Windrose Health Network, Inc.

PATIENT CARE POLICY **CODE: PC 11.01**

Reviewed/Revised Date: 8/23/14	Next Review Date: 10/16	Approved by: Windrose Health Network, Inc. Board of Directors	Date: Date: 9/23/14	Effective Date: 2/18/04

PRESCRIBING OPIOIDS AND OTHER CONTROLLED SUBSTANCES

PURPOSE: To delineate guidelines for the clinical use of controlled substances by clinical providers working for Windrose Health Network, Inc., ("WHN").

SCOPE: All WHN clinical providers

POLICY: WHN medical providers will prescribe controlled substances in a responsible manner consistent with established state and federal requirements as well as existing professional and community standards. It will develop and maintain guidelines for the use of controlled substances in order to ensure high quality clinical care as well as to avoid abuse of these substances.

PROCEDURE:

I. OPIOIDS

Initial Considerations:

In an attempt to meet the requirements outlined in P.L. 185-2013 (SEA 246) regarding physicians and midlevel providers prescribing opioids for chronic pain, WHN has incorporated the following policy: While recognizing that the mission of WHN is to provide comprehensive care to all of its patients, there are times when patients must be referred to specialists. There are times when chronic pain is best served by a pain management specialist.

Opioid Treatment Guidelines: the following guidelines meet or exceed the requirements outlined in Indiana Public Law 185-2013 (SEA 246) and prerequisites for WHN medical providers who choose to use opioids as a treatment intervention:

1. INSPECT Reports. During the Initial Appointment, at least annually thereafter if opioid treatment is being considered, a medical provider prescribing opioids for a patient shall run an INSPECT Report and note the results in the patient's medical record.

2. Perform or order a drug monitoring test, which must include a confirmatory test, on the patient.

3. See the patient for a follow-up, face-to-face appointment at least once every four (4) months.

4. If the patients Care Plan is modified, appointments must be scheduled at least every two months until the medication and treatment has been stabilized.

5. During each office visit for opioid management:

a. The medical provider shall evaluate the patient's progress and compliance with the Care Plan and document his/her impressions in the patient's medical record.

b. Review the Care Plan and CSA with the patient, setting clear expectations regarding the completion of identified goals.

6. If the patient's opioid dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day, the following must occur:

a. a face-to-face appointment with the patient to review and evaluate the Care Plan, including documentation of consideration of referral to a specialist.

b. if the medical provider elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the provider must develop a revised assessment and Care plan for ongoing treatment. The revised assessment and Care Plan must be documented in the patient's chart and include an assessment of increased risk for adverse outcomes of therapy, including death.

Care Plan Development: the following concepts should be taken into considerations when developing a plan:

1. Goal Development: a useful Care Plan is comprised of effective, meaningful goals. "SMAART Goals are crafted using the following concepts:

- **S**pecific: the goal focused upon achieving a particular target or end point;
- **M**easureable: there is a concrete way of quantifying the desired outcome;
- **A**chievable: the goal is reasonably attainable - - a stretch, but it can be reached;
- **A**ccepted: the goal-setter fully agrees to work toward the identified goal
- **R**elevant: the goal fits the overall plan; it is appropriate to treatment; and
- **T**ime-bound: a reasonable target date is agreed upon.

2. Alternative Interventions: if viable treatment modalities for managing the patient's pain **other than opioids** exist, they should be discussed with the consumer. When developing a Care Plan, documentation that non-opioid alternatives, or a combination of non-opioid alternatives with non-pharmaceutical options, were considered and/or utilized as an initial clinical intervention, should occur.

3. Related Health Improvement Efforts: along with pain management interventions, the Care Plan could include pertinent health improvement goals such as weight and diet management, smoking cessation or alcohol abuse management.

A. Definitions:

1. "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or injury.
2. "Controlled Substance" has the meaning set forth in IC 35-48-1-9.
3. "Morphine Equivalent Dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.
4. "Outset of an opioid treatment plan" means that a patient has been given a prescription for opioids.
5. "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:

a. There can be no recovery; and
b. Progression to death can be anticipated as an eventual consequence of that condition.

B. Evaluation & Treatment (Initial Appointment): In nearly all instances, the medical use of controlled substances is done in order to accomplish the following outcomes:

- decrease or eliminate pain
- increase function.

Consequently, a thorough assessment of a patient's medical condition(s) with respect to the degree of pain/discomfort or dysfunction reported should occur (see item #1.d. and 1.e. below):

1. Initial Appointment - - Minimum Evaluation Requirements: In order to receive a controlled substance(s) for a term longer than fifteen (15) days, the following evaluation and risk assessment must be completed by the attending medical provider and documented in the patient's medical record AS PART OF THE INITIAL APPOINTMENT:

   a. Medical History & Physical: a detailed assessment with appropriate testing should occur and be documented in the patient's Medical Record.

   b. Review of Previous Medical Records: evidence should exist that a bona fide effort to obtain and review pertinent medical information took place.

   c. Previous Treatment: documentation should occur that indicates a review of previous treatment measures, (e.g., Physical Therapy, cognitive behavioral therapy, NSAIDS, antidepressants, anti-epileptics, etc.), utilized for the presenting problem as well as the relative effectiveness of those treatment approaches

   d. Diagnostic Testing: evidence should exist that appropriate diagnostic testing occurred.

   e. Related Assessments: use of WHN-approved screening tools to assess the patient's mental health status, risk for substance abuse and relative degree of functioning and pain should occur:

      1) Behavioral Health/Substance Abuse: evidence that the patient completed at least one validated assessment tool from each category listed below:

Behavioral Health	Substance Abuse
1. PHQ-9	1. Opioid Risk Tool
2. GAD-7	2. CAGE

      2) INSPECT Report: as part of a holistic evaluation of the patient's presentation, an INSPECT Report should be done in order to help verify the consumer's medication usage history.

      3) Schedule a Behavioral Health Assessment: in order to proceed to a second visit, an evaluation by a licensed Behavioral Health clinician should occur if indicated by results of behavioral health/substance abuse screens. This activity is designed to obtain a more complete evaluation of any behavioral health or substance abuse needs the patient might have.

      4) Formal Pain Assessment: at a minimum, the following activities should take place:

         a) Completion of the Baseline Assessment of Function & Pain (2-item Graded Pain Scale)

b) A clinical interview should occur related to the patient's experience. Assessment and documentation of the patient's verbal responses regarding his/her pain should be done by addressing the following features ("APQRST"):

- **A**ssociated findings (e.g., nausea, vomiting, photophobia);
- **P**alliation of pain (what circumstances alter or change the pain experienced);
- **Q**uality of pain (e.g., sharp, dull, throbbing, stabbing);
- **R**egion of pain;
- **S**everity Intensity Scale of pain: "SIS" of pain shall be assessed initially as well as reassessed throughout the duration of treatment. The Severity Intensity Scale shall be based on a scale from one to ten (1 - 10); and
- **T**iming of pain (e.g., intermittent, remittent, continuous, fleeting).

Listed below is an example of a viable Pain Assessment Tool:

2 Item Graded Pain Scale

Patient Name _____ Date of Birth _____ Date _____

Pain intensity and interference										
In the last month, on average, how would you rate your pain? Using a scale from 0 to 10, where) is "no pain" and 10 is "pain as bad as could be"? (That is, your usual pain at times you were in pain.)										
No Pain										**As Bad As Pain Could Be**
0	1	2	3	4	5	6	7	8	9	10
In the last month, how much has pain interfered with your daily activities? Using a scale from 0 to 10, where) is "no interference" and 10 is "unable to carry on my activities"?										
No Interference										**Unable to Carry on My Activities**
0	1	2	3	4	5	6	7	8	9	10

2. Second Appointment: ~~Two of~~ The major goals of the second visit should be to review all medical records and reports to determine whether it is appropriate to start the patient on a chronic opioid treatment.

With the above-indicated goals in mind, the following activities should occur in the Second Appointment:

a. Data Review: a review of all diagnostic test results as well as the behavioral health assessment report should occur.

b. Establishing a Clinical Diagnosis: after reviewing the data from the Initial Appointment and subsequent testing/assessments, documentation of a specific, working diagnosis should occur.

c. Initiate Trial Opioid Treatment: If the provider determines it is appropriate to start the patient on an opioid treatment regimen, the provider will initiate a trial period to evaluate the effectiveness of a chronic opioid treatment.

d. Creating a Care Plan: In addition to evidence of a working diagnosis, the completion of a Care Plan that is congruent with the clinical diagnosis and comprised of meaningful and functional goals should take place; specifically addressing improvement in function and decrease in pain.

e. Other Key Activities: the medical provider, or a member of the clinical team, should:

1) Discuss and document the risks and benefits of this course of care with the patient.

2) Counsel women between the ages of 14 and 55 with child bearing potential about the risks to the fetus when the mother has been taking opioids while pregnant. Such described risks shall include fetal opioid dependency and neonatal abstinence syndrome.

3) Provide a simple and clear explanation of the Care Plan - - i.e., its purpose and goals - - to help patients understand the key elements of his/her treatment. This activity should be documented review that of the goals of treatment:
    a) reduce pain and
    b) increase functioning as a result of a trial of opioids.

4) Present the Care Plan as one component of a "Controlled Substances Agreement" (CSA) between the patient and WHN that includes the patient's understanding of and commitment to the following CSA requirements:

    a) to identify a specific pharmacy which will be the only store where the prescribed medication(s) may obtained;
    b) to sign a Release of Information that allows the medical provider to communicate fully with the identified pharmacy or appropriate law enforcement agencies, if indicated.
    c) to be open and forthcoming with the clinical team about:
        - his/her pain,
        - the effects of pain upon his/her daily life, and
        - the effects of the medication on his/her pain.
    d) to attend follow-up clinical appointments as indicated in the Care Plan.
    e) to take the medication(s) as prescribed.
    f) to not share, trade or sell the prescribed medication(s).

g) to not use controlled substances from other medical providers or illegal drugs/ substances throughout the course of treatment, and to tell the clinical team if this item is violated.
h) to participate in urine or blood testing whenever determined by the clinical team.
i) to participate in pill counts whenever determined by the clinical team.
j) to acknowledge WHN's prescribing policies for controlled substances- - i.e., prescription refills occur as scheduled and are not done prematurely due to medications being used too quickly or being lost.
k) to request an explanation for the medical provider's rationale for changing or discontinuing opioid therapy.

5) Confirm the follow-up appointment date for ongoing monitoring.

3. Third Appointment (& Subsequent Visits): Similar to ongoing care for other medical conditions, the third appointment and subsequent visits should focus on monitoring the patient's progress using the Care Plan, Controlled Substances Agreement, and other related tools as listed above. Such monitoring can be accomplished through the following activities:

a. Assessment of progress toward major goals of REDUCING PAIN and INCREASING FUNCTIONING and documentation of findings.

b. Assessment of progress toward other Care Plan goals (e.g., weight reduction), documenting the findings, and modifying the Care Plan, if indicated.

c. If indicated, completing one or more of CSA adherence methods and documenting the findings:
1) Conducting/requesting urine or blood testing;
2) Running an INSPECT Report; and/or
3) Conducting/requesting a pill count.

d. Completing an "opioid dose calculation" and scanning the data into the patient's medical record - - (www.agencymeddirectors.wa.gov/guidelines.asp).

e. Refill the patient's prescription, if indicated.

f. Establishing a follow-up date if treatment is to continue.

g. The provider shall refill medications, as determined by his or her medical judgment for each individual patient according to the following:

- Monthly face-to-face visits: for those patients that are not yet stabilized or who the provider would consider high risk for addiction/diversion/overdose

- Quarterly face-to-face visits:
  With monthly office pick up of controlled substance prescriptions for those patients who are stabilized, but maybe at risk for addiction/diversion/overdose

  -OR-

- Quarterly face-to-face visits:
  With receipt of (3) 30 day prescriptions-each labeled “do not fill until mm/dd/yy” so that patient does not need to return to office for prescription

pick up monthly for those patients who are stabilized and low risk for addiction/diversion/overdose.

C. ADDITIONAL CONSIDERATIONS:

1. Provider Responsibilities. When it comes to the use of opioids to treat a patient's pain, a WHN clinical provider has the following responsibilities:

   a. Address Potential for Addiction/Habituation. As a general rule, potentially habit-forming opioid medications should not be used if a non-opioid medication will suffice. If opioids are indicated, they shall be used in adequate dose and duration to relieve symptoms but discontinued as soon as possible. The following standards should be adhered to:

      1) Whenever possible, a provider should use long-acting medications for patients in order to achieve baseline pain relief, while also utilizing short-acting medications for breakthrough pain.

      2). A provider should not prescribe opioids to patients with a history of chemical dependency. Exceptions to this standard may be made for pain relief following acute trauma (i.e., fractures), dental procedures, or at the time of a terminal illness.

      3) A provider should not utilize an opioid without taking into account:
         - the drug's potential for abuse,
         - the possibility the drug may lead to dependence,
         - the possibility the patient will obtain the drug for non-therapeutic use or to distribute to others, and
         - the possibility of an illicit market for the drug.

      4) A provider shall maintain accurate and complete medical records reflecting his/her examination, evaluation and treatment of all patients. Such medical records shall accurately reflect the utilization of any opioids in the treatment of a patient and shall indicate the diagnosis and purpose for which the opioids are utilized and additional information supporting the diagnosis.

2. Treating Other Providers' Patients. WHN providers are permitted to refill prescriptions for opioids utilized in managing the chronic pain disorders of WHN patients who receive care from an absent WHN colleague, provided that:

   a. Provider Agreement. If the covering clinician agrees with the historic evaluation and the treatment methodology outlined in the patient's medical record and the patient has been adherent with treatment recommendations and generally compliant with appointments with the absent provider, the provider should continue the course of treatment prescribed in the Care Plan. In such instances, the covering provider should document in the medical record that he/she agrees with historic findings that justify the use of the opioids.

   b. Provider Disagreement. If the covering provider DOES NOT agree with the indications for the medication delineated in the patient's medical record, the covering provider should administer an adequate pain assessment. This assessment may result in the prescribing of the same drug regimen, a modified regimen, or another interim regimen with an appropriate quantity and number of refills, if applicable, that will suffice until the patient's designated health care provider resumes caring for the patient.

   c. Additional Clinical Issues.

1) The potential for withdrawal complications shall be incorporated in the covering provider's decision to alter the drug regimen and will be sufficiently documented in the patient's health record.

2) If the covering provider significantly changes the previous medication regimen, the patient shall be given an appointment with the patient's regular provider as soon as possible.

3. Discharging Patients: Whenever a WHN provider decides to treat a patient with a controlled substance, as part of the treatment process, the patient will be required to review and sign a Controlled Substances Agreement (CSA) that includes a Care Plan.

   a. The patient's acceptance of the terms in the CSA will be noted in the patient's medical record. Within WHN's Electronic Medical Record, that notation should be placed in the "Medication" section of the chart. Most importantly, the notation should include the CSA's "renewal date," which can vary from one (1) to twelve (12) months.

   b. The CSA shall be updated as needed, but no more than 12 months should pass before updating this document.

   c. Per this policy, copies of the signed CSA will be:
      - given to the patient,
      - sent to the pharmacy chosen by the patient, and
      - scanned into the patient's Medical Record.

   d. When it comes to refilling a prescription, under NO circumstances should a prescription for a controlled substance be called into a pharmacy.

   e. If a patient violates the terms of his/her CSA, the medical provider may:
      1) Discontinue addressing the patient's pain management needs while continuing to assist the patient with his/her primary care needs. Or
      2) May submit a written request to WHN's Risk Manager requesting to dismiss the patient from WHN.

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Per the procedures outlined in WHN Policy AD 113 ("Discharging Patients), WHN's Risk Manager will review the request with WHN's Risk Management Team, (comprised of WHN's CEO, COO, Medical Director and Director of Quality). That team will review and they will either support the WHN provider's request or meet with the medical provider to propose an alternative strategy.

If the decision involves discharging the patient, the appropriate Health Center Practice Manager will follow the procedural steps outlined in section 2.b. of Policy AD 113 including sending the patient a dismissal letter indicating the patient has thirty (30) days to find a new provider. This notice should be sent via certified mail. In addition, the Practice Manager will inactivate the patient's medical record. Once a dismissal letter has been mailed, the patient will have medical care available through WHN for up to thirty (30) calendar days from the date of the letter. During that time period, if appropriate, a taper of opioids will be prescribed for the patient.

II. ANXIETY

A. **Evaluation & Treatment:** In nearly all instances, the medical use of controlled-substances for anxiety is done in order to accomplish one or more of the following outcomes:
   - clinically impact cognition (i.e., reduce thought-production);

- clinically alter mood (i.e., reduce anxiety, relieve depression);

1. A provider should not utilize a controlled substance without taking into account:
    - the drug's potential for abuse,
    - the possibility the drug may lead to dependence,
    - the possibility the patient will obtain the drug for non-therapeutic use or to distribute to others, and
    - the possibility of an illicit market for the drug.

2. A provider shall maintain accurate and complete medical records reflecting his/her examination, evaluation and treatment of all patients. Such medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized and additional information supporting the diagnosis.

B. Care Plan Development: the following concepts should be taken into consideration when developing a plan:

1. Goal Development: a useful Care Plan is comprised of effective, meaningful goals. "SMAART Goals are crafted using the following concepts:

    - **S**pecific: the goal focused upon achieving a particular target or end point;
    - **M**easureable: there is a concrete way of quantifying the desired outcome;
    - **A**chievable: the goal is reasonably attainable - - a stretch, but it can be reached;
    - **A**ccepted: the goal-setter fully agrees to work toward the identified goal
    - **R**elevant: the goal fits the overall plan; it is appropriate to treatment; and
    - **T**ime-bound: a reasonable target date is agreed upon.

2. Alternative Interventions: if viable treatment modalities for managing the patient's anxiety **other than controlled substances** exist, they should be discussed with the consumer. When developing a Care Plan, documentation that non-controlled substance alternatives, or combining non-controlled substance alternatives with non-pharmaceutical options, were considered and/or utilized as an initial clinical intervention, should occur.

C. Additional Considerations:

1. Treating Other Providers' Patients. WHN providers are permitted to refill prescriptions for controlled substances utilized in managing the chronic anxiety disorders of WHN patients who receive care from an absent WHN colleague, provided that:

    a. Provider Agreement. If the covering clinician agrees with the historic evaluation and the
    b. treatment methodology outlined in the patient's medical record and the patient has been adherent with treatment recommendations and generally compliant with appointments with the absent provider, the provider should continue the course of treatment prescribed in the Care Plan. In such instances, the covering provider should document in the medical record that he/she agrees with historic findings that justify the use of the controlled substance.

    b. Provider Disagreement. If the covering provider DOES NOT agree with the indications for the medication delineated in the patient's medical record, the covering provider should

administer an adequate anxiety assessment. This assessment may result in the prescribing of the same drug regimen, a modified regimen, or another interim regimen with an appropriate quantity and number of refills, if applicable, that will suffice until the patient's designated health care provider resumes caring for the patient.

c. Additional Clinical Issues.

1) The potential for withdrawal complications shall be incorporated in the covering provider's decision to alter the drug regimen and will be sufficiently documented in the patient's health record.

2) If the covering provider significantly changes the previous medication regimen, the patient shall be given an appointment with the patient's regular provider as soon as possible.

2. Discharging Patients: Whenever a WHN provider decides to treat a patient with a controlled substance, as part of the treatment process, the patient will be required to review and sign a Controlled Substances Agreement (CSA) that includes a Care Plan.

a. The patient's acceptance of the terms in the CSA will be noted in the patient's medical record. Within WHN's Electronic Medical Record, that notation should be placed in the "Medication" section of the chart. Most importantly, the notation should include the CSA's "renewal date," which can vary from one (1) to twelve (12) months.

b. The CSA shall be updated as needed, but no more than 12 months should pass before updating this document.

c. Per this policy, copies of the signed CSA will be:
- given to the patient,
- sent to the pharmacy chosen by the patient, and
- scanned into the patient's Medical Record.

d. When it comes to refilling a prescription, under NO circumstances should a prescription for a controlled substance be called into a pharmacy.

e. If a patient violates the terms of his/her CSA, the medical provider may:
1) discontinue addressing the patient's anxiety management needs while continuing to assist the patient with his/her primary care needs. Or
2) may submit a written request to WHN's Risk Manager requesting to dismiss the patient from WHN.

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Per the procedures outlined in WHN Policy AD 113 ("Discharging Patients), WHN's Risk Manager will review the request with WHN's Risk Management Team, (comprised of WHN's CEO, COO, Medical Director and Director of Quality). That team will review and they will either support the WHN provider's request or meet with the medical provider to propose an alternative strategy.

If the decision involves discharging the patient, the appropriate Health Center Practice Manager will follow the procedural steps outlined in section 2.b. of Policy AD 113 including sending the patient a dismissal letter indicating the patient has thirty (30) days to find a new provider. This notice should be sent via certified mail. In addition, the Practice Manager will inactivate the patient's medical record. Once a dismissal letter has been mailed, the patient will have medical care available through WHN for up to thirty (30) calendar days from the date of the letter. During that time period, if appropriate, a taper of the controlled substance will be prescribed for the patient.

III. CONTROLLED STIMULANT MEDICATIONS

A. **Evaluation & Treatment:** In nearly all instances, the medical use of controlled-substances for ADD/ADHD is done in order to accomplish one or more of the following outcomes:

- clinically impact cognition (i.e., reduce thought-production);
- modify behavior (i.e., reduce hyperactivity)

1. A provider should not utilize a controlled substance without taking into account:
   - the drug's potential for abuse,
   - the possibility the drug may lead to dependence,
   - the possibility the patient will obtain the drug for non-therapeutic use or to distribute to others, and
   - the possibility of an illicit market for the drug.

2. A provider shall maintain accurate and complete medical records reflecting his/her examination, evaluation and treatment of all patients. Such medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized and additional information supporting the diagnosis.

B. Care Plan Development: the following concepts should be taken into consideration when developing a plan:

1. Goal Development: a useful Care Plan is comprised of effective, meaningful goals. "SMAART Goals are crafted using the following concepts:

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   - **R**elevant: the goal fits the overall plan; it is appropriate to treatment; and
   - **T**ime-bound: a reasonable target date is agreed upon.

3. Alternative Interventions: if viable treatment modalities for managing the patient's ADD/ADHD

   other than controlled substances exist, they should be discussed with the consumer. When developing a Care Plan, documentation that non-controlled substance alternatives, or combining non-controlled substance alternatives with non-pharmaceutical options, were considered and/or utilized as an initial clinical intervention, should occur.

C. Additional Considerations:

1. Treating Other Providers' Patients. WHN providers are permitted to refill prescriptions for controlled substances utilized in managing ADD/ADHD of WHN patients who receive care from an absent WHN colleague, provided that:

   a. Provider Agreement. If the covering clinician agrees with the historic evaluation and the treatment methodology outlined in the patient's medical record and the patient has been adherent with treatment recommendations and generally compliant with appointments

with the absent provider, the provider should continue the course of treatment prescribed in the Care Plan. In such instances, the covering provider should document in the medical record that he/she agrees with historic findings that justify the use of the controlled substance.

b. Provider Disagreement. If the covering provider DOES NOT agree with the indications for the medication delineated in the patient's medical record, the covering provider should administer an adequate anxiety assessment. This assessment may result in the prescribing of the same drug regimen, a modified regimen, or another interim regimen with an appropriate quantity and number of refills, if applicable, that will suffice until the patient's designated health care provider resumes caring for the patient.

c. Additional Clinical Issues.

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b. The CSA shall be updated as needed, but no more than 12 months should pass before updating this document.

c. Per this policy, copies of the signed CSA will be:
- given to the patient,
- sent to the pharmacy chosen by the patient, and
- scanned into the patient's Medical Record.

d. When it comes to refilling a prescription, under NO circumstances should a prescription for a controlled substance be called into a pharmacy.

e. If a patient violates the terms of his/her CSA, the medical provider may:
1) discontinue addressing the patient's ADD/ADHD management needs while continuing to assist the patient with his/her primary care needs. Or
2) may submit a written request to WHN's Risk Manager requesting to dismiss the patient from WHN.

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