

# C.34

Maine General Medical Center  
(2011) Compassionate Limits  
Prescription Program

# CLIPP

## Compassionate Limits Prescription Program

### PREAMBLE

The country at large and Maine in particular has reached a crisis with respect to prescription drug use and its related effects on the community. The statistics are compelling and reflect that Maine has reached an epidemic level with an increase in opiate related deaths from 34 in 1997 to 179 in 2009 with 80-90% involving a pharmaceutical drug in some way. In Maine the number of opiate related deaths (2000: 169 Hwy Related 60 Drug OD) has exceeded the number of motor vehicle related deaths (2010: 161 Hwy Related 167 Drug OD)! Prescription drugs are often the first step in introducing young people to illegal substances. Data from the National Survey on Drug Use and Health show that nearly one-third of people aged 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically. Of Maine's high school seniors, 24% say they have misused a prescription pain killer during their lifetime. **Eleven percent** of students on grades 6 through 12 have used prescription drugs for a reason other than their intended purpose.

### Background (Ref. CDC)

According to the 2010 National Drug Threat Assessment report, "The threat posed by the diversion and abuse of controlled prescription drugs (CPDs), primarily pain relievers, is increasing, as evidenced by the sharp rise in the percentage (4.6 percent in 2007, 9.8 percent in 2009) of state and local law enforcement agencies reporting CPDs as the greatest drug threat in their area." Increased abuse of CPDs has led to elevated numbers of deaths related to prescription opioids, which **increased 98 percent** from 2002 to 2006. Figures from the National Drug Threat Assessment- Number of Reported Unintentional Poisoning Deaths with Mention of Opioid Analgesics **5,547 (2002) 11,001 (2006)**

The National Drug Threat Assessment report further states that, "The most commonly diverted CPDs are opioid pain relievers, according to Drug Enforcement Administration (DEA) and the National Survey of Drug Use and Health (NSDUH) data." Opioid pain relievers are popular among drug abusers because of the euphoria they induce. Opioid pain relievers include codeine, fentanyl (Duragesic, Actiq), hydromorphone (Dilaudid), meperidine (Demerol, which is prescribed less often because of its side effects), morphine (MS Contin), oxycodone (OxyContin), pentazocine (Talwin), dextropropoxyphene (Darvon), methadone (Dolophine), and hydrocodone combinations (Vicodin, Lortab, and Lorcet)."

In addition to opioids, it has been reported that significant diversion is occurring with high cost antipsychotic and mental health drugs, such as aripiprazole (Abilify), ziprasidone (Geodon), risperidone (Risperdal), quetiapine (Seroquel), and olanzapine (Zyprexa), as well as benzodiazepines such as alprazolam (Xanax), clonazepam (Klonopin) and lorazepam (Ativan).

The impact of drug diversion on the Medicaid program goes beyond just the cost of the prescription drugs. There are also the costs associated with doctor's visits, emergency department (ED) treatment, rehabilitation centers, and other health care needs, not to mention the human toll. In 2008, the Drug Abuse Warning Network (DAWN), operated by the Substance Abuse and Mental Health Services Administration (SAMHSA), estimated that prescription or over-the-counter drugs used non-medically were involved in **1.0 million ED visits**. Among the legal drugs, the most common drug categories involved were drugs acting on the central nervous system, especially opioid painkillers and psychotherapeutic drugs (especially sedatives and antidepressants). Opioid painkillers were associated with approximately 306,000 visits and benzodiazepines with 272,000 visits.

### **Dangers of Prescription Drug Abuse**

The increased misuse of prescription drugs has coincided with increased risks and mortality. Death from drugs is the second leading cause of accidental death in the U.S., exceeded only by motor vehicle accidents.<sup>16</sup> According to the CDC, unintentional drug overdose deaths increased 68% between 1999 and 2004.<sup>17</sup> In a recent study from West Virginia, 63% of deaths due to unintentional overdose of prescription drugs were associated with diversion of the drug (i.e., there was no documented prescription for the deceased person), while another 21% involved persons who had obtained prescriptions for controlled substances from five or more physicians (representing probable “doctor shopping”).<sup>18</sup> These data indicate that the primary cause of overdose death from prescription drugs results from their nonmedical use. Prescription drug overdose associated with diversion most closely resembles the profile of traditional abusers of street drugs, being highest in unmarried men and in the 18- to 24-year-old group.<sup>17</sup> This group was also more likely to have a history of other substance abuse and to combine prescription drugs with illicit drugs. In contrast, overdose linked to doctor shopping was highest in the group aged 35 to 44 years and was more likely to involve women.<sup>18</sup>

Nationally, the number of opioid analgesic poisonings listed on death certificates increased 91% between 1999 and 2002, while poisonings due to heroin and cocaine increased by much smaller percentages (12.4% and 22.8%, respectively).<sup>11</sup> Emergency room admissions for prescription opioid use increased 74% from 2002 to 2006, and the misuse of opioid analgesics now results in more drug overdose deaths than cocaine and heroin combined.<sup>16</sup> Overall, the nonmedical use of controlled prescription drugs is estimated to cost the health care system more than \$72 billion annually.<sup>16</sup>

Nearly one-third of new drug abusers report that their first experience involved a prescription drug, with 19% citing opioids.<sup>16</sup> These data highlight the risks associated with the intentional misuse of prescription drugs and are contrary to the belief among adolescents and their parents that prescription drug abuse represents a safer alternative to street drug use. Criminal activity, including thefts and robberies from pharmacies, is an additional risk.<sup>19</sup>

### **SOLUTION**

A collaborate approach between the community, clinicians, pharmacies and law enforcement is essential to the successful management of this crisis.

### **ACTIONS**

#### **Government**

- 1) Prescription Monitoring Program
  - a. Promote the subaccount users such as medical assistants, methadone detox treatment, VA & cash payments, simply the interface for easier access.
  - b. Remove registration barriers and functionality changes to PMP caused by frequent vendor changes.
- 2) Implement Electronic Prescribing for Controlled Substances

#### **Law Enforcement**

- 1) Prescription Drug Diversion Program (PDDP)
- 2) Law Enforcement Feedback to Prescription Writer when their Rx is recovered in an Law Enforcement Encounter
- 3) Participate in Processing Lost or Stolen Scheduled Drug Complaint (Consider polygraph screening as part of process)
- 4) Continued take back via drop boxes by local PD and Sheriff's offices and Encouraging beneficiary participation in the national prescription drug "Take-Back" campaign

**Pharmacies**

- 1) Participate in weekly dispensing program (Adjust Co-pays)
- 2) Increase efforts to notify physicians of diversion, multiple providers, fraud, aberrant behaviors
- 3) Blister packaging
- 4) Controlled substance prescription valid only within the county of origin (use override certificate)
- 5) Photo ID required for controlled substance prescription

**Physician Voluntary Program Limits for Non-Cancer Related Pain**

- 1) Documentation to support the need for opiate pain control
  - a. Follow the WHO guidelines for staged prescribing for pain control (Appendix C)
  - b. Clear documentation in the patient's medical record should include
    - i. The diagnosis for which the opioids are being prescribed.
    - ii. Ongoing assessment should specifically address:
      1. Degree of analgesia (on 0-10 scale or other scale acceptable to patient)
      2. Opioid-related side effects
      3. Functional status (e.g. physical activities, social functioning)
      4. Existence of aberrant drug-taking behaviors
- 2) Standardized controlled substances agreement for narcotic pain control
- 3) Implement and Register Pain Agreements (1 Clinician 1 Pharmacy) with ER, PMP or similar (?SCM)
- 4) Screen for aberrant behaviors and psychological co-morbidities
- 5) Screen PMP and PDDP at first visit and follow-up visits
- 6) Implement standardized protocol for urine drug screening
- 7) Use random urine drug testing and pill counts to monitor adherence to the treatment plan
- 8) First prescription not to exceed 1 week with 1 pre-dated refill
- 9) Anticipate and treat side effects: Start bowel regimen when opioids are started.
- 10) PO is the route of choice. Avoid the use of liquid formulations without documentation of swallowing disorder
- 11) Avoid exceeding 120-mg Total Oral Morphine Equivalent Dose (MED) per day
- 12) Break through pain medication not exceed 33% of total baseline dose.
- 13) If need to exceed 3-months of narcotic pain control consider pain management consultation; refer at the 8-week mark if needed.
- 14) When increasing doses document improvement in functioning and pain over prior lower dose
- 15) Avoid physician extenders escalating dosing without collaboration of attending physician.
- 16) Require police report for lost or stolen scheduled medications
- 17) Maximum of 2 lost or stolen scheduled medication replacement Rx
- 18) Post operatively up to 2-weeks by surgeons then followed by PCP
- 19) 1-week supply with 3 weekly pre-dated refills to minimize the impact of lost Rx
- 20) Rx to indicate photo ID required for controlled substance prescription
- 21) Controlled substance prescription valid only within the county of origin (use override certificate if necessary)
- 22) When changing medications; recall and collection of unused medications with witnessed destruction of unused medications. (standardized form for patient and clinician to sign)
- 23) Avoid writing prescriptions without seeing the patient
- 24) Avoid the prescription for concomitant sedative-hypnotics
- 25) Avoid mail order prescriptions for controlled prescription drugs
- 26) Use of a single agent preferred when possible
- 27) Avoid using more than one compounded opiate at a time.
- 28) Screen for sleep apnea (see Appendix B) before exceeding 120-mg MED with referral for sleep study if appropriate.

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- 29) Implement electronic prescriptions for scheduled drugs to decrease Rx fraud when available
- 30) Avoid concomitant use of opiates and medical marijuana without pain management consultation
- 31) Overdose Prevention – consider the prescription for intra-nasal naloxone with high risk patients
- 32) Emergency Department Guidelines to help coordinate care with primary care providers  
The Emergency Department Should Avoid
- a. Giving pain medication injections for sudden increases in chronic pain.
  - b. Refilling stolen or lost prescriptions for medication.
  - c. Prescribing missed methadone doses.
  - d. Prescribing long-acting pain medication such as OxyContin, MS Contin, fentanyl patches, or methadone for chronic non-cancer pain.
  - e. Prescribing pain medication if you already receive pain medication from another doctor or emergency department.
- 33) Referral for Chronic Pain Management
- a. Escalating doses that are likely to exceed 120-mg (MED)
  - b. Attending provider is treating a patient with escalating dose pattern, limited or no improvement in pain or function.
  - c. Symptoms without clear diagnosis for narcotic pain control
  - d. Patient with comorbidities and history of depression; suspect dependence or tolerance.
  - e. Narcotic pain control required beyond 90-days
  - f. Concomitant use of opiates and medical marijuana
  - g. Multiple medication intolerances limiting prescription selection
  - h. Questions about Methadone treatment for pain
  - i. Questions about BuTrans treatment for pain
  - j. Questions about overdose prevention with intra-nasal naloxone
  - k. Aberrant Behaviors
  - l. Tapering patients off opioids
- 34) Reasons to discontinue opioids or refer for Addiction Management
- No improvement in function and pain or opioid therapy produces significant adverse effects or Patient exhibits drug-seeking behaviors or diversion such as:
- |   |                                 |
|---|---------------------------------|
| Forging prescriptions   | Selling prescription drugs      |
| Stealing or borrowing drugs                                       | Unsanctioned dose escalation    |
| Frequently losing prescriptions                                   | Concurrent use of illicit drugs |
| Aggressive demand for opioids                                     | Failing a drug screen           |
| Injecting oral/topical opioids                                    | Multiple prescribers            |
| Recurring emergency department visits for chronic pain management |                                 |
- 35) Referrals for Addiction Management
- A patient who exhibits overt signs of alcohol or substance use disorder should be referred to an addiction specialist for appropriate treatment
- 36) Increase substance use disorder treatment capacity, primary care based, establishment of Outpatient Treatment Program, and community based recovery options.

**Community Based Treatment**

- 1) Suboxone
  - a. Opiate Treatment Clinic, Seton Center, MGMC (1-888-777-9393)
  - b. Primary Care Providers
- 2) Methadone
  - a. Discovery House, Airport Rd., Waterville
- 3) Behavioral Health Services
  - a. Inpatient detox
    - 1) 4 East, Thayer Campus, MGMC (1-888-777-9393)
  - b. Intensive Outpatient Program
    - 1) Day and Evening Programs, Seton Center, MGMC (1-888-777-9393)
    - 2) Day Program, Crisis & Counseling, Augusta
  - c. Individual, Group & Family Counseling:
    - 1) MaineGeneral Counseling, Augusta, Waterville, Fairfield, primary care sites (1-888-777-9393)
    - 2) Crisis & Counseling, Augusta
    - 3) Kennebec Behavioral Health, Augusta, Waterville
    - 4) Cornerstone Behavioral Health Care
    - 5) Private Providers
  - d. Residential:
    - 1) MaineGeneral Residential Care, Sidney (men), Augusta (women) (1-888-777-9393)
- 4) Enhance Access for Alternative Treatment Approaches
  - a. Cognitive behavioral therapy
  - b. Graded exercise
  - c. Activity coaching
  - d. Interdisciplinary care
  - e. Care coordination
  - f. Acupuncture
  - g. Kinesiology
  - h. Mind-Body/TAI CHI
  - i. Massage Therapy
  - j. Chiropractic Care
  - k. Osteopathic Therapy
  - l. Other Integrative Medicine Modalities
  - m. Stress Management
  - n. Chronic Pain educational classes

**Education**

- 1) Treating Professionals
- 2) Pharmacists
- 3) Patients- Pain management treatment options, and address legalities and responsibilities of scheduled drug use.
- 4) Insurance Industry
- 5) Law Enforcement
- 6) Schools - Address legalities and responsibilities of scheduled drug use.
- 7) Encouraging beneficiary participation in the national prescription drug "Take-Back campaign"

Community Mobilization/Metrics

- 1) Monitoring and assessment of impact of CLIPP on population
- 2) Development of community based strategies to address economic and social impact of CLIPP
- 3) Advocacy for increased addiction treatment capacity

Appendices

- A. Open Source Tools
- B. Sleep Apnea Screening Tools
- C. World Health Organization Guideline for Analgesic Orders
- D. Opiate Conversion Tables
- E. Behavioral Risk Analysis
  - DEA Criteria That Indicate a Prescription May Not Be for a Legitimate Medical Purpose
  - Behavioral Traits That Might Trigger Suspicion of Drug Abuse
  - Deceptive Practices Used to Procure Prescriptions
- F. Urine Drug Screen Frequency Recommendations

**APPENDIX A: Open Source Tools**

- Opioid Risk Tool: Screen for past and current substance abuse
- CAGE-AID: Screen for alcohol or drug abuse
- Patient Health Questionnaire-9: Screen for depression
- SF36 Health Survey
- Brief Pain Inventory

**APPENDIX B: Sleep Apnea Screening Tools**

- Epworth Sleepiness Scale
- Berlin Questionnaire for Sleep Apnea

**APPENDIX C: WHO Guideline for Analgesic Orders**

**Step 1 Analgesics (mild pain); (non-opioids)**

- NSAID's
- Acetaminophen

**\*\*Guideline:** Only one NSAID should be ordered at any one time; Acetaminophen may be ordered at the same time as an NSAID.

**Step 2 Analgesics (moderate pain); combination opioid/non-opioids and weak opioids**

- Propoxyphene and propoxyphene combination products (e.g. Darvocet)
- Codeine and codeine combination products (e.g. Tylenol #3)
- Oxycodone and oxycodone combination products (e.g. Percocet)
- Hydrocodone combination products (e.g. Vicodin)
- Tramadol (Ultramm) (e.g. Ultracet)

**\*\*Guideline:** Only one Step 2 opioid is to be ordered at any one time.

**Step 3 Analgesics (severe pain); long-acting opioids**

- Oramorph SR, MS Contin;
- OxyContin
- Transdermal Fentanyl
- Methadone

**\*\* Guideline:** only one long-acting opioids at any one time

**Step 3 Analgesics (severe pain); short acting opioids**

- Morphine
- Hydromorphone
- Oxycodone
- Meperidine

**\*\* Guideline:** only one short-acting opioid at any one time

**APPENDIX D: Opiate Conversion Tables, MED Calculation, Dosing Thresholds**

<b>Morphine Equivalent Dose Calculation</b>
<p>For patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose (see Table 5 in Appendix A for MEDs of selected medications). For example, if a patient takes six hydrocodone 5mg / acetaminophen 500mg and two 20mg oxycodone extended release tablets per day, the cumulative dose may be calculated as follows:</p> <ol style="list-style-type: none"> <li>1) Hydrocodone 5mg x 6 tablets per day = 30mg per day.</li> <li>2) Using the Equianalgesic Dose table in Appendix A, 30mg Hydrocodone = 30mg morphine equivalents.</li> <li>3) Oxycodone 20mg x 2 tablets per day = 40mg per day.</li> <li>4) Per Equianalgesic Dose table, 20mg oxycodone = 30mg morphine so 40mg oxycodone = 60mg morphine equivalents.</li> <li>5) Cumulative dose is 30mg + 60mg = 90mg morphine equivalents per day.</li> </ol>

<b>MED for Selected Opioids</b>	
<b>Opioid</b>	<b>Approximate Equianalgesic Dose (oral &amp; transdermal)</b>
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Methadone	Chronic: 4mg

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Oxycodone	20mg
Oxymorphone	10mg

<b>Dosing Threshold for Selected Opioids</b>			
<b>Opioid</b>	<b>Recommended dose threshold for pain consult (not equianalgesic)</b>	<b>Recommended starting dose for opioid-naïve patients</b>	<b>Considerations</b>
Codeine	800mg per 24 hours	30mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Fentanyl Transdermal	50mcg/hour (q 72 hr)		Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer
Hydrocodone	120mg per 24 hours	5-10mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Hydromorphone	30mg per 24 hours	2mg q 4–6 hours	
Methadone	40mg per 24 hours	2.5-5mg BID – TID	Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids.
Morphine	120mg per 24 hours	Immediate-release: 10mg q 4 hours	Adjust dose for renal impairment.
		Sustained-release: 15mg q 12 hours	
Oxycodone	80mg per 24 hours	Immediate-release: 5mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.

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		Sustained Release: 10mg q 12 hours	
Oxymorphone	40mg per 24 hours	Immediate-release: 5–10mg q 4–6 hours	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol.
		Sustained Release: 10mg q 12 hours	

**APPENDIX D: Behavioral Risk Analysis**

**DEA Criteria That Indicate a Prescription May Not Be for a Legitimate Medical Purpose**

- A prescriber's prescription pattern is different from that of other prescribers in the area (e.g., more prescriptions for controlled substances or prescriptions for larger quantities of controlled drugs)
- Prescriber writes for antagonistic drugs (e.g., stimulant and depressant at the same time)
- Patient returns to the pharmacy more frequently than expected (e.g., prescription quantities do not last as long as expected)
- Patient presents multiple prescriptions for the same drug written for different people
- A number of people appear within a short time period for the same controlled drug from the same physician, or a large number of previously unknown patrons show up with prescriptions from the same physician
- The patron presents a prescription that shows evidence of possible forgery (e.g., unusual directions or quantities, no abbreviations, apparent erasures, unusual legibility, evidence of photocopying)

*DEA: Drug Enforcement Agency. Source: Reference 22.*

**Behavioral Traits That Might Trigger Suspicion of Drug Abuse**

- Depression
- Loss of interest in personal appearance or activities that used to bring enjoyment
- Low self-esteem
- Feelings that the individual does not fit in or is not popular
- Feeling sluggish or exhibiting sleep disturbances
- An aggressive or rebellious attitude toward authority figures
- Difficulty paying attention
- A shift in pattern of attending social functions
- Vague physical complaints that the subject indicates need to be treated by drugs or exaggeration of medical problems
- A family history of substance or alcohol abuse
- Seeing multiple physicians for prescriptions (“doctor shopping”)
- Frequently borrowing money or having unexpected extra cash

Source: References 6, 14, 20, 29.

**Deceptive Practices Used to Procure Prescriptions**

- The patient must be seen right away
- The patient is visiting friends or relatives or is passing through town and cannot see his or her regular physician
- The individual claims to be a patient of a practitioner who is unavailable, or will not name the practitioner
- The individual requests only specific drug brand names and is reluctant to try an alternative or claims to be “allergic” or nonresponsive to non-opiate alternatives
- The patient shows unusual knowledge of controlled substances
- The patient claims that his or her prescription has been lost or stolen
- The patient pressures the practitioner by eliciting sympathy or guilt or uses direct threats
- The patient uses a surrogate, such as a child, when seeking methylphenidate, or an elderly person when seeking opiates

Source: Reference 20.

**APPENDIX F: Urine Drug Testing & Red Flags**

Recommended Frequency of UDT	
Risk Category	Recommended UDT Frequency
Low Risk by ORT (Opioid Risk Tool)	Periodic (e.g. up to 1/year)
Moderate Risk by ORT	Regular (e.g. up to 2/year)
High Risk by ORT or opioid doses >120 mg	Frequent (e.g. up to 3–4/year)

