opioids:** Norco (hydrocodone & acetaminophen), MS Contin, Dilaudid (hydromorphone), Methadone, Percocet, (oxycodone & acetaminophen), Tylenol with Codeine, Morphine, Oxycontin (oxycodone), Tramadol, Buprenorphine, Fentanyl
- Benzodiazepines:** Klonopin (clonazepam), Ativan (lorazepam), Xanax (alprazolam), Valium (diazepam), Librium (chlordiazepoxide)
- Hypnotics:** Ambien (zolpidem), Lunesta (eszopiclone), Sonata (zaleplon)
- Muscle Relaxants:** SOMA (carisoprodol)
- Stimulants:** Ritalin (methylphenidate), Concerta (methylphenidate), Adderall (amphetamine/dextroamphetamine), Dexedrine (dextroamphetamine), Focalin (dexmethylphenidate), Metadate (nethykohenudate), Vyvanse (lisdexamfetamine).
- Other: _____

Risks of controlled medications may include:

- **Risk of tolerance over time:** You may experience less symptom relief when a medication is used daily for long periods of time. Higher doses increase the risk for side effects and even death.
- **Risk of addiction:** Addiction means you have strong cravings and use the medication compulsively and uncontrollably despite negative impacts on your life.
- **Risk of physical dependence and withdrawal:** Withdrawal symptoms may occur when you attempt to stop the medication. Withdrawal from opioids may cause flu-like symptoms with stomach pain, nausea, diarrhea, anxiety, body aches, and restlessness. Withdrawal from benzodiazepines may cause anxiety, difficulty sleeping, irritability, seizure, and even death.
- **Risk of accidents:** Controlled medications may affect your ability to safely drive and operate heavy machinery and may increase your risk for falls and other accidents.
- **Risk of death:** Controlled medications can cause death, especially if taken more than prescribed, and even if taken as directed. For example, if you become ill, the medication may have a stronger effect. Taking controlled medications with street drugs or alcohol increases this risk. Your provider may prescribe you naloxone (Narcan), which is used in the event of opioid overdose. It is dangerous to combine opioids with sedating meds or substance because of risk of respiratory depression
- **Risk to baby or fetus:** Taking controlled medications during pregnancy or nursing can cause harm to your baby. Please tell your provider if you are pregnant, planning to become pregnant or are breastfeeding.

In order for your provider to safely prescribe controlled medicines, you must agree to the following:

1. **Follow through.** It is important that you follow through with all agreements and care plans you make with your medical team.
2. **Take medicines as prescribed.** Taking more medications than prescribed can cause accidental overdose and death. If you take more than prescribed and run out of medication early you may experience withdrawal. Your provider may not refill your medication early. If you feel you need a different dose, schedule an appointment with your provider to discuss your care.



SAN MATEO COUNTY HEALTH
**SAN MATEO
MEDICAL CENTER**



3. **Tell your other providers that you have a controlled medicine agreement.** If another provider gives you a controlled medication in addition to the one subject to this agreement, you must let the provider prescribing the medication subject to this agreement know within one (1) business day. This applies to medication given following accidents, crises, and emergencies (for example, new injury or dental problems).
4. **We participate in California's controlled medicine monitoring program.** Your medical team is required to work with law enforcement to investigate possible misuse of controlled medication. Your medical team checks CURES (Controlled Substance Utilization Review and Evaluation System) routinely to monitor when you have your prescription filled.
5. **Combining alcohol or street drugs with controlled medications is very dangerous.** If you are drinking alcohol or taking street drugs, your provider may not be able to continue to prescribe controlled medications. Your medical team may also require random urine drug tests.
6. **For refills, call your pharmacy 5 working days prior to running out of the medicine.** Controlled medication refills require time for processing. Your regular provider or clinic will only process refills during normal business hours. You must not seek or obtain controlled medications from other sources (including other medical providers, friends, family, etc.).
7. **It is your responsibility to safeguard your controlled medicine.** Your medical team may not replace lost or stolen controlled medications. It is your responsibility to store your medication in a secure place where it will not be lost or stolen and is out of reach of children or pets.
8. **Never share or sell your controlled medication.** This is called diversion and is against the law.
9. **Respectful communication and behavior.** We are here to address your concerns and connect you to proper channels in the event you feel frustrated. Throughout your treatment, we expect you to treat all staff with courtesy and respect.
10. **Controlled medicines may affect your ability to think clearly.** If controlled medications are impairing your thinking, its your responsibility not to drive, operate heavy machinery, perform difficult tasks, or make important decision
11. **If your provider believes controlled medicine is no longer appropriate for your care, he or she may slowly reduce your medicine or refer you to a specialist who can help you transition off the medicine.**
If you feel the medicine is not providing you benefit or causing you too many side effects, DO NOT STOP THE MEDICINE SUDDENLY. Please discuss with your provider so they can assist you in getting off the medication safely.
12. By signing this document, it means you have read, understood, and agreed to follow the above requirements. If you do not follow these requirements, you understand your provider may stop prescribing these Medicine(s) to you.

PRINT NAME: _____ DOB: _____

SIGNATURE (Patient/Guardian): _____ DATE (MM/DD/YY): _____

IF THIS DOCUMENT WAS TRANSLATED (Language): _____

PRINT INTERPRETER NAME: _____ OR INTERPRETER ID#: _____

PRINT PROVIDER NAME: _____ DATE (MM/DD/YY): _____

PROVIDER SIGNATURE _____

This agreement will remain in effect until it is replaced or if a new provider becomes responsible for your care. If a new provider becomes responsible for your care, a new agreement must be signed.



Controlled Medication Safe Use Agreement

Los medicamentos controlados se pueden usar para aumentar su capacidad de participar de manera significativa en sus actividades diarias, pero tienen serios riesgos de seguridad. El propósito de este acuerdo es revisar cómo usar estos medicamentos de manera segura y garantizar que se sigan los estándares de atención éticos y legales.

Algunos ejemplos de medicamentos controlados pueden incluir:

- Opioides:** Norco (hidrocodona y paracetamol), MS Contin, Dilaudid (hidromorfona), Metadona, Percocet (oxicodona y paracetamol), Tylenol con Codeína, Morfina, Oxycontin (oxicodona), Tramadol, Buprenorfina, Fentanilo
- Benzodiazepinas:** Klonopin (clonazepam), Ativan (lorazepam), Xanax (alprazolam), Valium (diazepam), Librium (clordiazepóxido)
- Hipnóticos:** Ambien (zolpidem), Lunesta (eszopiclona), Sonata (zaleplon)
- Relajantes musculares:** SOMA (carisoprodo)
- Estimulantes:** Ritalin (metilfenidato), Concerta (metilfenidato), Adderall (anfetamina/dextroanfetamina), Dexedrine (dextroanfetamina), Focalin (dexmetilfenidato), Metadate (nethykohenudate), Vyvanse (lisdexanfetamina).
- Otros: _____

Los riesgos de los medicamentos controlados pueden incluir:

- **Riesgo de tolerancia en el tiempo:** es posible que experimente menos alivio de los síntomas cuando se usa un medicamento a diario durante largos períodos de tiempo. Las dosis más altas aumentan el riesgo de efectos secundarios e incluso la muerte.
- **Riesgo de adicción:** la adicción significa que tiene fuertes antojos y usa el medicamento de manera compulsiva e incontrolable a pesar de los impactos negativos en su vida.
- **Riesgo de dependencia física y abstinencia:** Los síntomas de abstinencia pueden ocurrir cuando intenta suspender el medicamento. La abstinencia de los opioides puede causar síntomas similares a los de la gripe con dolor de estómago, náuseas, diarrea, ansiedad, dolores corporales e inquietud. La abstinencia de las benzodiazepinas puede causar ansiedad, dificultad para dormir, irritabilidad, convulsiones e incluso la muerte.
- **Riesgo de accidentes:** Los medicamentos controlados pueden afectar su capacidad para conducir y operar maquinaria pesada de manera segura y pueden aumentar su riesgo de caídas y otros accidentes.
- **Riesgo de muerte:** Los medicamentos controlados pueden causar la muerte, especialmente si se toman más de lo recetado e incluso si se toman según las indicaciones. Por ejemplo, si se enferma, el medicamento puede tener un efecto más fuerte. Tomar medicamentos controlados con drogas callejeras o alcohol aumenta este riesgo. Su proveedor puede recetarle naloxona (Narcan), que se usa en caso de sobredosis de opioides. Es peligroso combinar opioides con medicamentos o sustancias sedantes debido al riesgo de depresión respiratoria.
- **Riesgo para el bebé o el feto:** Tomar medicamentos controlados durante el embarazo o la lactancia puede causar daño a su bebé. Informe a su proveedor si está embarazada, planea quedar embarazada o está amamantando.

Para que su proveedor le recete medicamentos controlados de manera segura, debe aceptar lo siguiente:

1. **Cumplir todo.** Es importante que cumpla con todos los acuerdos y planes de atención que realice con su equipo médico.
2. **Tome los medicamentos según lo prescrito.** Tomar más medicamentos de los recetados puede causar una sobredosis accidental y la muerte. Si toma más de lo recetado y se le acaba el medicamento antes de tiempo,



SAN MATEO COUNTY HEALTH
**SAN MATEO
MEDICAL CENTER**

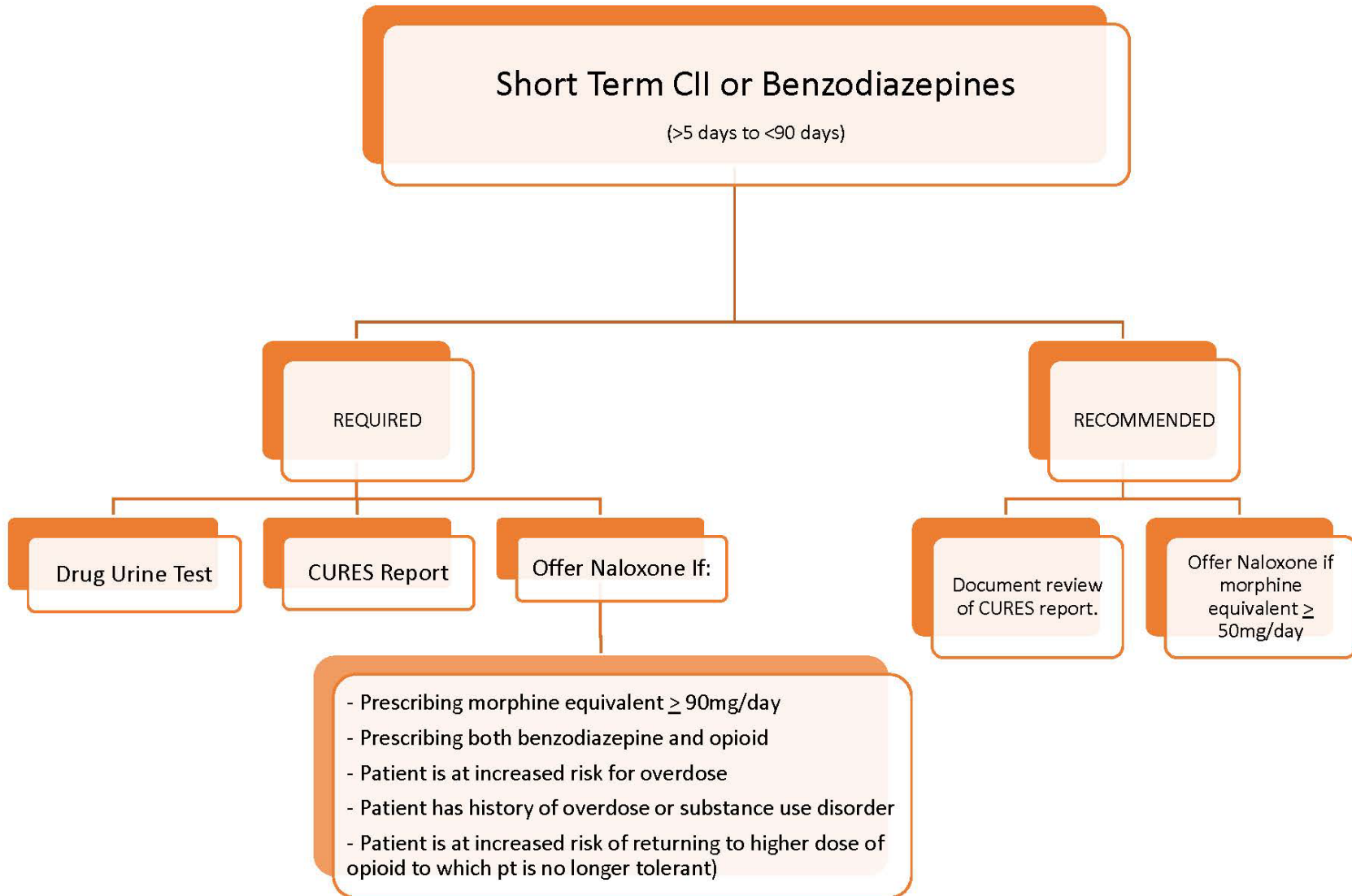


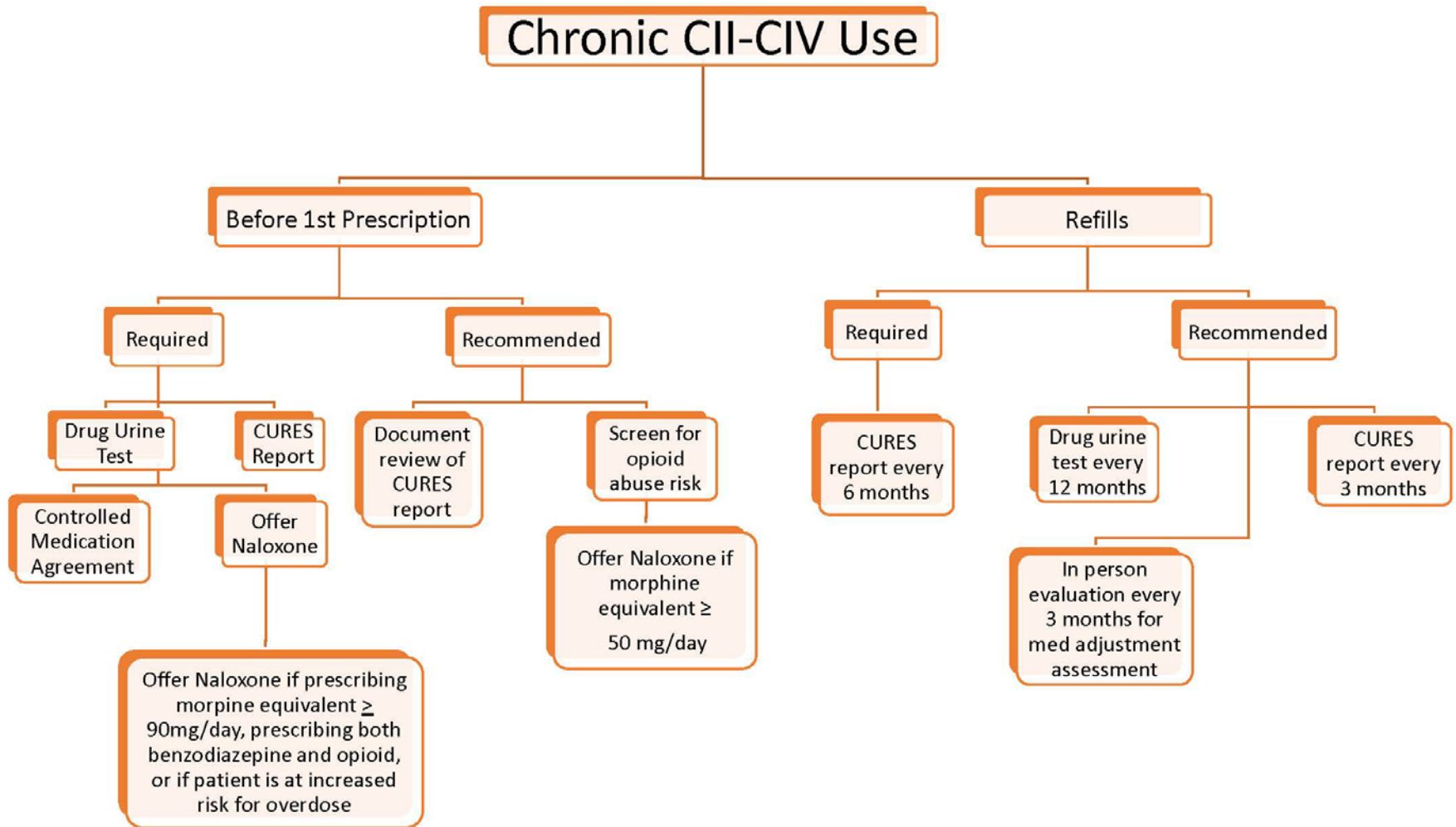
puede experimentar abstinencia. Es posible que su proveedor no renueve su medicamento antes de tiempo. Si cree que necesita una dosis diferente, programe una cita con su proveedor para analizar su atención.

3. **Informe a sus otros proveedores que tiene un acuerdo de medicamentos controlados.** Si otro proveedor le da un medicamento controlado además del sujeto a este acuerdo, debe informarle del acuerdo dentro de un (1) día hábil. Esto se aplica a los medicamentos administrados después de accidentes, crisis y emergencias (por ejemplo, nuevas lesiones o problemas dentales).
4. **Participamos en el programa de monitoreo de medicamentos controlados de California.** Se requiere que su equipo médico trabaje con la policía para investigar el posible uso indebido de medicamentos controlados. Su equipo médico revisa CURES (Sistema de Evaluación y Revisión de Utilización de Sustancias Controladas) de forma rutinaria para monitorear que tenga su receta despachada.
5. **Combinar alcohol o drogas callejeras con medicamentos controlados es muy peligroso.** Si está bebiendo alcohol o tomando drogas ilícitas, es posible que su proveedor no pueda seguir recetando medicamentos controlados. Su equipo médico también puede requerir pruebas aleatorias de drogas en orina.
6. **Para nuevos despachos, llame a su farmacia 5 días hábiles antes de que se le acabe el medicamento.** Las recargas de medicamentos controlados requieren tiempo para su procesamiento. Su proveedor habitual o clínica solo procesará despachos durante el horario comercial normal. No debe buscar ni obtener medicamentos controlados de otras fuentes (incluidos otros proveedores médicos, amigos, familiares, etc.).
7. **Es su responsabilidad salvaguardar su medicamento controlado.** Su equipo médico no puede reemplazar los medicamentos controlados perdidos o robados. Es su responsabilidad guardar su medicamento en un lugar seguro donde no se pierda o sea robado y esté fuera del alcance de niños o mascotas.
8. **Nunca comparta ni venda su medicamento controlado.** Esto se llama desviación y es ilegal.
9. **Comunicación y comportamiento respetuoso.** Estamos aquí para abordar sus inquietudes y conectarlo con los canales adecuados en caso de que se sienta frustrado. A lo largo de su tratamiento, esperamos que trate a todo el personal con cortesía y respeto.
10. **Los medicamentos controlados pueden afectar su capacidad para pensar con claridad.** Si los medicamentos controlados están afectando su habilidad para pensar, es su responsabilidad no conducir, operar maquinaria pesada, realizar tareas difíciles o tomar decisiones importantes.
11. **Si su proveedor cree que los medicamentos controlados ya no son apropiados para su atención, es posible que reduzca lentamente su medicamento o lo remita a un especialista que pueda ayudarlo a dejar el medicamento.**
Si cree que el medicamento no le brinda ningún beneficio o le causa demasiados efectos secundarios, NO DEJE DE TOMAR EL MEDICAMENTO REPENTINAMENTE. Hable con su proveedor para que puedan ayudarlo a dejar el medicamento de manera segura.
12. Al firmar este documento, significa que ha leído, entendido y aceptado seguir los requisitos anteriores. Si no cumple con estos requisitos, comprende que su proveedor puede dejar de recetarle estos Medicamentos.

NOMBRE (IMPRESA): _____ Fecha de Nacimiento: _____
 FIRMA (Paciente/Tutor): _____ FECHA (MM/DD/YY): _____
 SI ESTE DOCUMENTO FUE TRADUCIDO (Idioma): _____
 NOMBRE DEL INTERPRETE (IMPRESA): _____ o ID# INTERPRETE: _____
 NOMBRE DEL PROVEEDOR (IMPRESA): _____ FECHA (MM/DD/YY): _____
 FIRMA DEL PROVEEDOR _____

This agreement will remain in effect until it is replaced or if a new provider becomes responsible for your care. If a new provider becomes responsible for your care, a new agreement must be signed.





Chronic CII defined as any amount of medication written for more than three consecutive months
 Chronic CIII-CIV defined as more than 15 pills per month for more than three consecutive months