



CONTROLLED SUBSTANCE CLINICAL DOCUMENTS RESOURCE

Bangor Area Controlled Substance Work Group

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Bangor Area Controlled Substance Work Group Practice Standards

The Opioid Risk Tool (ORT) and screening for at risk alcohol use, drug use and depression should be carried out and entered into the patient's medical record before initiating chronic opioid therapy or for any patient receiving chronic opioids who has not been screened. Positive screens should be appropriately evaluated and treated.

Opioid therapy should be avoided in patients taking benzodiazepines, and in those with significant lung disease, with heart disease, or with sleep apnea. Palliative care patients and hospice patients are exceptions to this standard.

If a Patient Provider Agreement (PPA) violation occurs all controlled substances will be appropriately tapered off and the violation should be documented in the patient's chart.

The following will be considered violations of the PPA:

- Receiving controlled substances from another provider without primary care provider's knowledge.
- Taking more controlled substance than is prescribed.
- Repeated (more than two in a calendar year) requests for early refills of a controlled substance.
- Being short by more than one day's supply of controlled substance on any pill count.
- Repeated inability (more than twice in a calendar year) to be reached for random pill count or urine drug screen
- Any refusal or inability to present for a pill count or urine drug screen.
- Any confirmed, unexpected urine drug screen result.
- Any refusal to submit to a urine drug screen, including inability to provide a urine sample.
- Any tampering with a urine drug screen sample.
- Repeated (more than one) reports of lost or stolen drugs.
- Any use of illegal drugs while receiving opioids.
- Any arrest or conviction on drug or alcohol related charges (regular use of Diversion Alert is strongly encouraged).

The following should be considered as non-reassuring behavior and should result in appropriate tapering and discontinuation of controlled substances unless the prescribing provider documents sufficient extenuating circumstances to justify continuing the medication and if the medication is continued, monitoring should be intensified with more frequent pill counts and urine drug screens:

- Any request for an early refill.
- Any inability to reach a patient for a pill count or urine drug screen.
- Any arrest on criminal charges (not drug or alcohol related).
- Medical complications such as opioid related bowel obstruction, falls, motor vehicle accidents, exploitation for medications, and depression refractory to treatment.
- Any report of lost or stolen drugs.

- Failure to keep scheduled appointments with the prescribing provider or those to whom the patient is referred.
- Any report of diversion or abuse, identified or anonymous (this should also result in pill count and urine drug screen as soon as possible).

*These standards were developed through a collaborative effort of clinical leaders from Acadia Hospital, Bucksport Regional Health Center, The Center for Family Medicine, Community Health and Counseling Services, Eastern Maine Medical Center, Health Access Network, Penobscot Community Health Care, and St. Joseph Hospital under the auspices of the Community Health Leadership Board.

Adopted on November 9, 2015

Patient/Provider Agreement for Controlled Drug Prescriptions*

The following items numbered 1 to 4 are the same for Acadia Hospital, Bucksport Regional Health Center, The Center for Family Medicine, Community Health and Counseling Services, Eastern Maine Medical Center, Health Access Network, Penobscot Community Health Care and St. Joseph Healthcare.

1. We wish to have clear, shared goals for your treatment.

- a. I am being treated with controlled drug for a diagnosis of _____.
- b. The goal of my treatment is to improve my function. .

2. We want you to be safe in taking these drugs.

- a. I should take controlled drugs only as prescribed. I will not change the dose unless directed by my provider.
- b. I will not give or sell these drugs to anyone.
- c. I will store these drugs safely so that they cannot be stolen or taken by other people. I know that lost or stolen drugs will not be replaced.
- d. If I have unused drugs I will dispose of them by dissolving them in water mixed with kitty litter, through drug drop off sites (local police) and through drug take back days
- e. I will notify my provider if I receive controlled drugs from other providers.
- f. I will not use controlled drugs which are not prescribed for me and I will not use illegal drugs.
- g. I will use only one pharmacy for controlled drugs. I will notify you if that pharmacy changes.
- h. I agree that my provider may share information about my use of controlled drugs with my pharmacy, with emergency rooms and with other providers involved in my care.
- i. I agree to keep my appointments and to notify my provider and reschedule when I must miss one.
- j. I agree to notify my provider if my health changes in an important way or if I become pregnant.
- k. I will sign releases so that my provider can share information with all other providers involved in my care.

3. We must monitor these medicines carefully.

- a. I agree to be called randomly for pill counts, and to present for a pill count on the same day on which I am contacted.
- b. I agree to be called randomly for urine drug tests, and to present for a urine drug test on the same day on which I'm contacted.
- c. I understand that if I cannot be reached for pill counts or urine drug tests my drugs may be stopped.
- d. I understand that if I lose my drugs or they are stolen my drugs may be stopped.
- e. I know that my provider and/or a team member will regularly look at the Prescription Monitoring Program to review all of my prescriptions for controlled drugs.

4. We want to manage these prescriptions in an orderly manner.

- a. I know prescriptions will be for 28 days at most, with no refills.
- b. I know I can only request refills on weekdays, during regular office hours, consistent with office policy.

c. I know that I may not request early refills.

In addition {NAME of ORGANIZATION} policy also requires that:

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-
-
-

I know that I must meet all of the requirements of this agreement or my controlled drugs may be stopped.

Name	Date
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Provider	Date
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Informed Consent for Stimulants for Adult Attention Deficit Disorders

Uses

I understand that stimulants are used to improve hyperactivity, impulsivity and inattention symptoms that may go along with Attention Deficit Disorders. These drugs include:

- Methylphenidate (Ritalin, Metadate, Aptensio, Daytrana, Methylin, Quillivant, Concerta)
- Dexmethylphenidate (Focalin)
- Dextroamphetamine (Dexedrine, ProCentra, Zenzedi)
- Dextroamphetamine and amphetamine mixed salts (Adderall)
- Lisdexamfetamine (Vyvanse)

Benefits Expected

- Improved attention
- Improved hyperactivity (restlessness)
- Improved impulsivity

Alternatives

- Atomoxetine
- Behavioral Therapy
- Clonidine or Guanfacine
- Bupropion

Risks

It has been explained to me and I understand that the use of stimulants can cause:

- Headache
- Difficulty sleeping
- Increase in blood pressure and heart rate
- Changes in behavior, mood and thinking
- Anxiety or panic symptoms
- Increased risk of seizures
- Diminished appetite, weight loss
- Abnormal movements
- Dependence (of the body and mind), substance abuse, and addiction
- Higher doses of these drugs cause even greater risks
- These drugs may increase my risk of being the victim of a crime

I also understand:

- That stimulant medication should be avoided in those with a history of addiction to any of the stimulant class of drugs.
- That caution should be exercised when prescribing stimulants to someone with any history of addiction and alternative treatments should be considered first.

- That alternative treatments should be considered when treating attention deficit disorder in those with co-morbid opioid use disorder on opioid replacement treatment.
- That stimulants should not be prescribed concurrently with an opioid or a benzodiazepine without psychiatric collaboration and clear rationale.
- That if I have high blood pressure, abnormal heart rhythms, bipolar disorder, anorexia, Tourette's syndrome or a history of psychosis the risks are increased.
- That Benzodiazepines, Alcohol, Opioids and Marijuana may cause symptoms of inattention.
- That attention deficit disorder is thought to be a chronic disease; however, I understand that the question about how long a person should stay on stimulants has not been answered.

Additional: _____

My provider, _____, and I have discussed the indications, risks, benefits, and alternatives for the use of stimulants to treat attention deficit disorder. I understand the risks described here and I know that by taking stimulants I accept all of these risks. I understand this prescription will be reviewed at least annually for evidence of effect, improved function and the need for continuation.

Patient Name: _____

Patient DOB: ___/___/___

Patient Signature: _____

Date: ___/___/___

Provider Signature: _____

Date: ___/___/___

Informed Consent for Benzodiazepines for Anxiety Disorders

Uses

I understand that benzodiazepines (drugs like lorazepam or Ativan, diazepam or Valium, clonazepam or Klonopin, alprazolam or Xanax) are sometimes used to lower high levels of anxiety. Some people report improved levels of anxiety when they take these drugs, but I understand that these drugs may not help people with anxiety when taken for more than 12 weeks. There are no studies that have answered this question.

Benefits Expected

- Improved function
- Lower levels of anxiety

Alternatives

I understand that benzodiazepines are not the first choice of treatment for anxiety disorders. There are safer drugs that work better called selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs), as well as cognitive behavioral therapy (counseling that teaches skills to manage anxiety).

Risks

It has been explained to me and I understand that the use of benzodiazepines can cause:

- Slowed thinking and reaction times, poor focus, confusion, and memory loss
- Less control of my emotions and actions
- Depression
- Weakness
- Falls and fractures (broken bones), especially in the elderly
- Car accidents
- Breathing problems (particularly with lung disease such as Asthma, COPD, or SleepApnea)
- Excessive sedation (sleepiness)
- Intoxication
- Tolerance, withdrawal sickness
- Dependence (of the body and mind), substance abuse, and addiction
- Increased risk of all side effects when used with alcohol
- Accidental overdose, especially when taken with certain pain drugs known as opioids
- Higher doses of these drugs cause even greater risks
- These drugs may increase my risk of being the victim of a crime
- These drugs create a greater risk if I have a history of addiction (especially to opioids and alcohol)

I also understand:

- That using alcohol, along with benzodiazepines, is dangerous and that I must not use alcohol while I am taking benzodiazepine drugs.
- That using marijuana, along with benzodiazepines, is dangerous as both may delay my reactions and increase my risk of accident.
- That using opioids, along with benzodiazepines, is dangerous. I should avoid using opioids while I am taking benzodiazepine drugs.
- That all of these risks are especially high in those age 65 and older.

Additional: _____

My provider, _____, and I have tried other more effective and safer treatments such as Cognitive Behavioral Therapy (counseling), SSRIs, SNRIs, and exercise. I understand the risks described here and I know that by taking benzodiazepine drugs I accept all of these risks. I will continue to work with my providers to explore other safer options to manage my excessive anxiety.

Patient Name: _____ Patient DOB: ___/___/___

Patient Signature: _____ Date: ___/___/___

Provider Signature: _____ Date: ___/___/___

Informed Consent for Opioids for Chronic Pain*

It has been explained to me that the use of opioid drugs (for example, methadone, hydromorphone, oxycodone, fentanyl, morphine, hydrocodone, tramadol) leads to a higher risk of accident, injury, falls, car accidents, breathing problems (including not breathing), heart disease, accidental overdose and death.

- I understand that our goal is improved function and not total relief of pain.
- I know that higher doses of these drugs lead to even greater risks.
- I know that there are not good studies that show that these drugs help people with chronic pain.
- I know that having these drugs may increase my risk of being the victim of a crime.
- I know that these drugs sometimes lead to dependence and misuse.
- I know that up to 35% of people using these drugs may develop addiction.
- I know that if I have a history of addiction of any kind (including alcohol) I should not take these drugs.
- I know that using alcohol with opioids is risky and I understand that my provider may take me off opioids if he/she feels that my use of alcohol places me at risk.
- I know that the use of certain anxiety drugs, known as *benzodiazepines* (“benzos”), along with opioids is dangerous and that my provider and I should avoid the use of these drugs while I am receiving prescriptions for opioid drugs. Examples of *benzodiazepines* include alprazolam, clonazepam, diazepam and lorazepam.
- I know that side effects of these drugs include sedation, constipation, reduced hormone levels and reduced sex drive, personality changes, falls and osteoporosis.
- I know that opioids should not be used routinely for headaches, fibromyalgia, chronic back pain and Chronic Regional Pain Syndrome (Reflex Sympathetic Dystrophy).
- I know that my provider will be checking on all of my controlled drug prescriptions through the Prescription Monitoring Program of the Office of Substance Abuse.
- I know that if I am on high dose opioids (over 100 morphine equivalents daily) these risks and side effects are more common. I know that my risk of accidental overdose is increased 11 fold and my risk of premature death is also significantly increased.
- I know that if I am on high dose opioids I may need additional testing to assess my risk of the drug causing a respiratory arrest (where I stop breathing).
- I know that if I am on high dose opioids my provider and I will work to reduce my dose to a less risky level.
- I know that while I am on high dose opioids my provider and I should discuss the possibility of a prescription for naloxone for treatment of overdose.

My provider, _____, and I have tried other more effective and safer treatments, such as physical therapy, osteopathic therapy, exercise, weight loss and counseling and they have not helped enough. We have also tried non-opioid drugs like acetaminophen, anti-inflammatory drugs, some anti-depressant drugs, and some anti-seizure drugs, which have been shown to work better and are much safer. I understand the risks described here and I know that by taking opioid drugs I accept all of these risks.

Patient Name: _____

Patient DOB: ___/___/___

Patient/Guardian Signature: _____

Date: ___/___/___

Provider Signature: _____

Date: ___/___/___

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Adopted on November 9, 2015

Adult ADD Guidelines

Important considerations for the diagnosis and treatment of adult attention deficit disorder in primary care

1. Care and caution need to be exercised when making the diagnosis of attention deficit disorder (ADD/ADHD) in adults. Consideration should be given to utilizing psychiatric or psychological collaboration or consultation when making the diagnosis. The differential diagnosis includes anxiety disorders, mood disorders, substance use disorders, personality disorders, psychotic disorders, chemically induced symptoms of attention deficit disorder, autistic spectrum disorder, oppositional defiant disorder, intermittent explosive disorder, learning disorder, reactive attachment disorder, intellectual developmental disability, neurocognitive disorders and neurodevelopmental disorders.
2. Stimulant medication should be avoided in those with a history of addiction to any of the stimulants. Caution should be exercised when prescribing stimulants to someone with any history of addiction and step-treatment should be considered as below;
 - a. Atomoxetine
 - b. Behavioral Therapy
 - c. Alpha 2 agonists (clonidine and guanfacine)
 - d. Bupropion
3. Step-treatment, as above, should be utilized when treating ADD/ADHD in those with co-morbid opioid use disorder on opioid replacement treatment.
4. Stimulants should not be prescribed concurrently with an opioid or a benzodiazepine in primary care without psychiatric collaboration and documented rationale of the exceptional reasons.
5. Stimulants may worsen psychosis, mood and anxiety symptoms. Stimulants may make bipolar disorder, anxiety disorders, and psychotic disorders worse.
6. Benzodiazepines, Alcohol, Opioids and Marijuana may cause symptoms of inattention.
7. Monitoring obligations for stimulants should be the same as they are for any other schedule II controlled substance (e.g. oxycodone).
8. Adult attention deficit disorder is a chronic disease; however, there is insufficient evidence due to lack of adequate long-term medication studies upon which to make clear conclusions on the appropriate duration of treatment or long-term chronic use of stimulants.
9. According to Lexi-Comp the medical contraindications for stimulants include:
hypersensitivity; use during or within 14 days following MAO inhibitor therapy; marked anxiety/ tension/agitation, glaucoma; family history or diagnosis of Tourette syndrome or tics; moderate to severe hypertension; hyperthyroidism; concomitant use of halogenated anesthetics; advanced arteriosclerosis; symptomatic cardiovascular disease; pheochromocytoma; and history of drug abuse. Additionally, stimulants may lower seizure threshold.
10. Long-acting formulations are preferred to short-acting formulations of stimulants secondary to convenience of dosing and to minimize abuse potential.
11. Prescriptions should be reviewed annually for efficacy, evidence of improved function and continuation need.

Community Guidelines of Chronic Care for Anxiety Disorders in Primary Care:

Exercise helps all. Anxiety Disorder, NOS is not an indication for a chronic benzodiazepine and there is not evidence to support this prescribing practice. Please exercise caution in using antidepressant anxiolytics if the patient has a diagnosis of bipolar disorder especially if not stable on a mood stabilizer. Individuals with anxiety disorders may be more sensitive to side effects on initiation of medication so start low.

Disorder	Generalized Anxiety Disorder	Social Anxiety Disorder	Panic Disorder	PTSD (BENZODIAZEPINES MAY CAUSE HARM-DO NOT RX)	OCD
Step 1 *Step not completed until adequate trial or all are proven to be intolerable.* (Note: many people have to try more than 1 psychotherapist before finding a match)	SSRI, SNRI Adequate trial = 6-8w at moderate to high dose or Cognitive Behavioral Therapy	SSRI, SNRI Adequate trial 6 weeks at moderate to high dose for initial response and 12 – 16w for full response or Cognitive Behavioral Therapy	SSRI or CBT SSRI Onset of effect may be 2-4 w, but clinical response can take 8-12 w. Trials have shown that therapeutic effects, particularly on anticipatory anxiety and phobic avoidance, can continue to increase over 6 to 12m. Moderate to High Dose	Trauma Focused Psychotherapy (TFP) or SSRI or SNRI Adequate = high dose 6-8w	SSRI and/or CBT (ERP) Adequate trial = High dose for 12w
Step 2	1 st /2 nd SSRI or SNRI or CBT	1 st /2 nd SSRI or SNRI or CBT	2 nd SSRI or SNRI or CBT	TFP or SSRI or SNRI	CBT (ERP) or 2 nd SSRI
Step 3	2 nd SSRI or SNRI or CBT	2 nd SSRI or SNRI or CBT	SNRI or CBT	TFP or SSRI or SNRI	Clomipramine
Step 4	Consider referral to or collaborating with a psychiatric NP or psychiatrist for consultation. Considerations = Buspirone, Off label meds with some evidence, Other psychosocial therapies, Benzodiazepine If no substance abuse history, benefits outweigh long-term risks, patient acknowledges and accepts risk, closely monitored, no escalating doses.	Consider collaborating with or referral to a psychiatric NP or psychiatrist for consultation. Considerations = Off label meds with some evidence, Other psychosocial therapies	Consider collaborating with or referral to a psychiatric NP or psychiatrist for consultation. Considerations = Off label meds with some evidence, other psychosocial therapies, Benzodiazepine If no substance abuse history, benefits outweigh long-term risks, patient acknowledges and accepts risk, closely monitored, no escalating doses.	Consider collaborating with or referral to a psychiatric NP or psychiatrist for consultation. Considerations = Off label meds with some evidence such as Prazosin for nightmares, Other psychosocial therapies	Consider collaborating with or referral to a psychiatric NP or psychiatrist for consultation.