Applicable To
This Standard Operating Procedure (SOP) applies to all clinic medical, associate, nursing and other staff of Gundersen Clinic, Ltd. caring for patients (ages 18-75 years) with chronic pain requiring Schedule II opioid medications for greater than six months and/or Schedule III opioids medications for a quantity greater than or equal to 84 tablets/caplets for greater than six months. This excludes terminal cancer patients, Hospice patients, patients receiving Palliative Care or hospitalized patients, long term nursing home or group home patients. Hospitalized patients will have their pain managed by the hospital MD/Provider.

NOTE: Part or all of the recommendations in this SOP may be applied to patients receiving chronic Schedule IV-V opioid medications per the provider’s discretion.

Detail
The purpose of this Standing Operating Procedure is to standardize safe care for patients with chronic pain who meet criteria by defining the following:

A. Responsibilities of the care team at the initiation and maintenance of the Chronic Pain Management Agreement
B. Prescribing practices for long-term opioid medications
C. Requirements for follow-up testing

Implementation
I. The management of chronic pain requires a collaborative approach for optimal effectiveness.

This SOP outlines the responsibilities of the ambulatory care providers for patients with chronic pain that are prescribed opioids

Patients are added to the Chronic Pain registry automatically if they meet the following criteria: Schedule II opioid therapy for greater than six months and/or Schedule III opioid medications for a quantity greater than or equal to 84 tablets/caplets for greater than six months.

Pain Management Agreement on the active problem list will place patients in the Chronic Pain registry regardless of whether or not the criteria for quantity or time specifics have been met as listed above. In addition, with provider discretion, patients receiving chronic Schedule IV-V can be also be added using the problem list.

A. Prescribing provider responsibilities include, but is not limited to, the following:
   1. Identify patients with Chronic Pain
2. Use Diagnosis Intractability Risk and Efficacy (DIRE) test score to determine initial candidacy for Opioid therapy
3. Add “Chronic Pain” to the Problem list
4. Add “Pain Management Agreement” to the Problem list
5. Pain Management agreements must be done annually and are necessary for the following patients: patients (ages 18-75 years) in the Chronic Pain registry
   a. Chronic Pain Management Agreement must be read to patient by RN or provider at the time of initiation or renewal
   b. New agreements and renewals require a witnessed signature
   c. Give copy of the agreement to the patient.
   d. Send copy to the pharmacy listed on the agreement
   e. Original Chronic Pain Management Agreement should be sent to HIM for scanning or be scanned into EMR within the department
   f. Click the New/Renewed button on the Chronic Pain Doc Flowsheet within Disease Management Chronic Pain tab or extended vitals in the EMR
6. Determine if Alcohol or Drug Addiction (AODA) consultation is appropriate at initiation of agreement and as needed
7. Assist patient in setting goals for improved function through pain control
8. Review the Chronic Pain Management Agreement annually with the patient. If any editing is needed, initiate a new agreement
9. Schedule office visit every six months with prescribing provider
10. Order urine “Lab Compliance Drug Monitoring” or blood toxicology screening tests at initiation of Chronic Pain Management agreement AND annually. Throughout the year, order random urine or blood toxicology at provider discretion. Blood toxicology screening tests may be considered for patients with CKD Stage 5 on renal replacement therapy, oliguric patients, or for patients who have potential to falsify urine testing. Blood toxicology screening tests must be collected before dialysis
   a. Unobserved urine collection is the standard
   b. Must be collected in the ordering department
   c. Urine should not be collected by lab personnel
11. Prepare and sign the Opioid pain medication prescription
12. Identify designated covering provider in the event of extended leave of absence
13. Interpret and act upon results of urine or blood toxicology screening tests. This may include discontinuing the Chronic Pain Management Agreement because patient has not been compliant with agreement
14. A failed agreement should be considered if the patient does not follow the components of the agreement
15. Discontinuation of a Chronic Pain Management Agreement occurs when pain is resolved or patient is no longer being prescribed opioids
16. Document all of the above in the electronic medical record (EMR)

B. Registered Nurse responsibilities (Steps 1-4 require prescribing provider if RN is not available):
   1. Complete a pain assessment using an appropriate pain rating scale if not already completed
   3. Initiate Chronic Pain Management Agreement as delegated by prescribing provider. If patient refuses agreement, notify prescribing provider prior to giving patient prescription
a. Chronic Pain Management Agreement must be read to patient by RN or provider at the time of initiation or renewal
b. New agreements and renewals require a witnessed signature
c. Give copy of the agreement to the patient.
d. Send copy to the pharmacy listed on the agreement
e. Original Chronic Pain Management Agreement should be sent to HIM for scanning or be scanned into EMR within the department
f. Assist in setting and reinforcing goals for patient to achieve improved function through pain control
g. Complete documentation in clinical support note
h. Click New or Renewed on the Chronic Pain Doc Flowsheet within Disease Management Chronic Pain tab or extended vitals in the EMR

4. Educate patient regarding chronic pain using Chronic Pain Management Patient Education found on the Disease Management website or the Patient Education Website

5. Order and collect “Lab Compliance Drug Monitoring” using Clinic Standing Order: Disease Management-Chronic Pain
   a. Document standing order criteria by using .csoutox
   b. Document urine collection by using .utox

6. Collect “Lab Compliance Drug Monitoring” when ordered by provider

7. Assist with opioid medication prescription refills using .medrefill for documentation in EMR

8. Refer to SOP GL-6076 Medication Prescription Pick Up: Outpatient for process of prescription pick-up

9. Alert prescribing provider when Chronic Pain Agreement is due for review and/or annual renewal

C. Licensed Practical Nurse or Medical Assistant (LPN or MA) delegated responsibilities:
   1. Give patient education handouts as delegated by the RN or prescribing provider
   2. Reinforce education initiated by the RN or prescribing provider
   3. Order and collect “Lab Compliance Drug Monitoring” using Clinic Standing Order: Disease Management-Chronic Pain
      a. Document standing order criteria by using .csoutox
      b. Document urine collection by using .utox

4. Collect “Lab Compliance Drug Monitoring” when ordered by provider

5. Assist with opioid medication prescription refills using .medrefill for documentation in EMR. If patient reports concerns, such as, but not limited to: increased pain, requesting refill prior to due date, or difficulty tolerating the medication, the LPN or MA must document and contact RN or prescribing provider to assess

6. Refer to SOP GL-6076 Medication Prescription Pick Up: Outpatient for process of prescription pick-up

7. Alert prescribing provider when Chronic Pain Agreement is due for renewal and/or annual renewal

II. “Lab Compliance Urine Drug Monitoring” Process

A. After test has been ordered, complete MedTox lab form with the following information:
   1. Patient first and last name
   2. Patient ID (clinic number)
   3. Date of collection
   4. Time of collection
5. All medications prescribed and used by the patient in the last five days (must verify with patient)
6. Urine temperature (after collecting urine sample)

**B. The Provider, RN, LPN or MA will:**

1. Reinforce reason for urine toxicology
2. Verify photo ID of person providing urine sample
3. Instruct patient to:
   a. remove any bulky clothing
   b. empty pants pockets
   c. not take purse, bag(s) or beverage(s) into bathroom
4. Allow only the patient to enter the bathroom when obtaining urine sample
5. Obtain unobserved urine sample of at least 15 mL using labeled specimen cup from toxicology test kit. Fifteen mL will be enough to run the test, but may not meet the indicator strip. Provider discretion whether the absence of temperature is acceptable for the test.
6. Observe temperature strip for green dot which indicates urine temperature (between 90 degrees F and 100 degrees F)
   a. If temperature strip remains black (indicating urine temperature is less than 90 degrees F) or strip changes color up to 100 degrees F mark and then turns black (indicating urine temperature is greater than 100 degrees F), recollect urine immediately or as soon as patient is able to urinate again
   b. Preferred that patient remain in clinic until recollection has occurred
7. Check appropriate box on the MEDTOX lab order form to indicate if urine temperature is “In Range” or “Out of Range”
8. After documenting urine temperature range, obtain patient initials at the bottom of the MEDTOX lab order form
9. Observe and report to the Provider the following possible indicators of tampering:
   a. smell of bleach on hands
   b. urine temperature less than 90 degrees F or greater than 100 degrees F for 2 consecutive samples
   c. In addition, if the collector suspects possible tampering based any unusual observations, he/she will report to prescribing provider
10. Apply tamper resistant strip over the lid of the container
11. Apply patient identification label around container so that it is clearly visible
12. Ask patient to initial the tamper resistant strip
13. Assure urine sample is sent to lab by the collecting department
14. Document in the EMR that unobserved urine collection has been completed using .utox

**C. Random toxicology screening:**

1. Patients should be instructed to report to the clinic within 24 hours for appointment with nurse or provider as part of the terms of their Chronic Pain Management Agreement. Patients should not be notified of urine test in advance
2. If patient is not present in the clinic remind patient to:
   a. bring a photo ID
   b. bring current prescription medications to appointment
3. Once patient has arrived for appointment, inform patient test has been ordered
4. Follow steps above for collection of unobserved urine toxicology screening
5. Document in the EMR that unobserved urine collection has been completed using utox.

D. Collection of Blood Toxicology screening:
   1. Prescribing provider or RN will explain reason for blood toxicology
   2. Prescribing provider or RN will instruct patient to go to lab for collection (must be done prior to dialysis)

E. Failed Urine or Blood Toxicology screening tests
   1. Prescribing provider will send letter to patient using “opioid termination letter”
   2. If letter template not used, dictated letter must include the following:
      a. explanation of failed test results
      b. explanation of termination of opioid prescribing if appropriate and tapering instructions if needed

III. Patient behaviors to monitor and report to provider; optimally face to face. Document in EMR as appropriate. (EMR documentation should only include factual information. EMR documentation should not include statements, such as: “I think patient is selling.”)

A. early requests for refills
B. numerous requests for refills due to vacations
C. escalations in doses or requests for more than one additional opioid medication
D. requests for name brand medications
E. abusive behavior/language during phone calls
F. patient report of stolen prescriptions, lost prescriptions, unusual circumstances or reports, prior failed or questionable toxicology screening results

IV. Preparation of Opioid prescription renewals

A. Prescription renewal must be authorized by prescribing provider
B. MA, LPN, RN or prescribing provider will:
   1. Confirm that patient has an active Chronic Pain Agreement and date of last agreement (must be documented annually)
   2. Determine if prescribing provider is available to refill prescription
   3. If prescribing provider is not available, identify designated covering provider
   4. Collect information after pending the medication for the provider to sign using EPIC smartphrase: .medrefill. This smartphrase will meet all documentation criteria for opioid refills. (Please see guided practice, Medication Refills, for specifics)
      a. Determine if patient is due for refill
         i. If patient is requesting refill prior to 3 business days before due date (early refill), staff will: communicate this with the patient communicate with the prescribing provider who will determine the next steps
         ii. If patient is due for refill, complete documentation and send encounter to provider for review and authorization/signature
      b. Ask patient for overall pain rating since last refill
      c. Ask patient for location of pain
      d. Ask patient if they are experiencing any side effects from medication. These are listed in .medrefill
         i. Patient denies having any new side effects from pain medication use: continue with refill process
         ii. Patient reports new side effects from pain medication use: RN to assess and document prior to sending encounter to provider
   5. Route encounter to provider for review and authorization/signature
a. Provider reviews and authorizes/signs as appropriate. This may include:
b. Printing of prescription
c. Signature on printed prescription
d. Denial of refill and documented rationale
e. Ordering “Lab Compliance Urine Drug Monitoring” if needed
f. Notifying nurse if renewal of agreement is needed
g. Provider routes encounter to nurse pool

6. Notify patient that prescription has been approved and is ready for pick up or has been faxed to pharmacy. If prescription cannot be faxed, ask patient’s plan to obtain the paper prescription
   a. Remind patient that whomever picks up the prescription will need to present a photo ID
   b. If person picking up prescription is not the patient, verify that this person has been named on the Chronic Pain Management Agreement and document in EMR
   c. If patient requests prescription to be mailed, it can only be mailed to the pharmacy listed on the agreement.

V. Prescribing provider extended leave of absence
   A. Prescribing provider will:
      1. Determine plan for refill coverage prior to leave of absence
      2. Communicate plan to covering provider if applicable

VI. Prescription pick-up
   1. RN, LPN or MA will follow the Standard Operating Procedure for Medication Prescription Pickup: Outpatient. This meets documentation requirements
   2. Verify via photo ID, that person picking up prescription is the patient
   3. The staff member who delivers the prescription must document name of patient or patient representative who picked-up the prescription in the EMR. Use .medrefill for documentation

VII. Termination of Chronic Pain Management agreement
   A. Prescribing provider will:
      1. Determine if patient has failed conditions of the agreement.
         a. Communicate termination of pain management agreement to patient face to face, via telephone or via letter using opioid termination letter template
         b. Offer patient an Alcohol or Drug Addiction (AODA) consultation, if appropriate
         c. Select “Failed” on Chronic Pain Agreement Status Doc Flowsheet and select Reason
         d. Document or delegate documentation of: “Pain Management Contract Broken” on the Active Problem List. Add comment regarding agreement status or reference date for supportive documentation
         e. Click Failed on the Chronic Pain Doc Flowsheet within Disease Management Chronic Pain tab or extended vitals in the EMR.
         f. Update Care Teams by ending chronic pain management prescriber
      2. If patient is no longer using opioids for pain control, determine if Chronic Pain Management agreement status should be resolved on the problem list. This is unrelated to pain agreement violation
a. “Pain Management Contract Agreement” may be resolved from Active Problem List, per provider discretion. Removal of Pain Management Contract Agreement from problem list will remove patient from the registry
b. Patient will be removed from the registry if the medication list is without opioids for six months
c. Maintain Chronic Pain on the Active Problem list when applicable