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- Palliative Medicine
- Prevention Screening
- Signs of Addiction-Responses to Abuse and Addiction
- End of Life Care

Note: The applicable statute, PHL §3309-a, does not specify the amount of time necessary for each of the required individual eight topics; meaning there is no minimum amount of time required in each topic.

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For more information on the mandatory prescriber education requirement of PHL § 3309-a(3), the attestation form, and Frequently Asked Questions, please visit the Department’s Bureau of Narcotic Enforcement website at: http://www.health.ny.gov/professionals/narcotic/, or call 1-866-811-7957.

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1. Describe how to assess patients for treatment with ER/LA opioid analgesics.

2. Recognize how to initiate therapy, modify dose, and discontinue use of ER/LA opioid analgesics.

3. Explain how to manage ongoing therapy with ER/LA opioid analgesics.

4. Discuss how to counsel patients and caregivers about the safe use of ER/LA opioid analgesics, including proper storage and disposal.

5. Identify general and product-specific drug information concerning ER/LA opioid analgesics.

6. Describe the two major competing responsibilities of clinicians related to the prescription of opioid pain medications.

7. List 3 advantages of creating written patient/provider opioid agreements.

8. Explain the value of function-based treatment goals as opposed to pain-relief goals.

9. List 2 ways to potentially address unpleasant or intolerable opioid side effects.

For New York Prescribers:

10. Discuss New York State Laws and Requirements for Prescribing Controlled substances

11. Discuss the process for formulating patient-centered goals for end-of-life care, including culturally sensitive communication skills.

12. Describe the differences between acute and chronic pain and the relative utility of opioids for each

13. Detail NYS requirements and policies for Palliative care and End-Of-Life Care patients, including advance directive planning.

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Per the criteria established by the NYS Department of Health and outlined in the Mandatory Prescriber Education Guidance, this course is valid for ALL New York prescribers required to complete the mandatory education.

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INTRODUCTION

Opioid analgesic medications are important tools for relieving moderate to severe pain arising from a wide range of conditions, disease states, or medical procedures. These drugs, however, may also be misused and abused, and overprescribing these agents can result in opioid use disorder or death from fatal overdose.1 The recognition of these problems has led in recent years to a re-thinking about the proper role of opioids, particularly for treating chronic non-cancer pain, and, specifically, about ER/LA opioid analgesics.

In February, 2016, for example, Dr. Robert Califf, Deputy FDA Commissioner for Medical Products and Tobacco, along with other FDA leaders, announced a “far-reaching action plan” to reassess the agency’s approach to opioid medications with the aim of reversing the epidemic of abuse and overdose while still providing patients in pain with access to effective relief.2,3 The new initiative will:

• Re-examine the risk-benefit paradigm for opioids.
• Develop changes to immediate-release opioid labeling similar to the ER/LA opioid labeling that is currently required.
• Update REMS requirements after hearing recommendations from a new advisory committee that will review current requirements.
• Improve access to naloxone and medication-assisted treatments such as methadone and buprenorphine for patients with opioid use disorders.
• Support non-opioid, alternative pain management strategies.

Also in 2016, the Centers for Disease Control and Prevention released its Guideline for Prescribing Opioids for Chronic Pain, which was developed using up-to-date data about the risks of opioids and an unusually comprehensive scientific review process.1 While acknowledging the continuing need for providing patients with adequate pain relief, the CDC guidelines go further than previous documents in recommending a very cautious approach to using opioids for chronic pain.

AN EPIDEMIC OF OPIOID ABUSE

The newly-announced steps by the FDA, as well as the new CDC guidelines, have come in response to the dramatic rise in the prescription and use of opioid analgesics in the past 20 years in the United States. Between 1999 and 2010, the use of opioids quadrupled.4 Much of this increase has been for the treatment of pain other than moderate-to-severe acute pain or intractable end-of-life pain, which have traditionally been seen as appropriate targets for opioids. In the past two decades, opioids have become widely-prescribed for chronic non-cancer conditions, such as back pain, osteoarthritis, fibromyalgia, and headache,5 despite an evidence base that is much weaker than has been generally appreciated by many physicians until recently.5

As opioid prescriptions rose, so, too, did rates of opioid abuse, addiction, and diversion for non-medical use. This is why the current level of prescription opioid abuse has been described as an “epidemic” by the Centers for Disease Control and Prevention.4 Some data now suggest that prescriptions of opioids may have peaked in 2012. The data research firm IMS Health reported in May of 2016 that opioid prescriptions fell about 12% nationally between 2013 and 2015.7 Thus far, however, the reduced numbers of prescriptions has not resulted in fewer opioid-related overdose deaths—approximately 28,000 people died from such overdoses in 2014 (this figure includes deaths from both prescription opioids and heroin).7

Significantly, despite the pronounced increase in opioid analgesic prescriptions in the U.S. over the past two decades, no overall national improvements in disability rates or health status measures among patients prescribed opioids has been demonstrated.3

BALANCING RISKS AND BENEFITS

The rising tide of problems associated with opioid analgesics has created tension for some prescribers, who must balance an awareness of the ongoing problems of opioid over-prescription and abuse with the equally compelling need to relieve their patients’ pain. Pain remains the most common reason people seek health care.9 In fact, the incidence of chronic pain in the U.S. is estimated to be greater than that of diabetes, heart disease, and cancer combined.10,11 Inadequately treating pain can lead to a wide range of adverse consequences (in addition to causing needless suffering) including diminished quality of life, and a higher risk for anxiety or depression.12 Pain is also a major cause of work absenteeism, underemployment, and unemployment.9

FIGURE 1. RATES* OF OPIOID PAIN RELIEVER (OPR) OVERDOSE DEATH, TREATMENT ADMISSIONS, AND KILOGRAMS SOLD IN THE UNITED STATES, 1999-2014

*Age-adjusted rates per 100,000 population for OPR deaths, crude rates per 10,000 population for OPR abuse treatment admissions, and crude rates per 10,000 population for kilograms of OPR sold.
Nonetheless, ER/LA opioid analgesics pose many risks, including:13

- Overdose (since most ER/LA formulations contain more opioid than immediate-release formulations)
- Life-threatening respiratory depression
- Abuse by patient or household contacts
- Misuse and addiction
- Physical dependence and tolerance
- Interactions with other medications and substances
- Risk of neonatal opioid withdrawal syndrome
- Inadvertent exposure/ingestion by household contacts, especially children
- Hypogonadism (decreased levels of FSH, LH, estrogen, testosterone)

Balancing the potential risks and benefits of a treatment is common in medicine. In the case of opioids, however, decisions are complicated by the fact that the drugs are potentially addictive and avidly sought by recreational users. But many guidelines exist that map out reasonable and practical ways to consider opioid analgesics for patients in pain. The 2016 CDC Guidelines, for example, make the following recommendations to clinicians about responsible opioid prescribing:1

- Do not prescribe ER/LA opioids for acute pain.
- Use opioid medications for acute or chronic pain only after determining that alternative therapies do not deliver adequate pain relief.
- The lowest effective dose of opioids should be used, and, for acute pain, the amount of opioids prescribed should be strictly limited to cover only the expected duration of severe pain (3 days or less will often be sufficient; more than 7 days will rarely be needed).
- In addition to behavioral screening and the use of patient-provider opioid agreements, consider random, periodic, urine testing for opioids and other drugs for patients with non-cancer pain being treated with opioids for more than six weeks.
- If your state has a prescription drug monitoring program (PDMP), periodically request, or check, a report on the history of opioid prescriptions to your patients by other providers.
- Use caution when prescribing opioids at any dosage, and carefully reassess evidence of benefits and risks when increasing dosage to $\geq 50$ morphine milligram equivalents (MME)/day, and avoid increasing the dose to $\geq 90$ MME/day.
- Consider offering naloxone when factors that increase risk of opioid overdose are present.

This CME program summarizes these and other evidence-based recommendations for prescribing opioid analgesics, with a focus on ER/LA opioid formulations, which have been associated with higher levels of abuse and/or overdose.

**FUNDAMENTAL CONCEPTS**

Traditionally, pain has been classified by its duration. Acute pain lasts for only a matter of days or, at most, a few weeks, arises from obvious tissue injury, and usually fades with healing.5 Chronic pain, in contrast, lasts longer than would be anticipated for the usual course of a given condition. The International Association for the Study of Pain defines this as pain lasting 3 months or longer.14 The labels “acute,” and “chronic,” however, do not provide any information about the etiology or biological of the pain being experienced.

Pain, therefore, is also classified on the basis of its pathophysiology. Nociceptive pain is caused by the activation of nociceptors (pain receptors), and is generally, though not always, short-lived, and associated with the presence of an underlying medical condition in response to injury.

Neuropathic pain, on the other hand, results either from an injury or disease affecting the somatosensory system or from inadequately-treated nociceptive pain. It is an abnormal response to a stimulus caused by aberrant neuronal firing in the absence of active tissue damage. It may be continuous or episodic and varies widely in how it is perceived. Neuropathic pain is complex and can be difficult to diagnose and to manage because available treatment options are limited.

Both nociceptive and neuropathic pain can arise from, or be exacerbated by, sensitization, which is a state of hyperexcitability in either peripheral nociceptors or neurons in the central nervous system. Sensitization may lead to either hyperalgesia (heightened pain from a stimulus that normally provokes pain) or allodynia (pain from a stimulus that is not normally painful).15 Sensitization may arise from intense, repeated, or prolonged stimulation of nociceptors, or from the influence of compounds released by the body in response to tissue damage or inflammation.16 Many patients—particularly those with chronic pain—experience pain that has both nociceptive and neuropathic components, which complicates assessment and treatment.

It’s important for clinicians to distinguish between nociceptive and neuropathic pain because the two types respond differently to pain treatments. Neuropathic pain, for example, typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory (NSAID) agents.17 Other classes of medications, such as anti-epileptics, antidepressants, or local anesthetics, may provide more effective relief for neuropathic pain.18

Pain associated with cancer is sometimes given a separate classification, even though the pain itself is either nociceptive or neuropathic (or both). Cancer-related pain includes pain caused by the disease itself, painful diagnostic or therapeutic procedures, or side effects from cancer therapies such as chemotherapy or radiation. ER/LA opioids often play a role in treating cancer-related pain because such pain may be of exceptional severity and duration.

Chronic non-cancer pain may be caused by many kinds of conditions or disease states such as musculoskeletal injury, lower back trauma, dysfunctional healing from a wound or surgery, or from autoimmune system disorders. With chronic non-cancer pain, the severity of pain experienced by a patient may not correspond well—or at all—to identifiable levels of tissue damage.

Related to the nomenclature of pain itself are terms used in the context of opioid analgesic medications. The American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM), and the American Pain Society (APS) have recommended the following definitions:19

**Tolerance.** A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.

**Physical Dependence.** A state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, and/or administration of an antagonist.

**Addiction** (also known as substance use disorder). A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
EXERCISE 1

Instructions: Read the case below and complete both learning activities that follow.

Ralph is an 83-year-old who lives at home with his wife. He has a history of cardiovascular disease and, 10 years earlier, had successful quadruple bypass surgery. He takes the following medications: fish oil, a statin, a thiazide diuretic, low-dose aspirin, and a non-benzodiazepine sedative to help him sleep. Lately he has been complaining of increasing pain and stiffness in his right knee and hip. He is physically deconditioned due to a lack of exercise, in part because walking is painful. He asks if you can prescribe something to ease his pain.

Part 1 - Application: Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.
II. Consider the expected outcome(s) of those applications.

Part 2 - Questions and Considerations: Spend 5 minutes considering the following questions as they relate to the case presented.

1. Is Ralph a good candidate for an ER/LA opioid? Why, or why not?

2. Would Ralph’s current medication need to be adjusted if he were to be prescribed an ER/LA opioid?

3. What kinds of non-opioid treatments might be tried to help Ralph with his pain?

OVERVIEW OF PAIN MANAGEMENT STRATEGIES

Although this monograph focuses on ER/LA opioid analgesics, a review of the many pharmacologic and non-pharmacologic approaches to treating painful conditions is appropriate because such options should usually be tried, or at least considered, before an opioid is considered. Pain treatment options should be employed using the following general principles:

- Identify and treat the source of the pain, if possible, although treatment can begin before the source of the pain is determined. In some cases of chronic pain, an identifiable source of pain may not be found.
- Initiate non-pharmacologic approaches first, such as physical therapy. If medications are offered, try medications with the least severe potential side effects first (i.e., non-opioid).
- Establish a function-based management plan if treatment is expected to be long-term.

Five basic pain-management approaches exist, each of which will be more fully described below:

- Cognitive-behavioral approaches (may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain).
- Rehabilitative approaches (may improve physical function, alter physiological responses to pain, help prevent recurrence of injury, and help reduce fear and anxiety).
- Complementary and alternative therapies (can reduce pain, induce relaxation, and enhance a sense of control over the pain or the underlying disease).
- Intervventional approaches (wide range of surgical and other interventional approaches to pain management including: trigger point injections; epidural injections; facet blocks; joint injections, sympathetic nerve blocks, targeted nerve blocks, radiofrequency denervation, pulsed radio frequency therapy, spinal cord stimulators; pain pumps, peripheral nerve stimulators, laminectomy; spinal fusion; and deep brain implants).
- Pharmacotherapy (NSAIDs, acetaminophen, topical agents, cannabis, antidepressants, anticonvulsants, opioids).

These modalities can be used alone or in combination to maximize pain control and functional gains. Which options are used in a given patient depends on the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses, patient life expectancy, cost, and the local availability of the treatment option.

COGNITIVE-BEHAVIORAL APPROACHES

Psychological therapies of all kinds can be critical for managing chronic non-cancer and cancer pain. Cognitive therapy techniques may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain. For example, some patients engage in an exaggeration of their condition called “catastrophizing” or they may have an overly passive attitude toward their recovery which leads them to inappropriately expect a physician to “fix” their pain without active self-management on their part. Individual, group, or family psychotherapy may be extremely helpful for addressing this and other psychological issues, depending on the specific needs of a patient. In general, psychological interventions may be best-suited for patients who express interest in such approaches, who feel anxious or fearful about their condition, have a history of trauma, or whose personal relationships are suffering as a result of chronic or recurrent pain.
Unfortunately, the use of psychological approaches to pain management can be hampered by such barriers as provider time constraints, unsupportive reimbursement policies, lack of access to skilled and trained providers, or a lack of awareness on the part of patients and/or physicians about the utility of such approaches for improving pain relief and overall functioning. Ideally this treatment modality should be provided by a trained pain psychologist who can help the patient set pain-specific self-management goals as part of his or her treatment plan.

**REHABILITATIVE APPROACHES**

In addition to relieving pain, a range of active rehabilitative therapies can improve physical function, alter physiological responses to pain, and help reduce fear and anxiety. Treatments used in physical rehabilitation include exercises to improve strength, endurance, and flexibility, gait and posture training, stretching, and education about ergonomics and body mechanics. Exercise programs that incorporate Tai Chi, swimming, yoga, or core-training work may also be useful. Other noninvasive, more passive, physical treatments for pain include thermotherapy (application of heat), cryotherapy (application of cold), counter-irritation, and electroanalgesia (e.g., transcutaneous electrical stimulation). Other types of rehabilitative therapies, such as occupational and social therapies, may be valuable for selected patients.

**INTERVENTIONAL APPROACHES**

Although beyond the scope of this CME program, many surgical and other interventional approaches to pain management exist, including: trigger point injections; epidural injections; facet blocks; joint injections; sympathetic nerve blocks; targeted nerve blocks; radiofrequency denervation; pulsed radio frequency therapy; spinal cord stimulators; pain pumps; peripheral nerve stimulators; laminctomy; spinal fusion; deep brain implants, and regenerative therapies such as platelet rich plasma and stem cell therapies. Many of these novel strategies may offer very effective options for pain relief in selected patients.

**NON-OPIOID PHARMACOTHERAPY**

Many options exist to treat both acute and chronic pain that do not involve opioids. These options should be thoroughly explored before an opioid is considered.

**ACETAMINOPHEN**

Acetaminophen, first introduced in the US market in 1953, provides predictable, if modest, pain relief, and is often recommended as a first-step treatment. It is used as an analgesic and antipyretic (fever reducer), but has poor anti-inflammatory properties. A Cochrane review found acetaminophen superior to placebo in pain reduction in patients with hip/knee osteoarthritis (OA).

Although “extra strength” doses are widely promoted, evidence suggests that doses of 1000 mg are no better than 650 mg in relieving mild to moderate pain, which is significant because higher doses increase the potential for adverse events, especially in combination with other acetaminophen-containing products.

Although acetaminophen’s overall side effect profile is benign,21 this analgesic can pose risks for hepatotoxicity. Acetaminophen liver damage is the leading cause of drug-induced acute liver failure in the U.S.22 More than 35,000 acetaminophen-related overdose hospitalizations occur in the US every year, and acetaminophen accounts for 5% of all calls to US poison control centers. The most commonly implicated products in overdoses are acetaminophen/opiate combinations.

The threshold dose for acetaminophen liver toxicity has not been established, although the FDA recommends that the total adult daily dose should not exceed 4 g/day in patients without liver disease (although a ceiling of 3 g/day is suggested for older adults).23

**NSAIDs**

Non-steroidal anti-inflammatory drugs (NSAIDs) have analgesic, anti-pyretic, and anti-inflammatory properties. They are some of the most commonly-prescribed medications in the U.S., with over 111 million prescriptions written annually, in addition to widespread use of the over-the-counter (OTC) NSAIDs.24,25

NSAIDs are moderately effective in reducing pain from a variety of conditions. While most studies compare an NSAID with a placebo, no consistent evidence shows that any NSAID confers greater analgesic efficacy than any other, at equipotent doses. A Cochrane review found celecoxib to be significantly better than placebo in reducing pain in rheumatoid arthritis and osteoarthritis.26 In the treatment of chronic low back pain, NSAIDs are also significantly better than placebo, with a mean difference (between groups) in pain scale scores of 12 (on a 100 point scale).27

The most serious NSAID side effects involve the GI tract, heart, and kidneys. The risk of GI bleeding may be mitigated by adding a proton-pump inhibitor (PPI).28,29 In 2015, the FDA strengthened existing “black box” warning for all NSAIIds that these agents can increase the chance of a heart attack or stroke.

**TOPICAL AGENTS**

Topical capsaicin and topical salicylates can both be effective for short term pain relief and generally have fewer side effects than oral analgesics, but their long term efficacy is not well studied.30,31 Topical NSAIDs and lidocaine have been reported to be effective for short term relief of superficial pain with minimal side effects, although both are more expensive than topical capsaicin and salicylates. None of the topical agents are useful for non-superficial pain. Topical lidocaine and topical high dose capsaicin are FDA approved for postherpetic neuralgia, and topical diclofenac is FDA approved for osteoarthritis.

**ANTIDEPRESSANTS**

Some antidepressants exhibit analgesic properties that do not depend on antidepressant activity, and antidepressants are equally effective in patients with and without depression.32 While analgesia may occur at lower doses and sooner than antidepressant activity, maximum efficacy may require high antidepressant doses and treatment of potentially lengthy duration.

Tricyclic antidepressants (TCAs) such as amitriptyline, nortriptyline, and imipramine, are used to treat a variety of types of chronic and neuropathic pain.33 Although often considered most effective for continuous burning pain or hypersensitivity conditions, TCAs also may relieve lancinating neuropathic pain.34

All TCAs are limited by anti-cholinergic side effects (dry mouth, urinary retention) and somnolence, which are dose-dependent. These side effects are less common with nortriptyline and desipramine than with amitriptyline. Side effects occur more commonly in elderly, so doses should be titrated cautiously. TCAs can also cause cardiac conduction abnormalities and should be avoided in patients with existing cardiac disease.

Selective norepinephrine reuptake inhibitors (SNRIs) are effective for a variety of neuropathic pain syndromes and myofascial pain conditions, with duloxetine having the most efficacy data for a variety of pain syndromes including diabet-
ic peripheral neuropathy, fibromyalgia, and the non-neuropathic condition of musculoskeletal pain. The benefits of SNRIs appear to arise because of norepinephrine uptake effects in the spinal cord. The data for venlafaxine primarily support their use in diabetic neuropathy, and for milnacipran primarily for fibromyalgia. All SNRIs are limited by GI and CNS side effects, and should be taken on a full stomach.

The selective serotonin reuptake inhibitors (SSRIs) paroxetine and citalopram appear to be superior to placebo in relieving neuropathic pain, based on 2 small randomized trials (<50 patients each), but fluoxetine is not better than placebo in diabetic neuropathy. The SSRIs are associated with weight gain, sexual dysfunction, and a minor increase in the risk of bleeding due to platelet dysfunction. In general, the SSRI’s are not particularly effective for pain, although they may be appropriate for patients with both chronic pain and a depressive disorder.

ANTICONVULSANTS

The increasing use of antiepileptic drugs (AEDs) for neuropathic pain is based on their ability to reduce membrane excitability and suppress abnormal discharges in pathologically altered neurons. The exact mechanism of action for their analgesic effects, however, is unclear. It does not appear to be specifically related to their antiepileptic activity. Other drugs that suppress seizures (e.g., barbiturates) do not relieve pain, and some AEDs with effective antiepileptic activity do not necessarily have good analgesic activity.

AEDs are used to treat neuropathic pain, especially lancinating (i.e., episodic shooting, stabbing, or knife-like) pain from peripheral nerve syndromes (e.g., diabetic neuropathy or fibromyalgia) and neuropathic pain arising from spinal cord injury. A Cochrane review of pregabalin for analgesia found a daily dose of 150 mg to be no more effective than placebo, but daily doses of 300-600 mg were significantly better than placebo. The most common side effects include peripheral edema, weight gain, and CNS side effects (including dizziness, somnolence, ataxia, and headache).

Gabapentin also effectively reduces diabetic neuropathic pain and other forms of neuropathic pain. In a trial comparing gabapentin to placebo, pain on 10-point scale decreased from 6.4 to 3.9 in the treatment group as compared to 6.5 to 5.1 in the placebo group after 8 weeks of treatment. Side effects are similar to pregabalin. The optimal dose of gabapentin is 600 – 1200 mg three times daily. The dose should be reduced in patients with severe kidney insufficiency. A Cochrane review assessed 14 studies evaluating the efficacy of carbamazepine in the treatment of neuropathic pain (e.g., diabetic neuropathy and postherpetic neuropathy) and found that 70% of carbamazepine patients had some improvement in pain (versus 12% of placebo). Carbamazepine is the standard of care for the treatment of trigeminal neuralgia pain.

CANNABIS

Cannabis sativa has been used for centuries to treat ailments ranging from nausea to glaucoma. Cannabinoids act, at least in part, through the cannabinoid receptors CB-1 and CB-2, and an opioid receptor mechanism that increases dopamine concentrations in the nucleus accumbens. The primary pain-relieving cannabinoid is cannabidiol, which is not psychoactive. A meta-analysis of 18 randomized trials of cannabis use in various chronic pain syndromes (1/3 of which were cancer) found a standardized mean difference in pain improvement of -0.61 (-0.84 to -0.37) indicating a moderate treatment effect. However, the individual studies were small (sample size ranging from 10-177), short-term (mean duration 25 days) and of overall poor methodological quality. Many of the studies had an “open phase” in which patients took the drug before randomization, to screen out those with low tolerance for side effects. No significant differences for dysphoria were observed between cannabis and placebo. Side effects of cannabis included euphoria, alterations in perception, events relating to cognitive function, and events concerning motor function.

Lynch et al., in a 2011 systematic review of RCTs of cannabinoids for CNCP (e.g., neuropathic pain, fibromyalgia, and rheumatoid arthritis), found that 15 of 18 trials demonstrated “significant analgesic effects compared to placebo.” Adverse effects in this review were generally well-tolerated, and cannabinoids were found to be “moderately effective” in neuropathic pain. Cannabis has been used to help stabilize patients on methadone maintenance treatment and cannabis use has been associated with modest reductions in opioid withdrawal symptoms for such patients. Cannabis use has also been associated, on a state-wide level, with reduced rates of opioid overdose. Buchhuber et al., in a time-series analysis, found that between 1999 and 2010 states with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95% CI: -37.5% to -9.5%; p=0.003) compared with states without medical cannabis laws.

Smoking cannabis has been associated with twice the odds of pulmonary symptoms (cough, sputum, wheezing) but not associated with changes in lung function. Acutely, marijuana can impair short term memory, motor coordination, and judgement. Psychosis and paranoid ideation can also occur. Retrospective cohorts have found cannabis use may be associated with an “amotivational syndrome” and reproductive system changes (including reduced testosterone and libido in men, and increased prolactin in women). Amotivation can be particularly problematic for patients who have chronic pain because it can impair their ability to perform self-care. The use of cannabis can also lead to the development of marijuana use disorder, which in severe cases can take the form of addiction.

OPIOIDS

OPIOID MECHANISMS OF ACTION

Opioid analgesics work by binding to one or more of the three major types of opioid receptors in the brain and body: mu, kappa, and delta receptors. Opioids inhibit both ascending transmission of nociceptive information as well as descending pain control circuits. The most common opioid pain medications are “mu agonists” because they bind to and activate mu opioid receptors. Mu agonists include morphine, codeine, hydromorphone, oxycodone, and hydrocodone. The antagonists naloxone and nalbuphine competitively bind to opioid receptors, blocking or disrupting agonists without causing the receptor to respond.

The binding of mu agonist opioids to receptors in various body regions results in both therapeutic effects (such as pain relief) and side effects (such as constipation). Tolerance develops for some effects of opioids, but not others. For example, some tolerance develops to respiratory suppressant effects within 5-7 days of continuous use, whereas tolerance to constipating effects never occurs. Tolerance to analgesia may develop early, requiring an escalation of dose, but tolerance may lessen once an effective dose is identified and administered regularly, as long as the associated pathology or condition is stable. Prescribers should understand the specific opioid tolerance criteria defined in product labeling, and summarized in Table 1 of this document.
Table 1. Long-Acting vs. Immediate-Release Opioids

<table>
<thead>
<tr>
<th>Long Acting Opioids</th>
<th>Immediate Release Opioids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine patch (Butrans)</td>
<td>Codeine (generics)</td>
</tr>
<tr>
<td>Fentanyl patch (Duragesic)</td>
<td>Fentanyl – transmucosal (Abstral, Actiq, Fentora, Lazanda, Onsolis, Subsys)</td>
</tr>
<tr>
<td>Hydrocodone (Zohydro ER, Hysingla ER)</td>
<td>Hydrocodone + acetaminophen (generics, Norco, Vicodin, Xodol)</td>
</tr>
<tr>
<td>Hydromorphone ER (generics, Exalgo)</td>
<td>Hydromorphone (generics, Dilaudid)</td>
</tr>
<tr>
<td>Methadone (generics, Dolophine, Methadose)</td>
<td>Levorphanol (generics)</td>
</tr>
<tr>
<td>Morphine ER (generics, Avinza, Kadian, MS Contin, Embeda)</td>
<td>Meperidine (generics, Demerol, Meperitab)</td>
</tr>
<tr>
<td>Oxycodone (Oxycontin, Targiniq ER, Xtampza ER)</td>
<td>Morphine (generics)</td>
</tr>
<tr>
<td>Oxymorphone ER (generics, Opana ER)</td>
<td>Oxycodone (generics, Roxicodone)</td>
</tr>
<tr>
<td>Tapentadol (Nucynta ER)</td>
<td>Oxymorphone (generics, Opana)</td>
</tr>
<tr>
<td>Tramadol ER (generics, ConZip, Ultram ER)</td>
<td>Tramadol (generics, Ultram)</td>
</tr>
</tbody>
</table>

General Considerations in Opioid Selection

Opioids as a class include many specific agents available in a wide range of formulations and routes of administration, (all of them scheduled under the Controlled Substances Act) including:

- Oral (e.g., tablets, capsules, solutions, lozenges)
- Transdermal
- Transmucosal
- Rectal
- Intranasal
- Intravenous
- Epidural

Little evidence exists that specific analgesic formulations or dosing schedules affect efficacy or addiction risk, so selection of agent should be based on the patient’s pain complaint, lifestyle, and preferences. Generally, if opioids are used at all, it is better to offer short-acting opioids PRN as these are believed to present a lower risk of abuse or addiction. Long-acting (LA) or extended-release (ER) opioids may be helpful for patients who have difficulty managing an “as needed” regimen, or who are physically dependent on opioid analgesics and require continued use to maintain their functioning. (Prescribers, of course, should be aware of all relevant federal and state regulations pertaining to opioids prior to prescribing.)

See Appendix 2-4 for additional NYS Prescribing Laws (I-STOP/PNP, NYS PMP Registry; NYS Mandatory Electronic Prescribing; NYS Acute Pain 7 day limit for initial opioid prescription).

Scheduled long-acting opioids have the advantage of producing a steady state, without the cycling effect of pain relief and withdrawal associated with short-acting opioids, which could, theoretically, lead to problematic behavior patterns.

With ER/LA agents, however, patients may end up using more drug than is actually needed, and adaptations to the steady state may ultimately decrease efficacy. Clinicians should warn patients that oral ER/LA opioids should not be broken, chewed, or crushed, and patches should not be cut or torn prior to use, since this may lead to rapid release of the opioid and could cause overdose or death.

Avoid ER/LA Opioids for Acute Pain

As mentioned earlier, ER/LA opioids should NOT be used to treat acute pain. However, cautious use of short-acting opioids for moderate or severe acute pain may be considered for carefully-selected patients whose pain is not controlled with acetaminophen or NSAIDs, or for whom such medications are contraindicated. The opioid should be used at a minimum effective dose, and for a limited period of time, usually less than 2-3 days. Opioids should be used only as one part of a comprehensive pain care plan, and extended release opioids should be avoided in acute pain patients.

Studies show that physicians routinely over-prescribe opioids for acute pain. For example, Rodgers et al., found that after outpatient orthopedic surgery, most patients were prescribed 30 pills of an opioid analgesic, although the mean patient consumption of those analgesics was only 10 pills. Another study found that 72% of people who had been prescribed an opioid had leftover medication. This guideline recommends that no more than a one-week supply be prescribed following surgery.

By definition, treatment of acute pain should not last longer than the time required for the healing or resolution of the trauma or condition. Hence, it is unlikely that opioids, or any other analgesic, will be needed beyond 90 days from initiation of treatment. Research shows that after 90 days of continuous opioid use, treatment is more likely to become life-long. The 90-day mark, therefore, should be considered a “red flag” point at which use should be re-evaluated and patients should be offered opioid taper.

See Appendix 1 (CDC GUIDELINES: Recommendations-Opioids and Acute Pain)

Cautions About Opioids for Chronic Non-Cancer Pain

A broad consensus is developing that opioid analgesics are not, in fact, suited for many patients with chronic non-cancer pain. Clinical guidelines for the use of opioids in chronic non-cancer pain have shifted to stress the risks of opioids and strengthen procedures that prescribers should use to reduce the risk of addiction and misuse.

Little evidence supports the assertion that long-term use of opioids provides clinically significant pain relief or improves quality of life or functioning. The Agency for Healthcare Research and Quality (AHRQ), for example, recently found no studies that compare opioid therapy with either a placebo or a non-opioid treatment for long-term (>1 year) pain management. A Cochrane review of opioids for long-term...
treatment of non-cancer pain found that many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events or insufficient pain relief.53

Much evidence, on the other hand, shows that opioids pose many significant risks for adverse effects, abuse, addiction, and accidental overdose leading to death from respiratory depression. Estimating the magnitude of such risks is difficult because rigorous, long-term studies in patients without co-existing substance-use disorders have not been conducted.57 A few surveys conducted in community practice settings, however, estimate rates of prescription opioid abuse of between 4% to 26%,65,66,67,68 Risk rises with higher doses and longer durations.71 A 2011 study of a random sample of 705 patients undergoing long-term opioid therapy for non-cancer pain found a lifetime prevalence rate of DSM-5-defined opioid-use disorder of 35%.72 The variability in such results probably reflects differences in opioid treatment duration, the short-term nature of most studies, disparate study populations, and different measures used to assess abuse or addiction. Nonetheless, the levels of risk suggested by these studies are significant enough to warrant extreme caution in the prescription of any opioid for a chronic pain condition.

Caution is also required because many patients do not use opioids as prescribed by their physicians. Fleming et al., conducted in-depth interviews with 801 patients receiving long-term opioid therapy and found the following:68

- 39% of patients increased their dose without direction from a health care provider.
- 26% engaged in purposeful over-sedation.
- 20% drank alcohol concurrent with opioid use.
- 18% used opioids for purposes other than pain relief.
- 12% hoarded their pain medications.
- 8% obtained extra opioids from other doctors.

As already mentioned, the risk of overdose with opioid analgesics is significant and, as with risk of opioid use disorder, rises with both dose and duration.73 (FIGURE 2)

In addition to the risks already mentioned, opioids can exert a wide range of uncomfortable or harmful adverse effects, the most common of which are neurologic (somnolence, dizziness), endocrine (hypogonadism), gastrointestinal (nausea, vomiting, and constipation), sexual (erectile dysfunction), and cutaneous (pruritus). In randomized trials of opioids, 50%-80% of patients report a side effect, and about 25% withdraw due to an adverse event.65,74,75

Although less common, there is also a dose-dependent increase in risk of fractures among patients prescribed opioids compared to patients not prescribed opioids, with risk highest just after an opioid was started.76,77 Another concern is the possibility that chronic opioid use may be immunosuppressive.78 Dublin et al., in a population-based case-control study, found a significantly higher risk of pneumonia in immunocompetent older adults who were prescribed opioids.79 The risk was particularly high for adults taking ER/LA opioids.79 Finally, prescription opioid use in pregnant women has been associated with a range of adverse newborn outcomes, including low birth weight, premature birth, and hypoxic-ischemic brain injury, although it is difficult to separate the effects of opioid use from other maternal factors that may contribute to these adverse outcomes.

There are two specific situations in which opioids are contraindicated in current guidelines: clinicians should avoid using intravenous or intramuscular opioid injections for patients with exacerbations of chronic non-cancer pain, and opioids should also be avoided pre-surgically in instances of acute trauma or chronic degenerative diseases.

WHEN, AND HOW, TO PRESCRIBE OPIOIDS FOR CHRONIC NON-CANCER PAIN

The risks reviewed above suggest that only a minority of patients with chronic non-cancer pain

![FIGURE 2. PERCENT OF ANNUAL OVERDOSE RATES RISES WITH DAILY OPIOID DOSE]
it adversely impacts function or quality of life; when other pharmacologic agents are contra-indicated, and when the potential therapeutic benefits outweigh, or are likely to outweigh, potential harms. In these cases, clinicians should follow published guidelines to maximize the effectiveness of an opioid and minimize its risk to the patient and to society at large. This section reviews these steps in detail.

**PATIENT SELECTION AND RISK STRATIFICATION**

Pain assessment includes recording of: chief complaint; nature and intensity of pain; history of present illness; past medical, surgical, and psychosocial history; past treatments; co-morbid conditions; family history; physical examination; and examination of imaging and other diagnostic studies or tests (Table 2). As with every patient, clinicians should take the time to look beyond the specific complaint or body part/system and evaluate holistically the broader mental, cultural, and socioeconomic contexts within which the chief complaint may be embedded.

**PAIN ASSESSMENT TOOLS**

Unidimensional pain scales (e.g., numeric or “faces”) are seldom useful for guiding a decision to treat chronic pain because such pain is variable and scores from pain assessment tools are highly subjective. Multidimensional tools provide more information, such as the effects of pain on daily life. These tools can typically be administered in an office, examination room, or other clinical setting by either a physician or another health care professional, or they could be filled out by the patient, if appropriate. Examples of some multidimensional tools include:

- Initial Pain Assessment Tool
- Brief Pain Inventory
- McGill Pain Questionnaire (short-form available)
- Pain, Enjoyment, and General Activity Scale

**ASSESSING ABUSE RISK**

Another key component of assessment is ascertaining the patient’s risk of substance abuse, misuse, or opioid use disorder. Although the available evidence base is weak, professional guidelines suggest that the following patients or pain conditions are unlikely to benefit from opioid analgesics:

- Poorly-defined pain conditions
- Daily headache
- Fibromyalgia
- A likely or diagnosed somatoform disorder
- Patients with unresolved workers compensation or legal issues related to pain or injury

<table>
<thead>
<tr>
<th>Region</th>
<th>Rationale, Methods, and Potential findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Observe and/or identify:</td>
</tr>
<tr>
<td></td>
<td>• Patient's general appearance and vital signs</td>
</tr>
<tr>
<td></td>
<td>• Evidence of overt abnormalities (e.g., weight loss, muscle atrophy, deformities, trophic changes)</td>
</tr>
<tr>
<td></td>
<td>• Any subjective manifestations of pain (e.g., grimacing, splinting)</td>
</tr>
<tr>
<td>Site of pain</td>
<td>Inspect the pain site(s) for abnormal appearance or color of overlying skin or visible muscle spasm</td>
</tr>
<tr>
<td></td>
<td>Palpate the site(s) to assess for tenderness and correlate tenderness with any associated subjective or objective findings</td>
</tr>
<tr>
<td></td>
<td>Use percussion (or jarring) to elicit, reproduce, or evaluate the pain and any tenderness on palpation</td>
</tr>
<tr>
<td></td>
<td>Use the brush, pinch, pin prick, and/or scratch tests to assess for allodynia, hyperalgesia, or hyperesthesia</td>
</tr>
<tr>
<td></td>
<td>Determine the effects of physical factors (e.g., motion, applied heat or cold, deep breathing, changes in position) on pain</td>
</tr>
<tr>
<td>Other regions</td>
<td>Examine other regions as directed by the patient history or assessment of pain site</td>
</tr>
<tr>
<td>Neurological system</td>
<td>At minimum, perform a screening neurological examination (i.e., assess cranial nerves, spinal nerves, sympathetic nervous system function, coordination, and mental status) to screen for:</td>
</tr>
<tr>
<td></td>
<td>• Sensory deficits (e.g., impaired vision or hearing) or abnormal sensations (e.g., paresthesia, dysesthesia, allodynia, hyperpathia)</td>
</tr>
<tr>
<td></td>
<td>• Motor abnormalities or deficits (e.g., weakness, exaggerated or diminished reflexes)</td>
</tr>
<tr>
<td></td>
<td>• Lack of coordination</td>
</tr>
<tr>
<td></td>
<td>• Evidence of sympathetic nervous system dysfunction (e.g., skin flushing, unusual sweating)</td>
</tr>
<tr>
<td></td>
<td>• Abnormalities or deficits in orientation, recent or remote memory, parietal sensory function, language function, and mood</td>
</tr>
<tr>
<td>Musculoskeletal system</td>
<td>Observe and/or identify:</td>
</tr>
<tr>
<td></td>
<td>• Body type, posture, and overall symmetry</td>
</tr>
<tr>
<td></td>
<td>• Abnormal spine curvature or limb alignment and other deformities</td>
</tr>
<tr>
<td></td>
<td>• Abnormal movements and/or irregular gait during walking</td>
</tr>
<tr>
<td></td>
<td>• Range of motion (spine, extremities)</td>
</tr>
<tr>
<td></td>
<td>For muscles in neck, upper extremities, trunk, and lower extremities:</td>
</tr>
<tr>
<td></td>
<td>• Assess multiple parameters (e.g., tone, volume, contour, strength and power, range of motion)</td>
</tr>
<tr>
<td></td>
<td>• Observe for any abnormalities (e.g., weakness, atrophy, hypertrophy, irritability, tenderness, trigger points)</td>
</tr>
</tbody>
</table>
Assessing a patient’s risk of opioid use disorder is at least somewhat subjective, and opinions differ about which patients should be more rigorously assessed. Some favor a “universal precautions” approach, in which all pain patients are considered to have some degree of vulnerability to opioid use disorder and, hence, all patients are given the same screenings and diagnostic procedures. Some patient characteristics, however, do appear to be predictive of a potential for drug abuse, misuse, or other aberrant behaviors, particularly a personal or family history of substance use disorder. Some studies also show that younger age and the presence of psychiatric conditions are associated with aberrant drug-related behaviors.

Relatively brief, validated tools can help formalize assessment of a patient’s risk of having a substance use problem (Table 3) and these tools should be considered for routine clinical use.

<table>
<thead>
<tr>
<th>Tool</th>
<th>Who Administers?</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis, Intractability, Risk, Efficacy (DIRE)</td>
<td>Clinician</td>
<td>7 items</td>
</tr>
<tr>
<td>Opioid Risk Tool (ORT)</td>
<td>Clinician or patient self-report</td>
<td>5 yes/no questions</td>
</tr>
<tr>
<td>Screener and Opioid Assessment for Patients with Pain, Version 1 and Revised (SOAPP, and SOAPP-R)</td>
<td>Patient self-report</td>
<td>24 items</td>
</tr>
</tbody>
</table>

**USE A HOLISTIC APPROACH TO PSYCHOSOCIAL EVALUATION**

Pain can perturb all aspects of a patient’s life, hence clinicians need to be alert to the ways pain may be impacting, or may be affected by, psychosocial elements of a patient’s life. For example, clinicians must check for signs of depression or anxiety, which are common in pain patients. Be particularly alert for suicidal behaviors.

### TABLE 3. TOOLS FOR INITIAL PATIENT RISK ASSESSMENT

**EXERCISE 2**

**Instructions:** Read the case below and complete the activities that follow.

Hannah is a 62-year-old woman who has been coping with persistent pain for more than a year since she was involved in a car accident. Her initial severe neck and low back pain was thought to be due to cervical and lumbar sprain/strain. She was prescribed a short-acting opioid, which she said helped with the pain, but led to constipation. After three months of using the opioid, Hannah decided to stop because she did not like the constipation and “brain fog” from the drug. She tried several types of alternative therapies, such as massage and acupuncture, both of which provided short-term relief, although the pain later returned. At 6 months post-accident, X-ray and MRI imaging revealed no obvious spinal pathophysiology, although Hannah reported the pain was spreading to her legs and arms. Hannah has a BMI of 31 and has been diagnosed with metabolic syndrome. She is physically inactive but currently takes no medications.

**Part 1 – Application:** Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.

II. Consider the expected outcome(s) of those applications.

**Part 2 – Questions and Considerations:** Spend 5 minutes considering the following questions as they relate to the case presented.

1. Given the subjective nature of pain, how can a clinician assess the kind of pain reported by patients such as Hannah?

2. Does the lack of obvious pathophysiology on imaging suggest that Hannah is a hypochondriac?

3. Would Hannah be a good candidate for an ER/LA opioid? Why or why not?
thoughts since the risk of suicide is roughly double for patients with chronic pain. Some free instruments for gathering a psychiatric history are the Depression Anxiety & Positive Outlook Scale (www.dapos.org) or the Patient Health Questionnaire (PHQ Screeners (www.phqscreeners.com). Referral to a mental-health professional is warranted if you suspect a patient has active psychological issues beyond your expertise.

Clinicians should also probe for ways in which pain may be affecting the patient’s family system, work, or social activities. Pain can seriously erode these spheres of life and evaluating these challenges and addressing them during treatment (for instance by referring to a vocational counselor or social worker) is just as important as treating the more immediate medical issues that may be contributing to chronic pain.

**PATIENT/PROVIDER AGREEMENTS**

An opioid “medication agreement” or “management plan” can help educate patients, clarify expectations, and establish goals, all of which may help a patient adhere to a pain management regimen. These agreements should be written and signed by the provider and the patient. (Table 4)

Avoid framing patient/provider agreements in terms of punishments for misbehaviors and avoid using language that is stigmatizing, dominating, or pejorative. Since written agreements must be clearly understood by the patient, they should be written at the sixth- to seventh-grade level, and translated into the patient’s language, if possible (in-person translators may also be used). When administering an agreement, allow time for patients to ask questions, and to ensure patients understand what they are being told. Some, or all, of these tasks may be handled by trained personnel (or staff members) rather than physicians.

Be aware that although the terms “agreement” or “plan” are more patient-friendly than the word “contract,” from a legal standpoint, any written or oral agreement between a prescriber and a patient may be considered a binding “contract.”

**TAKE A FUNCTIONAL APPROACH**

Since pain itself cannot be measured objectively, opioid management plans and provider/patient agreements should not be framed solely in terms of pain relief; functional goals are preferable. Chronic pain often impairs functioning in daily life, such as the ability to be physically active, mentally focused, and well-rested. Even relatively modest reductions in pain (e.g., a 20% reduction on a pain score) can allow for significant functional improvements. (Table 5)

By using functional goals a prescriber can make more objective decisions about prescribing, dose adjustments, and/or treatment termination. Objective data can be used such as attendance at physical therapy appointments, number of days sleeping in a bed instead of a chair, or distance walking (a pedometer is a good way to measure this). Taking a functional approach to pain management may also help you spot patients who are addicted to an opioid because addiction typically leads to decreased functioning, while effective pain relief typically improves functioning.

Functional treatment goals should be realistic and tailored to each patient. Because patients with long-standing chronic pain are frequently physically deconditioned, progress in achieving functional goals can be slow or interrupted with “setbacks.” It is better to set goals slightly too low than slightly too high. Raising goals after a patient has “succeeded” is preferable—and more motivational—than lowering goals after a patient has “failed.”

**INFORMED CONSENT**

Informed consent is a fundamental part of ethical treatment, and is particularly important when considering an opioid or other controlled substance, given their potential risks. Well-crafted informed consent documents that are explained clearly and carefully can actually improve the clinician/patient relationship. In creating and using informed consent documents, keep the following four questions in mind:

1. Does the patient understand their treatment options?
2. Has the patient been told of the potential benefits and risks associated with each of those options?

---

**TABLE 4: COMMON COMPONENTS OF OPIOID MEDICATION AGREEMENTS**

<table>
<thead>
<tr>
<th>Rationale (what you are treating and why)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risks of the drug (side effects as well as risk of dependence, tolerance, addiction, misuse, and overdose; and risk of driving, working, etc., under the influence of the drug)</td>
</tr>
<tr>
<td>Treatment goals (pain level, function level)</td>
</tr>
<tr>
<td>Monitoring plan (how often to return for follow up)</td>
</tr>
<tr>
<td>Refill policy</td>
</tr>
<tr>
<td>Action plan for suspected aberrant behavior (may include urine drug screens to ensure the patient is not diverting the medication)</td>
</tr>
<tr>
<td>Conditions for discontinuing opioids (lack of efficacy, pain resolution, aberrant behavior)</td>
</tr>
</tbody>
</table>

**TABLE 5. EXAMPLES OF FUNCTIONAL GOALS AND EVIDENCE USED TO ASSESS PROGRESS**

<table>
<thead>
<tr>
<th>Functional Goal</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begin physical therapy</td>
<td>Letter from physical therapist</td>
</tr>
<tr>
<td>Sleeping in bed as opposed to lounge chair</td>
<td>Report by family member or friend (either in-person or in writing)*</td>
</tr>
<tr>
<td>Participation in pain support group</td>
<td>Letter from group leader</td>
</tr>
<tr>
<td>Increased activities of daily living</td>
<td>Report by family member or friend</td>
</tr>
<tr>
<td>Walk around the block</td>
<td>Pedometer recordings or written log of activity</td>
</tr>
<tr>
<td>Increased social activities</td>
<td>Report by family member or friend</td>
</tr>
<tr>
<td>Resumed sexual relations</td>
<td>Report by partner</td>
</tr>
<tr>
<td>Returned to work</td>
<td>Pay stubs from employer or letter confirming the patient is off of disability leave</td>
</tr>
<tr>
<td>Daily exercise</td>
<td>Gym attendance records or report from family member or friend</td>
</tr>
</tbody>
</table>

* INVOLVING OTHER PERSONS REQUIRES EXPPLICIT PERMISSION FROM THE PATIENT, AND THIS PERMISSION SHOULD BE DOCUMENTED, PREFERABLY IN WRITING.
3. Is the patient free to choose among those options (meaning free from coercion by the healthcare professional, the patient’s family, or others?)

4. Does the patient have the cognitive and sensory capacity to communicate his or her preferences—verbally or in other ways?

Informed consent can be documented on paper or electronically, and the informed consent language can be incorporated into a larger treatment plan or patient/provider agreement.

WHO ARE PAIN MEDICINE SPECIALISTS?

Pain Medicine is the medical specialty dedicated to the prevention, evaluation and treatment of people with chronic pain. While most physicians, advanced practice nurses, and physician assistants have some training and experience in the management of chronic pain, Pain Medicine Specialists (physicians) have fellowship training from The American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), or additional training in pain medicine sufficient to obtain ABPM diplomat status. Current guidelines regarding the delineation of prescribing authority to and supervision of Advanced Practice Nurses with certificate of fitness for prescribing and Physicians Assistants for prescribing to treat chronic pain continue to apply. Pain Medicine Specialists may deal with patients being treated with more than 90 milligram morphine equivalents daily dose because they are at least eleven times more likely to suffer an adverse effect including overdose death.

INITIATING OPIOIDS

Before prescribing any opioid, confirm that:

- Other treatments with more optimal risk-benefit profiles have been exhausted
- The patient’s physical and psychosocial condition has been fully assessed
- Level of opioid tolerance has been determined or estimated (see below)
- Informed consent has been obtained and a management plan is in place

Opioid selection, initial dosing, and titration must be individualized to the patient’s health status, previous exposure to opioids, and treatment plan. Patients who are opioid-naïve or have modest previous opioid exposure should be started at a low dose, generally of a short-acting opioid because these confer a lower risk of overdose, and titrated slowly upward to decrease the risk of opioid-related adverse effects. If it is unclear whether a patient has recently been using opioids (either prescribed or non-prescribed), the clinician should assume that the patient is opioid-naïve (i.e., not tolerant) and proceed as just described. Some patients, such as frail older persons or those with comorbidities, may require an even more cautious therapy initiation. Prescribers should understand the warning signs and symptoms of significant respiratory depression (i.e., shallow, slow breathing, pinpoint pupils, cyanosis), communicate this information to patients, and be alert for the possibility of respiratory depression at the time of treatment initiation or dosage increase.

Prescribe opioids cautiously in patients with conditions that may be complicated by adverse effects from opioids, such as chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current or past substance use disorder, mental illness, advanced age, or patients with a history of renal or hepatic dysfunction.

Because of the risk of neonatal opioid withdrawal syndrome with prolonged use of an opioid during pregnancy, newly pregnant women should have a urine drug test administered to ascertain previous use, and, for women who are not pregnant, providers should discuss a birth control plan to prevent unintended pregnancy. In general, opioids should be avoided in this population.

Opioid prescriptions should be handled by a single provider or practice and all prescriptions should be filled in a single pharmacy, unless the provider is informed and agrees that the patient can go to another pharmacy for a specific reason. Prescribers should tell patients and caregivers to read the specific ER/LA opioid analgesic Medication Guide that they receive from the pharmacy and to tell their doctor about any side effects or adverse events they experience. An initial trial of an opioid should be assessed using the following outcome measures:

- Progress toward meeting functional goals
- Presence and nature of adverse effects
- Changes in the underlying pain condition
- Changes in medical or psychiatric comorbidities
- Degree of opioid tolerance in the patient
- Identification of aberrant behaviors, misuse, or diversion

Further studies are needed to confirm more consistent control of pain and improved adherence to prescribed therapy with use of ER/LA opioids. Although low-dose, short-acting opioids may offer the greatest safety for initiating opioid therapy, clinicians must recognize that short-acting opioids are not intrinsically safer than other formulations, and stress to their patients the importance of strict adherence to prescribed doses/administration.

The CDC recommends that patients on opioid doses of 90 morphine-equivalent dose/day (MEDD) or greater should be referred to a pain specialist for consultation and/or management. If a provider cannot make the required consultation, it is recommended that he/she should clearly document why not. (Note: a pain specialist is a physician who has undergone fellowship training from the American Board of Pain Medicine or other training sufficient to obtain diplomat status.) In general, current guidelines suggest that doses of >90 MEDD should be avoided.

PATIENT EDUCATION

Whenever an opioid is prescribed, the patient should be thoroughly educated about the safe use, storage, and disposal of opioid medications. This can be done by a non-physician, if desired, and the key points can be included in patient/provider agreements or treatment plans. (Prescribers should use the Patient Counseling Document as part of the discussion when prescribing opioid analgesics—see Table 11). Safe use means following clinician instructions about dosing (including how to handle missed doses), not using concurrent alcohol or sedatives, not sharing medications, not breaking, chewing, or crushing medicines, and not using transdermal products if they are broken or torn. (If a patient cannot swallow a capsule whole, prescribers should refer to the product labeling to determine if it is appropriate to sprinkle the contents of a capsule on applesauce or administer via a feeding tube.) Patients should also be warned not to abruptly discontinue or reduce their ER/LA opioid analgesic, and be informed about the potential risks of falls, driving, and working with heavy machinery (particularly after dose initiation or an upward change in dose).

Prescribers should instruct patients and caregivers to tell all of their doctors about all medications the patient is taking. Furthermore, prescribers should strongly discourage the use of benzodiazepine medications and other respiratory depressants, including alcohol, concurrent with an opioid. Safe storage means reminding patients that pain medications are sought-after by many people, and that opioids should be stored in a locked cabinet or other secure storage unit. If a locked unit is not available, patients should, at least, not keep opioids in a
place that is obvious to, or easily accessed by others, since theft by friends, relatives, and guests is a known route by which opioids become diverted. Storage areas should be cool, dry, and out of direct sunlight.

Proper disposal means getting rid of unused medications by: returning the medications to a pharmacy, health center, or other organization with a take-back program; flushing them down a toilet (unless prohibited by state law); or mixing the medication with an undesirable substance and putting it in the trash. In 2014, the DEA loosened regulations to allow pharmacies, hospitals, clinics, and other authorized collectors to serve as drop-off sites for unused prescription opioid drugs.

**OPIOID SELECTION**

Opioid analgesics are available in a wide range of formulations and routes of administration (Table 6). Little evidence exists that specific analgesic formulations affect efficacy or risk of opioid use disorder, so selection of an agent should be based on the patient’s pain complaint, lifestyle, and preferences. Generally, if opioids are used at all, it is better to offer short-acting opioids used on an as-needed basis. ER/LA opioids produce a more steady state of analgesia without the cycling effect of pain relief and withdrawal associated with short-acting opioids, which may be helpful for certain patients. With ER/LA agents, however, patients may end up using more drug than is actually needed, and physiological adaptations to the steady state may ultimately decrease analgesic efficacy. In addition, ER/LA opioids pose a higher risk for being abused or misused. Prescribers should educate themselves about the general characteristics, toxicities, and drug interactions for ER/LA opioid products. For detailed information on current ER/LA opioid analgesics, see the FDA Blueprint for Prescriber Education at the end of this document. For example, some ER/LA formulations may rapidly release opioid (dose dump) when exposed to alcohol. In addition using opioids with monoamine oxidase inhibitors (MAOIs) may increase the risk of respiratory depression and serotonin syndrome. Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone (ADH).

Combination products join an opioid with a non-opioid analgesic, usually for use in patients with moderate pain. Using a combination product when dose escalation is required risks increasing the adverse effects from the non-opioid co-analgesic, even if an increase of the opioid dose is appropriate. In such cases, using a pure opioid is preferable. Particular care must be made to not exceed maximal daily doses of acetaminophen.

**THE SPECIAL CASE OF METHADONE**

Methadone has received growing attention because it is frequently involved in unintentional overdose deaths. These deaths have escalated as methadone has increasingly been used as an analgesic drug for chronic pain. At one time, methadone had been used almost exclusively in opioid maintenance therapy programs to treat opioid use disorder. Its relatively long plasma elimination half-life compared to its relatively short analgesic half-life makes it optimal for maintenance, allowing for once-daily dosing. But methadone only exerts potent analgesic effects in the early phase of its elimination half-life (about 4 hours), and this, along with the fact that it is among the least expensive opioids, has led to a dramatic increase in its use for alleviating chronic non-cancer pain.

Methadone has unique pharmacokinetic and pharmacodynamic characteristics that add substantial risk to its use. Although its chemical structure is different from classic opioids such as morphine, methadone acts on the same set of opioid receptors, though with different affinities for the various opioid receptor subtypes. In addition, methadone possess non-opioid receptor effects that may explain some of its potential special efficacy. These varied effects across opioid receptors, along with its non-opioid properties, have garnered methadone the reputation of being a “broad spectrum opioid.” For a number of reasons, however, methadone must be titrated very carefully in order to avoid overdose. These reasons include:

- An analgesic half-life much shorter than its elimination half-life (leading to accumulation)
- Metabolism by a group of liver enzymes that differ from those associated with most other opioids, hence leading to unexpected drug-drug interactions
- Significant genetic variations in the liver enzymes that metabolize methadone, which contribute to the unpredictability of methadone’s effects and side effects
- Metabolism may be affected by cigarette smoking (which accelerates elimination) and alcohol consumption (which can augment methadone toxicity acutely and accelerate metabolism with chronic use)

The APS/AAPM guidelines recommend a starting dose in most opioid-naive patients of 2.5 mg every 8 hours, with dose increases occurring no more frequently than weekly. The lowest possible dose titration should be followed even in opioid-tolerant patients because methadone appears to be more potent in patients who have been using higher doses of the pre-switch opioid. The total daily dose of methadone on the first day of treatment should not ordinarily exceed 30-40 mg/d regardless of prior exposure. In older patients or those with renal or hepatic comorbidities, lower starting doses, less frequent dosing, and more cautious dose titration are recommended. Because of its long half-life and variable pharmacokinetics, methadone is not recommended to treat breakthrough pain or as an as-needed medication.

When rotating from another opioid to methadone, extreme caution must be used when referring to equianalgesic conversion tables. The consensus recommendations from an expert panel suggest a 75 to 90% decrement in the equianalgesic dose from conventional conversion tables when a switch is made from another opioid to methadone.

Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of mixing unauthorized substances with their medication. Benzodiazepines, in particular, pose a threat. Death investigations often find that benzodiazepines have been used in combination with methadone and other opioids. Other respiratory depressants, including alcohol, pose similar risks. Dosing should, therefore, be conservative and cautious until patients demonstrate the ability to tolerate and use the drug safely.

In 2006, the FDA issued a public health advisory warning that methadone can cause serious cardiac conduction disturbances, including QT interval prolongation and torsades de pointes, a potentially fatal ventricular arrhythmia. It appears that methadone-related corrected QT (QTc) interval prolongation (>450 ms) and cardiac arrhythmias can occur at any dose but are more likely at higher doses or with concomitant use of drugs that interact with methadone or that themselves prolong QTc. Although uncommon, the cardiac arrhythmias that can be induced by methadone can be lethal if not detected. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to any history of heart disease or arrhythmias.
<table>
<thead>
<tr>
<th>ROUTE</th>
<th>DEFINITION AND NOTES</th>
<th>DRUG TYPES</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>By mouth (per os) \nRequires functioning GI tract, intact swallowing mechanism, sufficient GI tract for absorption to occur</td>
<td>NSAIDS, opioids, adjuvant analgesics (TCA, Antiepileptics, SNRI)</td>
<td>Advantages: convenient, noninvasive, usually cost-effective, flexible, less discomfort than injections with comparable efficacy \nDisadvantages: requires functional GI system; slow onset of action and relatively delayed peak effects; requires patient compliance</td>
</tr>
<tr>
<td>Rectal</td>
<td>Insertion of suppository into rectum</td>
<td>Opioids</td>
<td>Useful in patients who cannot take medications by mouth \nAny opioid may be compounded for rectal administration</td>
</tr>
<tr>
<td>Intramuscular</td>
<td>Injection into large muscle (e.g., gluteus or vastus lateralis)</td>
<td>Opioids</td>
<td>IM administration should not be used, especially for chronic treatment, due to multiple disadvantages: \n• Painful injections \n• Wide fluctuations in drug absorption make it difficult to maintain consistent blood levels \n• Rapid fall-off of action compared with PO administration \n• Chronic injections may damage tissue (fibrosis, abscesses) IV and SC injections are appropriate alternatives</td>
</tr>
<tr>
<td>Intravenous</td>
<td>Injection into vein; may be single or repetitive bolus or continuous infusion with or without PCA</td>
<td>NSAIDS, opioids, ketamine, acetaminophen</td>
<td>IV is most efficient ROA for immediate analgesia and permits rapid titration \nIV bolus produces rapid onset of effect, but shorter duration of action than IM; not recommended for drugs with long half-lives \nContinuous IV infusion provides steadier drug blood levels, which maximize pain relief while minimizing side effects</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>Placement of drug just under skin with small needle \nContinuous SC infusion can be obtained with a small needle</td>
<td>Some opioids</td>
<td>Advantages: produces steady blood levels; time until onset of effect is comparable to IM administration and effects are longer lasting, with less painful administration; cheaper than IV administration; obviates need for GI function \nDisadvantages: slower onset and offset and lower peak effects than IV administration, time consuming, often disliked by patients</td>
</tr>
<tr>
<td>Topical</td>
<td>Applied directly to the skin, where the drug penetrates</td>
<td>NSAIDs, local anesthetics (e.g., lidocaine patch and gel, EMLA®), capsaicin</td>
<td>Advantages: local effect (i.e., no significant serum levels) limits side effects to local reactions; no drug-drug interactions; easy to use, no titration needed \nDisadvantages: may cause local skin reactions</td>
</tr>
<tr>
<td>Transdermal</td>
<td>Absorbed through skin with gradual release into the systemic circulation</td>
<td>Some opioids</td>
<td>Advantages: convenient, noninvasive, provides prolonged, relatively stable analgesia \nDisadvantages: delayed onset of action with first dose, drug absorption influenced by internal or external heat, may cause skin irritation</td>
</tr>
<tr>
<td>Oral transmucosal</td>
<td>Delivery of drug to mouth, including sublingual (under tongue) and buccal/gingival administration</td>
<td>Some opioids</td>
<td>Advantages: easy, requires little staff supervision; avoids significant liver metabolism associated with oral opioids \nDisadvantages: variable absorption, bitter taste, dose is limited</td>
</tr>
<tr>
<td>OTFC</td>
<td>Fentanyl incorporated into a sweetened matrix on a stick for consumption</td>
<td>Fentanyl</td>
<td>Some absorption via oral mucosa, but most via GI tract; yields higher drug levels and better bioavailability than oral fentanyl</td>
</tr>
<tr>
<td>Intranasal</td>
<td>Small aerosol device placed inside nostril that delivers a calibrated dose of a drug</td>
<td>Butorphanol, sumatriptan, fentanyl, naloxone</td>
<td>Takes advantage of rich blood supply to nose and also avoids significant liver metabolism associated with some drugs</td>
</tr>
<tr>
<td>Intraspinal</td>
<td>Epidural and intrathecal administration (see Table 29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (- sublingual, vaginal)</td>
<td>Placement of drug under the tongue (sublingual) or in the vagina</td>
<td>Opioids, benzodiazepines (intravaginal)</td>
<td>Most opioids can be absorbed sublingually or vaginally in patients who have problems such as impaired swallowing, short gut syndrome, or poor IV access</td>
</tr>
</tbody>
</table>
An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease or cardiac risk factors or is taking agents that may interact with methadone. Alternative treatments should be considered when the QTc is >450 ms.

**ABUSE-DETERRENT FORMULATIONS**

Concern about opioid misuse and abuse has spurred efforts to create abuse-deterrent opioid formulations. Three agents are currently available, which are co-formulated with an opioid antagonist:

- Targiniq ER (oxycodone and naloxone), Embeda ER (morphine and naloxone), and Troxyca ER (oxycodone HCL-naltrexone capsules). Abuse-deterrent forms of oxycodone ER, Hysingla ER, Zohydro ER, Exalgo, Opana ER, and Xtampza ER contain a variety of substances that make the pills difficult to crush, snort, or melt or which inactivate the opioid in other ways if a pill or capsule is altered. Transdermal opioid formulations were thought to be less vulnerable to misuse, but such formulations can be abused.97

**PATIENT MONITORING**

If an opioid medication appears to be beneficial (as determined by the functional goals outlined in the management plan) and therapy is continued, regular review and monitoring should be performed for the duration of treatment based on the needs and characteristics of each patient. Clinicians must evaluate progress against agreed-upon treatment goals for both pain relief and function, assess for physical and behavioral adverse effects, and confirm adherence to prescription regimens by performing medication reconciliation as indicated. Clinicians should also re-evaluate a patient’s underlying medical condition if the patient’s clinical presentation changes with time.13

The intensity and frequency of monitoring is guided, in part, by the clinician’s assessment of the patient’s risk for abuse, diversion, or addiction. Tools and techniques similar or identical to those used during an initial assessment of a patient’s risk can be used to re-assess or monitor risk on an on-going basis.

Patients who may need more frequent or intense monitoring include:

- Those with a prior history of an substance use disorder or other aberrant use
- Those in an occupations demanding mental acuity
- Older adults
- Patients with an unstable or dysfunctional social environment
- Those with comorbid psychiatric or medical conditions
- Patients on higher doses of opioids (>90 mg MEDD)

Patient monitoring includes re-evaluation of the patient’s underlying medical condition if the clinical presentation changes over time.

**EXERCISE 3**

**Instructions:** Read the case below and complete both learning activities that follow.

Zeke is a 25-year-old construction worker who is currently taking workman’s compensation to recover from a compound fracture of his right foot and ankle sustained when a cement block slipped off of a pallet and landed on his foot. The fractures required two surgeries to correct, with the implantation of several internal fixation devices. Zeke was prescribed a short-acting opioid after each surgery, which he has continued to use. He has been regularly attending physical therapy sessions to restore muscle tone in his right leg, but has come into the clinic today seeking an ER/LA opioid. The short-acting medication, he says, is “choppy” and allows his pain to return at the end of each dosing cycle. He says friends have suggested that a long-acting opioid would be easier to use and would provide him more steady pain relief.

**Part 1 – Application:** Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.

II. Consider the expected outcome(s) of those applications.

**Part 2 - Questions and Considerations:** Spend 5 minutes considering the following questions as they relate to the case presented.

1. What steps might you take before agreeing to a trial of an ER/LA medication for Zeke?

2. What specific kind of ER/LA medication might be most appropriate for Zeke if no contraindications were found in the pain and substance abuse assessment?

3. Name three specific functional goals that might be used as the basis for a pain management agreement with Zeke.

**URINE DRUG SCREENS**

Urine drug testing is an imperfect science, but such testing can be a helpful component of responsible opioid prescribing. Drug testing should be conducted in a consensual manner as part of an agreed-upon opioid management plan and with the idea that such testing benefits both the patient and the provider. The potential benefits of urine drug testing include:

- Serving as a deterrent to inappropriate use
- Providing objective evidence of compliance with prescribed drugs, or evidence that non-prescribed drugs are being used
- Evaluating for diversion
- Monitoring response to treatment
- Helping patients allay concerns by family members, employers, or law-enforcement
- Demonstrating to regulatory authorities a clinician’s dedication to “best practices”
In primary care settings, unobserved urine collection is usually acceptable, however, clinicians should be aware of the many ways in which urine specimens can be adulterated. Specimens should be shaken to determine if soap products have been added, for example. The urine color should be noted on any documentation that accompanies the specimen for evaluation, since unusually colored urine could indicate adulteration. If possible, urine temperature and pH should be measured immediately after collection.99

Prescribers should be familiar with the metabolites associated with each opioid that may be detected in urine, since the appearance of a metabolite can be misleading. A patient prescribed codeine, for example, may test positive for morphine because morphine is a codeine metabolite. Similar misunderstandings may occur for patients prescribed hydrocodeine who appear positive for hydromorphone or patients prescribed oxycodone who test positive for oxymorphone. In the event of an unexpected urine drug screen, prescribers should consider a differential diagnosis that includes: drug abuse or addiction; self-treatment of poorly-controlled pain; psychological issues; or diversion (which may be suggested by absence of prescribed opioids).5

PROTECTING AGAINST OPIOID-INDUCED ADVERSE EVENTS

The Veterans Administration/Department of Defense (VA/DoD) clinical practice guideline outlines a number of evidence-based strategies to reduce opioid-related adverse effects, summarized in Table 7.100 Prophylaxis for constipation—the most common opioid-induced adverse event—has been facilitated by the approval of methylnaltrexone subcutaneous administration and naloxegol oral administration for patients with chronic non-cancer pain. Note that one of the potential complications of treatment is opioid use disorder, and practitioners should be prepared to educate patients about this risk and to provide direct addiction treatment or referral to an addiction treatment program if needed.

Both male and female patients on long-term opioid therapy are at risk for hypogonadism, thus current guidelines suggest that the endocrine function of all patients should be assessed at the start of long-term opioid therapy and at least annually thereafter. The symptoms of hypogonadism in both genders may include fatigue, mood changes, decreased libido, loss of muscle mass, and osteoporosis. Although there are insufficient data to recommend routine endocrine screening of asymptomatic patients, current guidelines do recommend such testing for patients exhibiting any of the aforementioned signs and symptoms.5

OPPIOID ROTATION

Switching from one opioid to another may be needed to reduce side effects, improve efficacy, avoid dose limitations of co-compounded acetaminophen, or because of a patient’s inability to absorb the medication in its present form. Opioid rotation must be done cautiously because of the many pharmacokinetic and pharmacodynamic variables involved.61 An equianalgesic chart should be used when changing from one opioid to another or from one route of administration to another. Such charts must be used carefully, however. A high degree of variation has been found across the various charts and online calculators, and may account for some overdoses and fatalities.92 The optimal dose for a specific patient must be determined by careful titration and appropriate monitoring, and clinicians must remember that patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind. Do not simultaneously switch both an agent and a route of administration or type of release (e.g., ER/LA)

MANAGING PAIN FLARE-UPS

Pain is dynamic, and ER/LA analogesics may not control pain flare-ups. Having patients track flare-ups with paper or electronic pain diaries can help them spot correlations between the flare-ups and variables in their lives. If specific triggers are identified, patients may be able to make changes that will reduce the prevalence of episodes without recourse to increased medication.81

Non-opioid methods of dealing with pain flare-ups (e.g., cold or warmth, massage, yoga, acupuncture, meditation, electrical stimulation) should be tried—or at least considered—before the dose of an opioid is increased. As with the management of the underlying chronic pain condition, clinicians should use an agreed-upon set of functional goals as a way to monitor, and if necessary, adjust, the use of as-needed opioid medications for pain flares.

USING PRESCRIPTION MONITORING PROGRAMS

Prescription drug monitoring programs (PDMPs) offer point-of-care access to pharmacy dispensing records of controlled substances from prescribers. From these, clinicians can quickly assess patterns of prescription drug use that can be helpful in confirming or refuting suspicions of aberrant behaviors. Information from the PDMP may also reveal that a patient is being prescribed medications whose combinations are contraindicated. By reviewing the PDMP each prescriber can identify other prescribers involved in the care of their patient. This can be especially useful for new patients to a practice on high dose opioids, with suspect or concerning behaviors.

| Table 7: Recommendations for preventing or treating opioid-induced side effects100 |
|-------------------------------|---------------------------------|-----------------|
| Constipation                  | Methylnaltrexone or naloxegol   | Prophylactic mild peristaltic stimulant (e.g. bisacodyl or senna) |
|                               |                                 | If no bowel movement for 48 hours, increase dose of bowel stimulant |
|                               |                                 | If no bowel movement for 72 hours, perform rectal exam |
|                               |                                 | If not impacted, provide additional therapy (suppository, enema, magnesium citrate, etc.) |
| Nausea or vomiting            | Consider prophylactic antiemetic therapy | Add or increase non-opioid pain control agents (e.g. acetaminophen) |
|                               |                                 | If analgesia is satisfactory, decrease dose by 25% |
|                               |                                 | Treat based on cause |
| Sedation                      | Determine whether sedation is due to the opioid | Eliminate nonessential CNS depressants (such as benzodiazepines) |
|                               |                                 | Reduce dose by 10-15% |
|                               |                                 | Add or increase non-opioid or non-sedating adjuvant for additional pain relief (such as NSAID or acetaminophen) so the opioid can be reduced |
|                               |                                 | Add stimulant in the morning (such as caffeine) |
|                               |                                 | Change opioid |
| Pruritus                      | Consider treatment with antihistamines | Change opioid |
| Hallucination or dysphoria    | Evaluate underlying cause        | Eliminate nonessential CNS acting medications |
| Sexual dysfunction            | Reduce dose                      | Testosterone replacement therapy may be helpful (for men) |
|                               |                                 | Erection-enhancing medications (e.g., sildenafil) |
ADDRESSING CONCERNS ABOUT PRESCRIPTION ACTIVITY

Suspicion that a patient is non-adherent to a prescription or is engaging in aberrant drug-related behaviors should prompt a thorough investigation of the situation, including an honest evaluation of the patient/provider relationship, which may be strained by such behaviors. Possible reasons for non-adherence include:

- Inadequate pain relief
- Misunderstanding of the prescription
- Misunderstandings related to lack of fluency with English
- Attempts to “stretch” a medication to save money
- Cultural or familial pressure not to take a medication
- Stigma about taking a pain medication
- Patient fears about addiction
- Misuse, abuse, addiction
- Diversion

Here are some possible ways to respond to concerns about a patient’s prescription activity:

- Discuss the situation with the patient: express concern over the pattern of behavior; discuss how opioid use disorder begins; and emphasize its negative consequences on health, employment, finances, friends, family, etc.
- Clarify expectations (e.g., receiving controlled medications from only one prescriber, using only one pharmacy) and review existing patient/provider agreements
- Increase the intensity of patient monitoring (e.g., urine toxicology, pill counts and early refills) and establish limits on refills or lost medications

For persistent non-compliance, options include one or more of the following:

- Tapering drug therapy over several weeks to avoid withdrawal; consider incorporating non-opioid pain treatments
- Referral to specialists, e.g., a pain specialist, for evaluation of continued controlled substance prescribing
- Referral to an addiction management program

In criminal matters HIPAA restrictions generally do not apply. Legal input in difficult cases may be helpful.

DISCONTINUING OPIOID THERAPY

Stopping long-term opioid therapy is often more difficult than starting it. For most patients, a slow weaning is preferred (reducing MEDD by 10% weekly) although a faster weaning (i.e., 25% MEDD reduction weekly) may be possible in selected patients. The longer the patient has been on the drug, and the higher the initial dose, the slower should be the taper. Use caution when discontinuing opioids in patients with unstable angina or who are pregnant. Withdrawal symptoms can be eased with clonidine (0.2 mg po BID) or tizanidine (2 mg po TID).

Discontinuing an opioid may be needed for a variety of reasons, including the healing of an injury or condition, an inability to achieve adequate analgesia, the lack of progress toward functional goals, or the experience of intolerable side effects. If inappropriate use of an opioid is confirmed, treatment must usually be suspended, although provisions should be in place for continuing some kind of pain treatment and/or referral to other professionals or members of a pain management team. Discharge solely for opioid use disorder is not acceptable.

Some clinicians may be willing and able to continue a regimen of opioid therapy even after the discovery of aberrant behavior, although this would require intensified monitoring, patient counseling, and careful documentation of all directives. This level of vigilance and risk management, however, may exceed the abilities and resources of primary care physicians. In such cases, referral to a provider with specialized skill or experience in dealing with high-risk patients may be prudent.

Patients with opioid use disorder and/or complex chronic pain problems should maintain a relationship with a primary care provider, even if the management of the pain and/or opioid use disorder will be conducted by specialists. Providers are not required to take action that they believe to be contrary to the patient’s best interests. If the provider believes that a crime has been committed, he or she has the right to contact law enforcement and/or other providers.

EXERCISE 4

Instructions: Read the following case and complete the activities that follow.

Clara is a 77-year-old who has been diagnosed with lumbar spinal stenosis, which is causing a burning pain that radiates across her back and down into her buttocks. She has stage 2 kidney failure, although she is not on dialysis. In the previous two years, she has fallen twice at home, sustaining a subdural hematoma on one occasion and a sprained shoulder on the other. She lives alone and is fiercely independent, continuing to drive and adequately maintaining activities of daily living. She has tried numerous non-drug treatments for her pain, including physical therapy, acupuncture, massage, yoga, and even medical cannabis (which she said did help with the pain, but which she didn’t continue because she didn’t like the cognitive effects). She continues to have pain which disrupts her sleep and reduces her incentive to walk.

Part 1 – Application: Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.

II. Consider the expected outcome(s) of those applications.

Part 2 – Questions and Considerations: Spend 5 minutes considering the following questions:

1. Would treatment with an NSAID be appropriate for Clara? Why or why not?

2. Would treatment with an ER/LA opioid be appropriate for Clara? If so, what specific route of administration and/or agent might be best?

3. What aspects of Clara’s case should be considered when thinking about an initial dose selection of an ER/LA medication?

PATIENTS ON WORKERS’ COMPENSATION

Opioids and other associated analgesic medications represent a very significant portion of
Workers’ Compensation claims, and the use of opioids is associated with longer periods of disability and lost-work time.\textsuperscript{102} Effective oversight and appropriate use of these medications reduce their abuse and diversion, return injured workers to employment sooner, decrease long term disability, improve longevity, and improve patient function.

This population of patients presents its own unique circumstances. Injured workers are generally sent to an occupational medicine facility for treatment. Ideally, the injured worker recovers and returns to work in full capacity. If recovery or healing does not occur as expected, early triage and appropriate, timely treatment is essential to restore function and facilitate a return to work.

The use of opioids in this population of patients can be problematic. Some evidence suggests that early treatment with opioids may actually delay recovery and a return to work.\textsuperscript{102} Conflicts of motivation may also exist in patients on worker’s compensation, such as when a person may not want to return to an unsatisfying, difficult, or hazardous job. Clinicians are advised to apply the same careful methods of assessment, creation of treatment plans, and monitoring used for other pain patients but with the added consideration of the psycho-social dynamics inherent in the workers’ compensation system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

When a Workers’ Compensation patient is being prescribed chronic opioids, and that patient is also being prescribed other scheduled medications for a co-morbid mental or sleep disorder by a non-psychiatrist, use of chronic opioids for pain is generally not appropriate. If a co-morbid mental illness appears during tapering to require continued treatment with one or more other scheduled medications or anti-psychotics or anti-convulsants, a psychiatrist should be consulted for help with managing the mental illness during chronic pain management. The psychiatric evaluation and treatment is not the financial responsibility of the employer/insurer, unless the mental illness is accepted as work related.

The physician should do a face-to-face examination at least six times yearly if the patient is on any schedule II or III medication concurrently for chronic pain management and mental illness. Reexamination must be performed by the authorized treating physician/qualified physician/pain medicine specialist in person at least every 90 days (except in the special cases of catastrophic injury and persistent pain syndromes on long term stable opioid use for over two years).

In order to justify the continued use of opioids, the treating physician must document that with the use of opioids, the pain level has been measurably improved (based on Visual Analog Scores, in comparison of pain levels without use of opioids) and there has been a definite improvement in function with the use of the opioids, as measured by an objective functional assessment tool/questionnaire (such as the Physical Functional Ability Questionnaire).

In the absence of objective functional improvement, the physician must give a written opinion that “the present regimen is the best that can be done and that without it, deterioration in function or daily activities would likely occur.” An annual attempt should still be made to wean/taper the scheduled medications.

**PEDIATRIC PATIENTS**

Because of their more robust inflammatory response and immature central inhibitory influences, infants and young children may actually experience greater pain sensations and pain-related distress than adults.\textsuperscript{102} Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that opioids have a limited place in the treatment armamentarium. Developmental differences can make opioid dosing challenging, especially in the first several months of life. In the first week of a newborn’s life, for example, the elimination half-life of morphine is more than twice as long as that in older children and adults, as a result of delayed clearance.\textsuperscript{104} For older children, dosing must be adjusted for body weight.

The American Pain Society and the American Academy of Pediatrics have issued the following recommendations for pain management in children and teens:\textsuperscript{105}

- Provide a calm environment for procedures that reduce distress-producing stimulation
- Use age-appropriate pain assessment tools and techniques
- Anticipate predictable painful experiences, intervene, and monitor accordingly

- Use a multimodal approach (pharmacologic, cognitive, behavioral, and physical) to pain management and use a multidisciplinary approach when possible
- Involve families and tailor interventions to the individual child
- Advocate for the effective use of pain medication for children to ensure compassionate and competent management of their pain

**OPIOIDS AND PREGNANCY**

There are no adequate and well-controlled studies of ER/LA opioid analgesics in pregnant women. Current American Pain Society-American Academy of Pain Medicine (APS-AAPM) guidelines suggest that clinicians should avoid prescribing opioids during pregnancy unless the potential benefits outweigh risks.\textsuperscript{5} Some data suggest an association between the use of long-term opioid therapy during pregnancy and adverse outcomes in newborns, including low birth weight and premature birth, though co-related maternal factors may play a role in these associations and causality is not certain.\textsuperscript{5} Exposure to these medications has also been associated with birth defects in some studies. Opioid with-
drawal can be expected in up to half of newborns of opioid-dependent mothers (neonatal abstinence syndrome). If a mother is receiving long-term opioid therapy at or near the time of delivery, a professional experienced in the management of neonatal withdrawal should be available.

REDUCING THE RISK OF OVERDOSE
Opioid overdose is reversible through the timely administration of the medication naloxone. Naloxone is a prescription drug, but it is not a controlled substance and has no abuse potential. It is regularly carried by medical first responders and, in many states, can be prescribed like any other medication.

As an opioid antagonist, naloxone can quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of heroin or prescription opioid overdose. It’s critical to point out, however, that if a person was using an ER/LA medication, the duration of the opioid effect may last longer than the duration of the naloxone antagonism and, hence, the patient may regress into respiratory depression.

As of 2010, programs that distribute naloxone to nonmedical personnel had reported more than 10,000 overdose reversals nationwide since 1996. As of November 2014, 23 states had statutes allowing for “third-party” prescriptions of naloxone (i.e. the prescription can be written to a friend, relative, or person in a position to assist a person at risk of experiencing an opioid overdose).

Given the effectiveness of naloxone in overdose reversal, the FDA has encouraged innovations in more user-friendly naloxone delivery systems such as auto-injectors, made particularly for lay use outside of health care settings. The FDA approved such an auto-injector in 2014 (Evzio), and an intranasal form called Narcan in 2016.

OLDER ADULTS
The prevalence of pain among community-dwelling older adults has been estimated between 25% and 50%. The prevalence of pain in nursing homes is even higher. Unfortunately, managing pain in older adults is challenging due to: underreporting of symptoms; presence of multiple medical conditions; polypharmacy; declines in liver and kidney function; problems with communication, mobility, and safety; and cognitive and functional decline in general.

Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding, renal toxicities, and cognitive side-effects that have been observed with NSAIDs in older adults (although acetaminophen may pose a risk of liver damage). Opioids must be used with particular caution, and clinicians should “Start low, go slow” with initial doses and subsequent titration. Clinicians should consult the American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults for further information on the many medications that may not be recommended. Early referral and/or consultation with geriatric specialists or pain specialists may be advisable.

CANCER PAIN
Pain is one of the most common, and most-feared symptoms of cancer. Pain is experienced by about 30% of patients newly diagnosed with cancer, 30% - 50% of patients undergoing treatment, and 70% - 90% of patients with advanced disease. Unrelieved pain adversely impacts motivation, mood, interactions with family and friends, and overall quality of life. Survival itself may be positively associated with adequate pain control. ER/LA opioid pain medications are the mainstay of cancer pain management and a trial of opioid therapy should be administered to all cancer patients with moderate or severe pain, regardless of the known or suspected pain mechanism.

ER/LA opioid formulations may optimize analgesia and lessen the inconvenience associated with the use of short-acting opioids. Patient-controlled analgesia with subcutaneous administration using an ambulatory infusion device may provide optimal patient control and effective analgesia. If cancer pain occurs in the context of a patient nearing the end of life, other treatment and care considerations may be appropriate. In these cases, patient care integrated with a specialist in palliative care medicine may be advisable.

PAIN AT THE END OF LIFE
Pain management at the end of life seeks to improve or maintain a patient’s overall quality of life. This focus is important because sometimes a patient may have priorities that compete with, or supersede, the relief of pain. Some patients want to be mentally alert to allow them to have meaningful interactions with loved ones, even if this means enduring greater pain.

Since dying patients may be unconscious or only partially conscious, assessing their level of pain can be difficult. Nonverbal signs or cues must sometimes be used to determine if the patient is experiencing pain and to what degree an analgesic approach is effective. In general, even ambiguous signs of discomfort should usually be treated, although caution must be exercised in interpreting such signs. Reports by family members or other people close to a patient should not be overlooked. In the Study to Understand Prognosis and Preference for Outcomes and Risks of Treatment (SUPPORT), surrogates for patients who could not communicate verbally had a 73.5% accuracy rate in estimating presence or absence of the patient’s pain.

ER/LA opioids are critical to providing effective analgesia at the end of life, and they are available in such a range of strengths, routes of administration, and duration of action that an effective pain regimen can be tailored to nearly each patient. No specific opioid is superior to another as first-line therapy. Rectal and transdermal routes of administration can be valuable at the end of life when the oral route is precluded because of reduced or absent consciousness, difficulty swallowing, or to reduce the chances of nausea and vomiting. Clinicians should be aware, however, that for transdermal products, external heat, fever, and exertion can increase absorption of the opioid, leading to potential overdose. Also, transdermal products with metal foil backings are not safe for use in MRIs.

When selecting an opioid, clinicians should also consider cost, since expensive agents can place undue burden on patients and families.

Fear of inducing severe or even fatal respiratory depression may lead to under-prescribing and reluctance by patients to take an opioid medication. Despite this fear, studies have revealed no correlation between opioid dose, timing of opioid administration, and time of death in patients using opioids in the context of terminal illness. A consult with a specialist in palliative medicine in these situations may be advisable.

See Appendix 5-7 for additional EOL and Palliative Care Information (Dying in America -Key Findings and Recommendations; NYS Palliative care information and Access Acts; NYS End-of-Life Care and Advance Directive Planning).

TABLE 8: POTENTIAL PATIENT-CENTERED GOALS OF CARE

- Longer life
- Symptom relief
- Time at home
- Ability to travel
- Mental clarity
- Physical mobility
- Ability to interact with loved ones
- Minimizing burdens on loves ones
- Personal/Spiritual growth
- “Dignity” (though meanings will vary)

SPECIFIC DRUG INFORMATION FOR ER/LA OPIOID ANALGESIC PRODUCTS

Prescribers should be knowledgeable about general characteristics, toxicities, and drug interactions for ER/LA opioid analgesic products. Table 9 provides general drug information common to the class of ER/LA opioid analgesics.

In addition, prescribers should know specific characteristics of the ER/LA opioid analgesic products they prescribe, including the drug substance, formulation, strength, dosing interval, key instructions, specific information about conversion between products where available, specific drug interactions, use in opioid-tolerant patients, product-specific safety concerns, and relative potency to morphine. Table 10 provides specific drug information for extended-release and long-acting opioid analgesics.

Exercises 5 and 6 covers general and specific information for ER/LA Opioid Analgesics, including Table 9 and Table 10. PLEASE SPEND THE ALLOTTED TIME COMPLETING THESE EXERCISES.

For detailed information, prescribers can refer to prescribing information available online via DailyMed at www.dailymed.nlm.nih.gov or Drugs@FDA at www.fda.gov/drugsatfda.

Conclusions

ER/LA opioid analgesics can play an important, although limited, role in the treatment of patients with cancer pain, and end-of-life pain. Their use for treating chronic non-cancer pain is more problematic because of their known risks of abuse, addiction, and overdose, as well as the possibility of their being diverted for recreational or unprescribed use. The clinical evidence base supporting the use of ER/LA opioids for chronic non-cancer pain is much weaker than is often assumed, while the evidence for the many risks involved in long-term use of opioids is strong.

The risks of ER/LA opioids are amplified among older adults; those with impaired renal or hepatic function; individuals with COPD, cardiopulmonary disorders, sleep apnea, or mental illness; and in patients who are likely to combine opioids with other respiratory depressants such as alcohol or benzodiazepines.

This monograph summarizes established methods for appropriately prescribing opioid analgesics, a task that can be challenging, but it is not inherently different from what physicians face in other treatment settings.
EXERCISE 5
DRUG INFORMATION COMMON TO THE CLASS OF ER/LA OPIOID ANALGESIC PRODUCTS

Instructions: Spend 20-25 minutes completing the following

1. Conduct a detailed review of the information regarding general characteristics, toxicities, and drug interactions for ER/LA opioid analgesic products.
2. Read and Table 9 which includes additional general drug information common to ER/LA opioid analgesics.
3. Complete the learning questions below related to General Drug Information for ER/LA Opioid Analgesic's after completing steps 1 and 2.

LEARNING QUESTIONS EXERCISE 5
COMPLETE ONLY AFTER CONDUCTING STEPS 1 AND 2 ABOVE

1. Are ER/LA opioids recommended for treating acute pain? Why or Why Not?

2. Can ER/LA opioids be safely stopped or tapered rapidly? What methodology is recommended for discontinuing opioid treatment?

3. Name three classes of drugs that should be avoided by patients who have been prescribed an ER/LA opioid analgesic. Describe the underlying reasoning for avoiding concurrent use of the drugs.
DRUG INFORMATION COMMON TO THE CLASS OF ER/LA OPIOID ANALGESIC PRODUCTS

Prescribers should be knowledgeable about general characteristics, toxicities, and drug interactions for ER/LA opioid analgesic products. For Example:

a. ER/LA opioid analgesic products are scheduled under the Controlled Substances Act and can be misused and abused.
b. Respiratory depression is the most important serious adverse effect of opioids as it can be immediately life-threatening.
c. Constipation is the most common long-term side effect and should be anticipated.
d. Drug-drug interaction profiles vary among the products. Knowledge of particular opioid-drug interactions, and the underlying pharmacokinetic and pharmacodynamic mechanisms, allows for the safer administration of opioid analgesics.
i. Central nervous system depressants (alcohol, sedatives, hypnotics, tranquilizers, tricyclic antidepressants) can have a potentiating effect on the sedation and respiratory depression caused by opioids.
ii. Some ER opioid formulations may rapidly release opioid (dose dump) when exposed to alcohol. Some drug levels may increase without dose dumping when exposed to alcohol. See individual product labeling.
iii. Using opioids with monoamine oxidase inhibitors (MAOIs) may result in possible increase in respiratory depression. Using certain opioids with MAOIs may cause serotonin syndrome.
iv. Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone (ADH).
v. Some opioids (methadone, buprenorphine) can prolong the QTc interval.
vi. Concomitant drugs that act as inhibitors or inducers of various cytochrome P450 enzymes can result in higher or lower than expected blood levels of some opioids.

e. Tolerance to sedating and respiratory-depressant effects of opioids is critical to the safe use of ER/LA opioid analgesics.
i. For ER products, patients must meet the criteria for opioid tolerance, described in the table 10, before using:
a. certain products,
b. certain strengths,
c. certain daily doses, and
d. in specific indicated patient populations (e.g., pediatric patients).
i. See the (table 10) for product-specific information.
f. ER/LA opioid analgesic tablets must be swallowed whole. ER/LA opioid analgesic capsules should be swallowed intact or when necessary, the pellets from some capsules can be sprinkled on applesauce and swallowed without chewing.
g. For transdermal products, external heat, fever, and exertion can increase absorption of the opioid, leading to fatal overdose. Transdermal products with metal foil backings are not safe for use in MRIs.
h. For buccal film products, the film should not be applied if it is cut, damaged, or changed in any way. Use the entire film.
i. Follow the instructions for conversion in the Dosage and Administration section (2.1) in the Prescribing Information of each product when converting patients from one opioid to another.
## Key Instructions

◊ **Limitations of usage:**
- Reserve for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Not for use as an as-needed analgesic.
- Not for mild pain or pain not expected to persist for an extended duration.
- Not for use in treating acute pain.

◊ Individually titrate to a dose that provides adequate analgesia and minimizes adverse reactions.

◊ The times required to reach steady-state plasma concentrations are product specific; refer to product information for titration interval.

◊ Continually reevaluate to assess the maintenance of pain control and the emergence of adverse reactions.

◊ During chronic therapy, especially for non-cancer-related pain, periodically reassess the continued need for opioids.

◊ If pain increases, attempt to identify the source, while adjusting the dose.

◊ When an ER/LA opioid analgesic is no longer required, gradually titrate downward to prevent signs and symptoms of withdrawal in the physically-dependent patient. **Do not abruptly discontinue these products.**

◊ Solid oral dosage forms:
- Swallow tablets and capsules whole: crushing, chewing, breaking, cutting or dissolving may result in rapid release and absorption of a potentially fatal dose of opioid.
- Some capsules can be opened and pellets sprinkled on applesauce for patients who can reliably swallow without chewing and used immediately. See individual product information.
- Exposure of some products to alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of opioid.
- Dispose of unused product by flushing down the toilet.

◊ Transdermal dosage forms:
- Avoid exposure to external heat. Patients with fever must be monitored for signs or symptoms of increased opioid exposure.
- Location of application must be rotated.
- Prepare skin by clipping, not shaving hair, and washing area only with water.

◊ See individual product information for the following:
- Dosage reduction for hepatic or renal impairment.

### Table 9: Drug Information Common to the Class of Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

<table>
<thead>
<tr>
<th>Arymo ER (morphine sulfate ER tablets)</th>
<th>MorphaBond (morphine sulfate ER tablets)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avinza (morphine sulfate ER capsules)</td>
<td>MS Contin (morphine sulfate ER tablets)</td>
</tr>
<tr>
<td>Belbuca (buprenorphine buccal film)</td>
<td>Nucynta ER (tapentadol HCl ER tablets)</td>
</tr>
<tr>
<td>Butrans (buprenorphine transdermal system)</td>
<td>Opana ER (oxymorphone HCl ER tablets)</td>
</tr>
<tr>
<td>Dolopine (methadone HCl tablets)</td>
<td>OxyContin (oxycodone HCl ER tablets)</td>
</tr>
<tr>
<td>Duragesic (fentanyl transdermal system)</td>
<td>Targiniq ER (oxycodone HCl/naloxone HCl ER tablets)</td>
</tr>
<tr>
<td>Embeda (morphine sulfate ER-naltrexone capsules)</td>
<td>Troxyca ER (oxycodone HCl-naltrexone capsules)</td>
</tr>
<tr>
<td>Exalgo (hydromorphone HCl ER tablets)</td>
<td>Vantrela ER (hydrocodone bitartrate ER tablets)</td>
</tr>
<tr>
<td>Hysingla ER (hydrocodone bitartrate ER tablets)</td>
<td>Xtampza ER (oxycodone ER capsules)</td>
</tr>
<tr>
<td>Kadian (morphine sulfate ER capsules)</td>
<td>Zohydro ER (hydrocodone bitartrate ER capsules)</td>
</tr>
</tbody>
</table>

**Dosing Interval**

◊ Refer to individual product information.
### Table 9: Drug Information Common to the Class of Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

<table>
<thead>
<tr>
<th>Drug Interactions Common to the Class</th>
<th>Use in Opioid-Tolerant Patients</th>
<th>Contraindications</th>
<th>Relative Potency To Oral Morphine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Concurrent use with other central nervous system depressants (sedatives, hypnotics, general anesthetics, antiemetics, phenothiazines, other tranquilizers, and alcohol) can increase the risk of respiratory depression, hypotension, profound sedation, or coma. Reduce the initial dose of one or both agents.</td>
<td>◇ Adult patients considered opioid-tolerant are those receiving, for one week or longer:</td>
<td>• Significant respiratory depression</td>
<td>• <strong>These are intended as general guides.</strong></td>
</tr>
<tr>
<td>• Avoid concurrent use of mixed opioid agonist/antagonists (i.e., pentazocine, nalbuphine, and butorphanol) or partial opioid agonists (buprenorphine) in patients who have received or are receiving a course of therapy with a full opioid agonist. In these patients, mixed opioid agonist/antagonists and partial opioid agonists may reduce the analgesic effect and/or may precipitate withdrawal symptoms.</td>
<td>• at least 60 mg oral morphine/day o 25 mcg transdermal fentanyl/hour o 30 mg oral oxycodone/day</td>
<td>• Acute or severe asthma in an unmonitored setting or in the absence of resuscitative equipment</td>
<td>• Follow conversion instructions in individual product information.</td>
</tr>
<tr>
<td>• Opioids may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.</td>
<td>• 8 mg oral hydromorphone/day</td>
<td>• Known or suspected paralytic ileus</td>
<td>• Incomplete cross-tolerance and inter-patient variability require the use of conservative dosing when converting from one opioid to another - halve the calculated comparable dose and titrate the new opioid as needed.</td>
</tr>
<tr>
<td>• Concurrent use with anticholinergic medication increases the risk of urinary retention and severe constipation, which may lead to paralytic ileus.</td>
<td>• 25 mg oral oxymorphone/day</td>
<td>• Hypersensitivity(e.g.,anaphylaxis)</td>
<td></td>
</tr>
</tbody>
</table>
EXERCISE 6
SPECIFIC DRUG INFORMATION FOR ER/LA OPIOID ANALGESIC PRODUCTS

Instructions: Spend 20-25 minutes completing the following

1. Conduct a detailed review of table 10, which includes information regarding Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics Review
2. Read and Table 9 which includes additional general drug information common to ER/LA opioid analgesics.
3. Complete the learning questions below related to Specific Drug Information for ER/LA Opioid Analgesics only after completing steps 1.

LEARNING QUESTIONS EXERCISE 6
COMPLETE ONLY AFTER CONDUCTING STEPS 1

1. Describe Interactions with other medications and substances for the following: Butran, Dolophine, Hysingla ER, MS Contin.

2. Discuss product safety concerns for the following: Arymo ER, Duragesic, Opana ER, Targiniq ER?

3. List and describe which products and which doses are indicated for use only in opioid-tolerant patients. Which products are indicated for use only in opioid tolerant-patients?

SPECIFIC DRUG INFORMATION FOR ER/LA OPIOID ANALGESIC PRODUCTS

Prescribers should be knowledgeable about specific characteristics of the ER/LA opioid analgesic products they prescribe, including: Drug Substance, Formulation, Strength, Dosing Interval, Key Instructions, Specific Information About Conversion Between Products Where Available, Specific Drug Interactions, Use In Opioid-Tolerant Patients, Product-Specific Safety Concerns, And Relative Potency To Morphine.

The following Table (TABLE 10) is a reference. For detailed information, prescribers can refer to prescribing information available online via DailyMed at www.dailymed.nlm.nih.gov or Drugs@FDA at www.fda.gov/drugsatfda.
### Arymo ER

**Morphine Sulfate**  
Extended-Release Tablets, 15 mg, 30 mg, 60 mg

**Dosing Interval**  
Every 8 or 12 hours

**Key Instructions**  
- Initial dose in opioid-naïve and opioid non-tolerant patients is 15 mg every 8 or 12 hours.
- Dosage adjustment may be done every 1 to 2 days.
- Take one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.

**Specific Drug Interactions**  
P-gp inhibitors (e.g. quinidine) can increase the exposure of morphine by about two-fold and increase risk of respiratory depression.

**Use in Opioid-Tolerant Patients**  
A single dose of ARYMO ER greater than 60 mg, or total daily dose greater than 120 mg, is for use in opioid-tolerant patients only.

**Product-Specific Safety Concerns**  
- Do not attempt to chew, crush, or dissolve. Swallow whole.
- Use with caution in patients who have difficulty in swallowing or have underlying GI disorders that may predispose them to obstruction, such as a small gastrointestinal lumen.

### Avinza

**Morphine Sulfate ER**  
Capsules, 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, and 120 mg

**Dosing Interval**  
Once a day

**Key Instructions**  
- Initial dose in opioid non-tolerant patients is 30 mg.
- Titrate in increments of not greater than 30 mg using a minimum of 3 to 4 day intervals.
- Swallow capsule whole (do not chew, crush, or dissolve).
- May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing; use immediately.
- Maximum daily dose: 1600 mg due to risk of serious renal toxicity by excipient, fumaric acid.

**Specific Drug Interactions**  
- Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of morphine.
- P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold.

**Use in Opioid-Tolerant Patients**  
90 mg and 120 mg capsules are for use in opioid-tolerant patients only.

**Product-Specific Safety Concerns**  
None

### Belbuca

**Buprenorphine Buccal Film**, 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg

**Dosing Interval**  
Every 12 hours (or once every 24 hours for initiation in opioid naïve patients and patients taking less than 30 mg oral morphine sulfate equivalents)
### Key Instructions

◊ Opioid-naïve patients or patients taking less than 30 mg oral morphine sulfate equivalents: Initiate treatment with a 75 mcg buccal film, once daily, or if tolerated, every 12 hours.
- Titrate to 150 mcg every 12 hours no earlier than 4 days after initiation.
- Individual titration to a dose that provides adequate analgesia and minimizes adverse reactions should proceed in increments of 150 mcg every 12 hours, no more frequently than every 4 days.
◊ When converting from another opioid, first taper the current opioid to no more than 30 mg oral morphine sulfate equivalents per day prior to initiating Belbuca.
- If prior daily dose before taper was 30 mg to 89 mg oral morphine sulfate equivalents, initiate with 150 mcg dose every 12 hours.
- If prior daily dose before taper was 90 mg to 160 mg oral morphine sulfate equivalents, initiate with 300 mcg dose every 12 hours.
- Titration of the dose should proceed in increments of 150 mcg every 12 hours, no more frequently than every 4 days.
◊ Maximum dose: 900 mcg every 12 hours due to the potential for QTc prolongation.
◊ Severe Hepatic Impairment: Reduce the starting and incremental dose by half that of patients with normal liver function.
◊ Oral Mucositis: Reduce the starting and incremental dose by half that of patients without mucositis.
◊ Do not use if the package seal is broken or the film is cut, damaged, or changed in any way.

### Specific Drug Interactions

- CYP3A4 inhibitors may increase buprenorphine levels.
- CYP3A4 inducers may decrease buprenorphine levels.
- Benzodiazepines may increase respiratory depression.
- Class IA and III antiarrhythmics, other potentially arrhythmogenic agents, may increase risk for QTc prolongation and torsade de pointes.

### Use in Opioid-Tolerant Patients

Belbuca 600 mcg, 750 mcg, and 900 mcg are for use following titration from lower doses of Belbuca.

### Product-Specific Safety Concerns

- QTc prolongation and torsade de pointes
- Hepatotoxic

### Relative Potency To Oral Morphine

Equipotency to oral morphine has not been established.

### Butrans

- Buprenorphine Transdermal System, 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr

### Dosing Interval

One transdermal system every 7 days.
### TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

#### Key Instructions

- Initial dose in opioid non-tolerant patients when converting from less than 30 mg morphine equivalents, and in mild to moderate hepatic impairment - 5 mcg/hr dose.
- When converting from 30 mg to 80 mg morphine equivalents - first taper to 30 mg morphine equivalent, then initiate with 10 mcg/hr dose.
- Titrate in 5 mcg/hour or 10 mcg/hour increments by using no more than two patches of the 5 mcg/hour or 10 mcg/hour system(s) with a minimum of 72 hours between dose adjustments. The total dose from all patches should not exceed 20 mcg/hour.
- Maximum dose: 20 mcg/hr due to risk of QTc prolongation.
- Application
  - Apply only to sites indicated in the Full Prescribing Information.
  - Apply to intact/non-irritated skin.
  - Skin may be prepped by clipping hair, washing site with water only.
  - Rotate site of application a minimum of 3 weeks before reapplying to the same site.
  - Do not cut.
  - Avoid exposure to heat.
  - Dispose of used/unused patches by folding the adhesive side together and flushing down the toilet.

#### Specific Drug Interactions

- CYP3A4 Inhibitors may increase buprenorphine levels.
- CYP3A4 Inducers may decrease buprenorphine levels.
- Benzodiazepines may increase respiratory depression.
- Class IA and III anti arrhythmics, other potentially arrhythmogenic agents, may increase risk for QTc prolongation and torsade de pointe.

#### Use in Opioid-Tolerant Patients

- Butrans 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, and 20 mcg/hr transdermal systems are for use in opioid-tolerant patients only.

#### Drug-Specific Safety Concerns

- QTc prolongation and torsade de pointe.
- Hepatotoxicity
- Application site skin reactions

#### Relative Potency To Oral Morphine

- Equipotency to oral morphine has not been established.

#### Dolophine

- Methadone Hydrochloride Tablets, 5 mg and 10 mg

#### Dosing Interval

- Every 8 to 12 hours

#### Key Instructions

- Initial dose in opioid non-tolerant patients: 2.5 to 10 mg
- Conversion of opioid-tolerant patients using equianalgesic tables can result in overdose and death. Use low doses according to the table in the full prescribing information.
- Titrate slowly, with dose increases no more frequent than every 3 to 5 days. Because of high variability in methadone metabolism, some patients may require substantially longer periods between dose increases (up to 12 days).
- High inter-patient variability in absorption, metabolism, and relative analgesic potency.
- Opioid detoxification or maintenance treatment shall only be provided in a federally certified opioid (addiction) treatment program (Code of Federal Regulations, Title 42, Sec 8).
### Specific Drug Interactions

◊ Pharmacokinetic drug-drug interactions with methadone are complex.
  - CYP450 inducers may decrease methadone levels.
  - CYP450 inhibitors may increase methadone levels.
  - Anti-retroviral agents have mixed effects on methadone levels.
◊ Potentially arrhythmogenic agents may increase risk for QTc prolongation and torsade de pointe.
◊ Benzodiazepines may increase respiratory depression

### Use in Opioid-Tolerant Patients
Refer to full prescribing information.

### Product-Specific Safety Concerns

- QTc prolongation and torsade de pointe.
- Peak respiratory depression occurs later and persists longer than analgesic effect.
- Clearance may increase during pregnancy.
- False positive urine drug screens possible.

### Relative Potency To Oral Morphine
Varies depending on patient’s prior opioid experience.

### Duragesic

<table>
<thead>
<tr>
<th>Fentanyl Transdermal System, 12, 25, 37.5*, 50, 62.5*, 75, 87.5*, and 100 mcg/hr (*These strengths are available only in generic form)</th>
</tr>
</thead>
</table>

### Dosing Interval
Every 72 hours (3 days)

### Key Instructions

◊ Use product specific information for dose conversion from prior opioid
◊ Use 50% of the dose in mild or moderate hepatic or renal impairment, avoid use in severe hepatic or renal impairment
◊ Application
  - Apply to intact/non-irritated/non-irradiated skin on a flat surface.
  - Skin may be prepped by clipping hair, washing site with water only
  - Rotate site of application.
  - Titrate using a minimum of 72 hour intervals between dose adjustments.
  - Do not cut.
◊ Avoid exposure to heat.
◊ Avoid accidental contact when holding or caring for children.
◊ Dispose of used/unused patches by folding the adhesive side together and flushing down the toilet.

**Specific contraindications:**

- Patients who are not opioid-tolerant.
- Management of acute or intermittent pain, or in patients who require opioid analgesia for a short period of time.
- Management of post-operative pain, including use after out-patient or day surgery.
- Management of mild pain.

### Specific Drug Interactions

- CYP3A4 inhibitors may increase fentanyl exposure.
- CYP3A4 inducers may decrease fentanyl exposure.
- Discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in fentanyl plasma concentration.

### Use in Opioid-Tolerant Patients
All doses of Duragesic are indicated for use in opioid-tolerant patients only.

### Product-Specific Safety Concerns
- Accidental exposure due to secondary exposure to unwashed/unclothed application site.
- Increased drug exposure with increased core body temperature or fever.
- Bradycardia
- Application site skin reactions
<table>
<thead>
<tr>
<th><strong>TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics</strong>&lt;br&gt;(ER/LA opioid analgesics)</th>
<th><strong>Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics</strong>&lt;br&gt;(ER/LA opioid analgesics)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative Potency To Oral Morphine</strong></td>
<td>See individual product information for conversion recommendations from prior opioid</td>
</tr>
<tr>
<td><strong>Embeda</strong></td>
<td>Morphine Sulfate ER-Naltrexone Capsules, 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg, 100 mg/4 mg</td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
<td>Once a day or every 12 hours</td>
</tr>
<tr>
<td><strong>Key Instructions</strong></td>
<td>• Initial dose as first opioid: 20mg/0.8mg.&lt;br&gt;• Titrate using a minimum of 1 to 2 day intervals.&lt;br&gt;• Swallow capsules whole (do not chew, crush, or dissolve)&lt;br&gt;• Crushing or chewing will release morphine, possibly resulting in fatal overdose, and naltrexone, possibly resulting in withdrawal symptoms.&lt;br&gt;• May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing, use immediately.</td>
</tr>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
<td>• Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of morphine.&lt;br&gt;• P-gp inhibitors (e.g., quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold.</td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
<td>Embeda 100 mg/4 mg capsule is for use in opioid-tolerant patients only.</td>
</tr>
<tr>
<td><strong>Product-Specific Safety Concerns</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Exalgo</strong></td>
<td>Hydromorphone Hydrochloride Extended-Release Tablets, 8 mg, 12 mg, 16 mg or 32 mg</td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
<td>Once a day</td>
</tr>
<tr>
<td><strong>Key Instructions</strong></td>
<td>• Use the conversion ratios in the individual product information.&lt;br&gt;• Start patients with moderate hepatic impairment on 25% dose that would be prescribed for a patient with normal hepatic function.&lt;br&gt;• Start patients with moderate renal impairment on 50%, and patients with severe renal impairment on 25% of the dose that would be prescribed for a patient with normal renal function.&lt;br&gt;• Titrate in increments of 4 to 8 mg using a minimum of 3 to 4 day intervals&lt;br&gt;• Swallow tablets whole (do not chew, crush, or dissolve).&lt;br&gt;• Do not use in patients with sulfite allergy—contains sodium metabisulfite.</td>
</tr>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
<td>All doses of Exalgo are indicated for opioid-tolerant patients only.</td>
</tr>
<tr>
<td><strong>Drug-Specific Adverse Reactions</strong></td>
<td>Allergic manifestations to sulfite component.</td>
</tr>
<tr>
<td><strong>Relative Potency To Oral Morphine</strong></td>
<td>Approximately 5:1 oral morphine to hydromorphone oral dose ratio, use conversion recommendations in the individual product information.</td>
</tr>
<tr>
<td><strong>Hysingla ER</strong></td>
<td>Hydrocodone bitartrate Extended-Release Tablets, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg</td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
<td>Every 24 hours (once-daily)</td>
</tr>
</tbody>
</table>
### Key Instructions

- **Opioid-naive patients:** initiate treatment with 20 mg orally once daily. During titration, adjust the dose in increments of 10 mg to 20 mg every 3 to 5 days until adequate analgesia is achieved.
- Swallow tablets whole (do not chew, crush, or dissolve).
- Consider use of an alternative analgesic in patients who have difficulty swallowing or have underlying gastrointestinal disorders that may predispose them to obstruction.
- Take one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.
- Use 1/2 of the initial dose and monitor closely for adverse events, such as respiratory depression and sedation, when administering Hysingla ER to patients with severe hepatic impairment or patients with moderate to severe renal impairment.

### Specific Drug Interactions

- CYP3A4 inhibitors may increase hydrocodone exposure.
- CYP3A4 inducers may decrease hydrocodone exposure.
- Concomitant use of Hysingla ER with strong laxatives (e.g., Lactulose) that rapidly increase GI motility may decrease hydrocodone absorption and result in decreased hydrocodone plasma levels.
- The use of MAO inhibitors or tricyclic antidepressants with Hysingla ER may increase the effect of either the antidepressant or Hysingla ER.

### Use in Opioid-Tolerant Patients

A single dose of Hysingla ER greater than or equal to 80 mg is only for use in opioid tolerant patients.

### Product-Specific Safety Concerns

- Use with caution in patients with difficulty swallowing the tablet or underlying gastrointestinal disorders that may predispose patients to obstruction.
- Esophageal obstruction, dysphagia, and choking have been reported with Hysingla ER.
- In nursing mothers, discontinue nursing or discontinue drug.
- QTc prolongation has been observed with Hysingla ER following daily doses of 160 mg. Avoid use in patients with congenital long QTc syndrome. This observation should be considered in making clinical decisions regarding patient monitoring when prescribing Hysingla ER in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QTc interval. In patients who develop QTc prolongation, consider reducing the dose.

### Relative Potency To Oral Morphine

See individual product information for conversion recommendations from prior opioid.

### Kadian

**Morphine Sulfate**

- **Extended-Release Capsules,** 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, and 200 mg

**Dosing Interval**

- Once a day or every 12 hours

**Key Instructions**

- Product information recommends not using as first opioid.
- Titrate using a minimum of 2-day intervals.
- Swallow capsules whole (do not chew, crush, or dissolve).
- May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing, use immediately.
<table>
<thead>
<tr>
<th>Specific Drug Interactions</th>
<th>Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)</th>
</tr>
</thead>
</table>
| • Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of morphine.  
• P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold. |  |
| Use in Opioid-Tolerant Patients | Kadian 100 mg, 130 mg, 150 mg, and 200 mg capsules are for use in opioid-tolerant patients only |
| Product-Specific Safety Concerns | None |
| **MorphaBond** | Morphine Sulfate  
Extended-release Tablets, 15 mg, 30 mg, 60 mg, 100 mg |
| Dosing Interval | Every 8 hours or every 12 hours |
| Key Instructions | • Product information recommends not using as first opioid.  
• Titrate using a minimum of 1 to 2-day intervals.  
• Swallow tablets whole (do not chew, crush, or dissolve). |
| Specific Drug Interactions | P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold. |
| Use in Opioid-Tolerant Patients | MorphaBond 100 mg tablets are for use in opioid-tolerant patients only |
| Product-Specific Safety Concerns | None |
| **MS Contin** | Morphine Sulfate  
Extended-release Tablets, 15 mg, 30 mg, 60 mg, 100 mg, and 200 mg |
| Dosing Interval | Every 8 hours or every 12 hours |
| Key Instructions | • Product information recommends not using as first opioid.  
• Titrate using a minimum of 1 to 2-day intervals.  
• Swallow tablets whole (do not chew, crush, or dissolve). |
| Specific Drug Interactions | P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold. |
| Use in Opioid-Tolerant Patients | MS Contin 100 mg and 200 mg tablet strengths are for use in opioid-tolerant patients only |
| Product-Specific Safety Concerns | None |
| **Nucynta ER** | Tapentadol  
Extended-Release Tablets, 50 mg, 100mg, 150 mg, 200 mg, and 250 mg |
| Dosing Interval | Every 12 hours |
| Key Instructions | • Use 50 mg every 12 hours as initial dose in opioid nontolerant patients  
• Titrate by 50 mg increments using a minimum of 3-day intervals.  
• Maximum total daily dose is 500 mg  
• Swallow tablets whole (do not chew, crush, or dissolve).  
• Take one tablet at a time and with enough water to ensure complete swallowing immediately after placing in the mouth.  
• Dose once daily in moderate hepatic impairment with 100 mg per day maximum  
• Avoid use in severe hepatic and renal impairment. |
TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

| Specific Drug Interactions | • Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of tapentadol. • Contraindicated in patients taking MAOIs. |
| Use in Opioid-Tolerant Patients | No product-specific considerations. |
| Product-Specific Safety Concerns | • Risk of serotonin syndrome • Angioedema |
| Relative Potency To Oral Morphine | Equipotency to oral morphine has not been established. |

**Opana ER**

Oxymorphone Hydrochloride ER Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg

**Dosing Interval**

Every 12h dosing, some may benefit from asymmetric (different dose given in AM than in PM) dosing.

**Key Instructions**

• Use 5 mg every 12 hours as initial dose in opioid non-tolerant patients and patients with mild hepatic impairment and renal impairment (creatinine clearance < 50 mL/min) and patients over 65 years of age
• Swallow tablets whole (do not chew, crush, or dissolve).
• Take one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.
• Titrate in increments of 5 to 10 mg using a minimum of 3 to 7-day intervals.
• Contraindicated in moderate and severe hepatic impairment.

**Specific Drug Interactions**

Alcoholic beverages or medications containing alcohol may result in the absorption of a potentially fatal dose of oxymorphone.

**Use in Opioid-Tolerant Patients**

No product-specific considerations.

**Product-Specific Safety Concerns**

Use with caution in patients who have difficulty in swallowing or have underlying GI disorders that may predispose them to obstruction, such as a small gastrointestinal lumen.

**Relative Potency To Oral Morphine**

Approximately 3:1 oral morphine to oxymorphone oral dose ratio

**OxyContin**

Oxycodone Hydrochloride Extended-release Tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg

**Dosing Interval**

Every 12 hours
TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

<table>
<thead>
<tr>
<th>Key Instructions</th>
<th>◊ For Adults:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Initial dose in opioid-naïve and opioid non-tolerant patients is 10 mg every 12 hours.</td>
</tr>
<tr>
<td></td>
<td>• If needed, adult dosage may be adjusted in 1 to 2 day intervals.</td>
</tr>
<tr>
<td></td>
<td>• When a dose increase is clinically indicated, the total daily oxycodone dose usually can be increased by 25% to 50% of the current dose.</td>
</tr>
<tr>
<td></td>
<td>◊ For Pediatric patients (<strong>11 years and older</strong>): Use only in opioid-tolerant patients (see below, Use in Opioid-Tolerant Patients for dosing information).</td>
</tr>
<tr>
<td></td>
<td>◊ For all patients:</td>
</tr>
<tr>
<td></td>
<td>• Hepatic impairment: start with one third to one half the usual dosage</td>
</tr>
<tr>
<td></td>
<td>• Renal impairment (creatinine clearance &lt;60 mL/min): start with one half the usual dosage.</td>
</tr>
<tr>
<td></td>
<td>• Consider use of other analgesics in patients who have difficulty swallowing or have underlying GI disorders that may predispose them obstruction. Swallow tablets whole (do not chew, crush, or dissolve).</td>
</tr>
<tr>
<td></td>
<td>• Take onetabletatatime, withenoughwatertoenureswallowing immediately after placing in the mouth.</td>
</tr>
</tbody>
</table>

| Specific Drug Interactions | • CYP3A4 inhibitors may increase oxycodone exposure. |
|                          | • CYP3A4 inducers may decrease oxycodone exposure. |

| Use in Opioid-Tolerant Patients | ◊ For Adults: |
|                                | • Single dose greater than 40 mg or total daily dose greater than 80 mg are for use in adult patients in whom tolerance to an opioid of comparable potency has been established. |
|                                | ◊ For Pediatric patients (**11 years and older**): |
|                                | • For use only in opioid-tolerant pediatric patients already receiving and tolerating opioids for at least 5 consecutive days with a minimum of 20 mg per day of oxycodone or its equivalent for at least two days immediately preceding dosing with OxyContin. |
|                                | • If needed, pediatric dosage may be adjusted in 1 to 2 day intervals. |
|                                | • When a dose increase is clinically indicated, the total daily oxycodone dose usually can be increased by 25% of the current total daily dose. |

| Product-Specific Safety Concerns | • Choking, gagging, regurgitation, tablets stuck in the throat, difficulty swallowing the tablet. |
|                                | • Contraindicated in patients with gastrointestinal obstruction. |

| Relative Potency To Oral Morphine | Approximately 2:1 oral morphine to oxycodone oral dose ratio. |

| Targiniq ER | Oxycodone Hydrochloride / Naloxone Hydrochloride |
|            | Extended-release tablets, 10 mg/5 mg, 20 mg/10 mg, and 40 mg/20 mg |

<p>| Dosing Interval | Every 12 hours |</p>
<table>
<thead>
<tr>
<th><strong>TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)</strong></th>
<th></th>
</tr>
</thead>
</table>
| **Key Instructions** | **Vantrela ER**  
Hydrocodone Bitartrate  
Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg  
Dosing Interval  
Every 12 hours |
| • Opioid-naive patients: initiate treatment with 10 mg/5 mg every 12 hours.  
• Titrate using a minimum of 1 to 2 day intervals.  
• Do not exceed 80 mg/40 mg total daily dose (40 mg/20 mg q12) of Targiniq ER  
• May be taken with or without food.  
• Swallow tablets whole. Do not chew, crush, split, or dissolve, as this will release oxycodone, possibly resulting in fatal overdose, and naltrexone, possibly resulting in withdrawal symptoms.  
• Hepatic impairment: contraindicated in moderate and severe hepatic impairment. In patients with mild hepatic impairment, start with one third to one half the usual dosage.  
• Renal impairment (creatinine clearance < 60 mL/min): start with one half the usual dosage. | **Troxyca ER**  
Oxycodone Hydrochloride/Naltrexone Hydrochloride  
Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg  
Dosing Interval  
Every 12 hours |
| **Specific Drug Interactions** | **Use in Opioid-Tolerant Patients**  
Single dose greater than 40 mg/20 mg or total daily dose of 80 mg/40 mg are for use in opioid-tolerant patients only.  
**Product-Specific Safety Concerns**  
Contraindicated in patients with moderate to severe hepatic impairment.  
**Relative Potency To Oral Morphine**  
See individual product information for conversion recommendations from prior opioid.  
**Troxyca ER**  
Oxycodone Hydrochloride/Naltrexone Hydrochloride  
Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg  
Dosing Interval  
Every 12 hours |
| • CYP3A4 inhibitors may increase oxycodone exposure.  
• CYP3A4 inducers may decrease oxycodone exposure. |  |
| **Use in Opioid-Tolerant Patients** | **Product-Specific Safety Concerns**  
None  
**Relative Potency To Oral Morphine**  
See individual product information for conversion recommendations from prior opioid. |
| **Specific Drug Interactions** |  |
| • CYP3A4 inhibitors may increase oxycodone exposure.  
• CYP3A4 inducers may decrease oxycodone exposure. |  |
| **Use in Opioid-Tolerant Patients** |  |
| Single doses of greater than 40 mg/4.8 mg, or a total daily dose greater than 80 mg/9.6 mg are only for use in opioid-tolerant patients only. |  |
| **Product-Specific Safety Concerns** |  |
| None |  |
| **Relative Potency To Oral Morphine** |  |
| See individual product information for conversion recommendations from prior opioid. |  |
| **Vantrela ER**  
Hydrocodone Bitartrate  
Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg  
Dosing Interval  
Every 12 hours |  |
### TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics

(ER/LA opioid analgesics)

<table>
<thead>
<tr>
<th>Drug Information</th>
<th>Key Instructions</th>
<th>Specific Drug Interactions</th>
<th>Use in Opioid-Tolerant Patients</th>
<th>Product-Specific Safety Concerns</th>
<th>Relative Potency To Oral Morphine</th>
<th>Dosing Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Xtampza ER</strong></td>
<td>Opioid naïve and opioid nontolerant patients: Initiate with 9 mg every 12 hours. Dose can be increased from the current dose to the next higher dose every 3 to 7 days as needed.</td>
<td>CYP3A4 inhibitors may increase hydrocodone exposure. CYP3A4 inducers may decrease hydrocodone exposure.</td>
<td>A single dose greater than 36 mg or a total daily dose greater than 72 mg is for use in opioid-tolerant patients only.</td>
<td>None</td>
<td>See individual product information for conversion recommendations from prior opioid.</td>
<td>Every 12 hours</td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
<td>Every 12 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Key Instructions</strong></td>
<td>Titrate using a minimum of 1 to 2 day intervals. Take Xtampza ER capsules with the same amount of food in order to ensure consistent plasma levels are achieved. Maximum daily dose: 288 mg (8 x 36 mg capsules) because the safety of excipients has not been established for higher doses. For patients that have difficulty swallowing, Xtampza ER can also be taken by sprinkling the capsule contents on soft foods or into a cup and then administering directly into the mouth and swallowing immediately. Xtampza ER may also be administered through a gastrostomy or nasogastric feeding tube. Hepatic impairment: Initiate therapy at 1/3 to 1/2 the usual dosage. Renal impairment: (creatinine clearance &lt;60 mL/min): Follow a conservative approach to dose initiation and adjust according to the clinical situation.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
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<tr>
<td><strong>Product-Specific Safety Concerns</strong></td>
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</tr>
<tr>
<td><strong>Relative Potency To Oral Morphine</strong></td>
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</tr>
<tr>
<td><strong>Relative Potency To Oral Morphine</strong></td>
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</tr>
</tbody>
</table>

| **Zohydro ER** | Hydrocodone Bitartrate Extended-Release Capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg | | | | There are no established conversion ratios for conversion from other opioids to Xtampza ER defined by clinical trials | Every 12 hours |
| **Dosing Interval** | Every 12 hours | | | | | |
| **Key Instructions** | Initial dose in opioid non-tolerant patient is 10 mg. Titrate in increments of 10 mg using a minimum of 3 to 7 day intervals. Swallow capsules whole (do not chew, crush, or dissolve). | | | | | |
TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

| Specific Drug Interactions | • Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of hydrocodone.  
|                           | • CYP3A4 inhibitors may increase hydrocodone exposure.  
|                           | • CYP3A4 inducers may decrease hydrocodone exposure.  
| Use in Opioid-Tolerant Patients | Single dose greater than 40 mg or total daily dose greater than 80 mg are for use in opioid-tolerant patients only.  
| Product-Specific Safety Concerns | None  
| Relative Potency To Oral Morphine | Approximately 1.5:1 oral morphine to hydrocodone oral dose ratio.  


TABLE 11. PATIENT COUNSELING DOCUMENT ON EXTENDED-RELEASE / LONG-ACTING OPIOID ANALGESICS

Patient Name:  

The DOs and DON'Ts of Extended-Release / Long-Acting Opioid Analgesics

**DO:**  
- Read the Medication Guide  
- Take your medicine exactly as prescribed  
- Store your medicine away from children and in a safe place  
- Flush unused medicine down the toilet  
- Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Call 911 or your local emergency service right away if:**  
- You take too much medicine  
- You have trouble breathing, or shortness of breath  
- A child has taken this medicine

**Talk to your healthcare provider:**  
- If the dose you are taking does not control your pain  
- About any side effects you may be having  
- About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements

**DON'T:**  
- Do not give your medicine to others  
- Do not take medicine unless it was prescribed for you  
- Do not stop taking your medicine without talking to your healthcare provider  
- Do not break, chew, crush, dissolve, or inject your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.  
- Do not drink alcohol while taking this medicine

For additional information on your medicine go to:  

Patient Specific Information

Take this card with you every time you see your healthcare provider and tell him/her:  
- Your complete medical and family history, including any history of substance abuse or mental illness  
- If you are pregnant or are planning to become pregnant  
- The cause, severity, nature of your pain  
- Your treatment goals  
- All the medicines you take, including over-the-counter (non-prescription) medicines, vitamins, and dietary supplements  
- Any side effects you may be having  
- Take your opioid pain medicine exactly as prescribed by your healthcare provider.
American Pain Society; 1999.
pain. 2009.
95. Food and Drug Administration. Public Health Advisory: Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat. November 27.
100. VA/DoD. The management of opioid therapy for chronic pain. 2003(contract number: V101 (93)).
1. Extended-release (ER) and Long-acting (LA) formulations of opioids should typically not be used for which of the following?
   A. Treating cancer pain
   B. Treating acute pain
   C. Treating end-of-life pain
   D. Treating nociceptive pain

2. If an organic pathology cannot be found to explain a patient’s pain, what should a clinician infer?
   A. The pain is real, though unexplained
   B. The pain is psychosomatic
   C. The patient is seeking opioids for illegal use
   D. The pain is the result of a mental health condition

3. Which of the following is the appropriate use of “universal precautions” as it applies to patients with chronic pain?
   A. Exploring patients’ HIV status
   B. Having all patients submit to a screening urine toxicology test
   C. Being vigilant about the possibility of misuse or abuse with all patients
   D. Both B and C

4. The DIRE and the ORT are examples of which kind of assessment?
   A. Quantifying patients’ pain perceptions
   B. Assessing patient risk of opioid misuse or abuse
   C. Evaluating risk of physical adverse reactions to opioids
   D. Determining a reason for opioid pain medications

5. All of the following need to be documented in writing as part of an overall therapeutic approach to managing chronic pain patients EXCEPT:
   A. Informed consent
   B. Patient/provider agreements
   C. Treatment agreements
   D. Expected cost of prescribed medications

6. All of the following are possible advantages of patient/provider agreements EXCEPT:
   A. Provides a foundation for subsequent decisions about treatment termination
   B. Can help clinicians identify a patient’s level of risk for opioid abuse
   C. Can help avoid misunderstandings between provider and patient
   D. Can document informed consent

7. All of the following are examples of functional goals EXCEPT:
   A. Reduced anxiety about pain
   B. Walking around the block
   C. Increased sexual activity
   D. Returning to work

8. A fundamental part of ethical treatment for patients with chronic pain is:
   A. Assessing a patient’s risk for opioid use disorder
   B. Obtaining informed consent
   C. Proper insurance coverage
   D. Avoiding high doses of opioids

9. When opioid treatment is initiated, both the patient and clinician should view the commitment as:
   A. Short-term trial of therapy
   B. A long-term use of opioid therapy
   C. A titration of the opioid to reach optimal pain relief
   D. Continued therapy until adequate pain relief is achieved

10. It can be particularly unsafe to combine opioids with which of the following other medicines?
    A. Stimulant medications
    B. SSRI antidepressants
    C. Benzodiazepines or barbiturates
    D. Anti-hypertensive medications
11. Which class of antidepressant medications has been shown to be effective in treating some neuropathic pain conditions?
A. SNRIs
B. SSRIs
C. MAOIs
D. DNSIs

12. Combination products are those that include an opioid with which of the following elements?
A. Non-opioid coanalgesic
B. Non-opioid narcotic medication
C. Opioid antagonist to prevent abuse
D. Caffeine

13. In general, the amount of opioids prescribed for acute pain should be limited to a _____ day supply:
A. 1
B. 3
C. 7
D. 10

14. Uncomfortable or unpleasant side effects (aside from constipation) may potentially be reduced by which approach?
A. Switching to another opioid
B. Using adjunctive medications to treat symptoms
C. Changing the route of administration
D. All of the above

15. All of the following are valid reasons to pursue opioid rotation EXCEPT:
A. Lack of efficacy
B. Bothersome or unacceptable side effects
C. Desire to prevent the patient from illegally diverting opioids
D. Change in patient’s ability to absorb a medication in its present formulation

16. One reason that methadone must be prescribed with particular caution is that:
A. Methadone is only appropriate for opioid maintenance therapy programs
B. Methadone’s analgesic half-life is much shorter than its elimination half-life
C. Methadone has uniquely powerful respiratory depressive effects
D. Methadone may produce visual disturbances

17. Which of the following is not a potential benefit of urine drug testing?
A. May deter inappropriate use
B. Provides objective evidence of abstinence from drugs of abuse
C. May demonstrate to regulatory authorities a clinician’s dedication to patient monitoring
D. Can differentiate between specific opioid products that a patient may be using

18. All of the following are of particular concern when prescribing an ER/LA opioid pain medication EXCEPT:
A. Abuse by breaking, chewing, or crushing tablets
B. Risk of overdose if long-duration drugs are combined with short-acting medications
C. ER/LA medications tend to be costlier than short-acting formulations
D. Some opioids with ER/LA characteristics (i.e., methadone) may have atypical pharmacokinetics

19. In 2006, the FDA added a caution to the “black box” warning that methadone may cause which of the following serious adverse effects?
A. Respiratory depression
B. Cardiac conduction disturbances
C. Myoclonus
D. Renal failure

20. Which of the following is the APS-AAPM guideline regarding the prescription of opioids to pregnant women?
A. Avoid prescribing opioids unless potential benefits outweigh risks
B. Completely avoid prescribing opioids to this population
C. Prescribe ER/LA opioids rather than short-acting opioids to avoid spike exposure to fetus
D. Prescribe opioids as needed for maternal pain, but monitor infant after delivery for possible neonatal abstinence syndrome
OPIOIDS AND ACUTE PAIN

6.) Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4).

The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use (KQ5). Several guidelines on opioid prescribing for acute pain from emergency departments (192–194) and other settings (195,196) have recommended prescribing ≤3 days of opioids in most cases, whereas others have recommended ≤7 days (197) or <14 days (30). Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days (contextual evidence review), limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days’ supply will minimize the number of pills available for unintentional or intentional diversion.

Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. The lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and on other clinical factors such as renal or hepatic insufficiency (see Recommendation 8). Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days’ supply of opioids will be sufficient. For example, in one study of the course of acute low back pain (not associated with malignancies, infections, spondylarthropathies, fractures, or neurological signs) in a primary care setting, there was a large decrease in pain until the fourth day after treatment with paracetamol, with smaller decreases thereafter (198). Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Acute pain can often be managed without opioids. It is important to evaluate the patient for reversible causes of pain, for underlying etiologies with potentially serious sequelae, and to determine appropriate treatment. When the diagnosis and severity of nontraumatic, non-surgical acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids, often 3 days or less, unless circumstances clearly warrant additional opioid therapy. More than 7 days will rarely be needed. Opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere (30). Clinicians should not prescribe additional opioids to patients “just in case” pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly. Given longer half-lives and longer duration of effects (e.g., respiratory depression) with ER/LA opioids such as methadone, fentanyl patches, or extended release versions of opioids such as oxycodone, oxymorphone, or morphine, clinicians should not prescribe ER/LA opioids for the treatment of acute pain.

I-STOP/PMP
INTERNET SYSTEM FOR TRACKING OVER-PRESCRIBING

NYS PRESCRIPTION MONITORING PROGRAM REGISTRY
Effective August 27, 2013, most prescribers are required to consult the Prescription Monitoring Program (PMP) Registry when prescribing for Schedule II, III, and IV controlled substances. The PMP Registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients. The PMP is available 24 hours a day/7 days a week via an application on the Health Commerce System (HCS) at https://commerce.health.state.ny.us. Patient reports will include all controlled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past year. This information will allow practitioners to better evaluate their patients’ treatment with controlled substances and determine whether there may be abuse or nonomedical use.

PMP FOR PRACTITIONERS
Effective August 27, 2013, most prescribers are required to consult the PMP registry when writing prescriptions for Schedule II, III, and IV controlled substances. Practitioners may authorize designee(s) to check the registry on their behalf. Each prescriber and authorized designee(s) must have an individual Health Commerce System (HCS) account to gain access to the PMP.

PMP FOR VETERINARIANS
Veterinarians are specifically exempted from the requirement that the PMP Registry be consulted before prescribing or dispensing a controlled substance for a patient. Veterinarians and other dispensing practitioners are required to report controlled substance dispensing activity to the NYS DOH Bureau of Narcotic Enforcement (BNE) within 24 hours.

PMP FOR PHARMACISTS
Effective August 27, 2013, the PMP Registry is available to NYS licensed pharmacists. Each NYS licensed pharmacist must have an individual Health Commerce System (HCS) account to gain access to the PMP Registry. Pharmacists may apply now for their individual HCS account by accessing the link below.

HOW TO ADD AN UNLICENSED RESIDENT OR MEDICAL INTERN TO THE PMP DESIGNEE ROLE

AND A HCS USER TO THE PMP DESIGNEE REVIEWER ROLE AT MEDICAL TEACHING FACILITIES
Two new roles are currently available on the Health Commerce System (HCS) under the Hospital (pfi) organization: PMP DESIGNEE and PMP DESIGNEE REVIEWER. The PMP Designee role allows unlicensed residents/interns of a medical teaching facility to access the Prescription Monitoring Program (PMP) Registry on behalf of the institution. The PMP Designee Reviewer role allows employees of the medical teaching facility to monitor the use of the PMP application by unlicensed residents/interns. A HCS coordinator can assign unlicensed resident/interns with a HCS account to the PMP Designee role and hospital employees with a HCS account to the PMP Designee Reviewer role. Please note: Residents/interns working in multiple facilities need to be assigned to the PMP Designee role by a coordinator from each facility. See attached document for instructions to assign roles and get HCS accounts. (PDF, 395KB)

DUTY TO CONSULT--PRACTITIONERS
Practitioners must consider their patient’s information presented in the PMP Registry prior to prescribing or dispensing any controlled substance listed in Schedule II, III, or IV:

• The data considered by the practitioner must be obtained from the PMP Registry no more than 24 hours before the prescription is issued

EXCEPTIONS
• Practitioner administering a CS
• Prescribed for use within an institutional dispenser (does not include discharge, therapeutic leave, or other off-premise use)
• Prescribed within an ED attached to a general hospital (limited to 5 day supply)
• Hospice
• Technological failure of PMP or practitioner’s hardware
• Practitioner must take reasonable steps to correct the technological failure or limitation
• If consulting the PMP Registry would result in a patient’s inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient
• It is not reasonably possible to access the PMP, no other practitioner/designee may access for practitioner, AND the quantity prescribed is 5 days or less
• All three elements must be satisfied. Merely writing a 5 day prescription does not relieve a practitioner from having to check the PMP

PMP DATA SUBMISSION
Effective August 27, 2013, pharmacies are required to submit prescription data to BNE within 24 hours:
• Real Time” defined in PMP regulations After receiving these records, BNE Screens all records for critical errors;
• Rejects any record containing a critical error and notifies the submitter so it can be corrected;
• De-duplicates any identical records;
• Matches new record to existing patient records;
• Presents new record in PMP Registry

This process takes about 2 hours from when BNE receives the original record

Be aware of what your vendor is doing on your behalf:
• Check for data submission errors daily
• Understand the difference between a critical error—data will not display in the PMP until corrected and resubmitted to BNE—and a warning
• A new Submitter’s Guide to Electronic Data Transmission is available

Effective October 1, 2014, all data submitted to BNE must be submitted using the ASAP 4.2 standard of reporting:
• Affected Field Names include:
  • Date Sold
  • Species Code
  • Name of Animal
  • DEA Number Suffix

The following requirements are currently in effect for electronic prescriptions for controlled substances:
• Electronic Prescription Reference Number
• Electronic Prescription Order Number

**These come from the initiator of the prescription**
FREQUENTLY ASKED QUESTIONS (FAQ’S) PRESCRIPTION MONITORING PROGRAM

Q: What is the purpose of the Prescription Monitoring Program (PMP) Registry (formerly CSI)?
A: The Prescription Monitoring Program Registry provides practitioners and pharmacists with direct, secure access to view their patients’ recent controlled substance prescription history to help them better evaluate a patient’s treatment as it pertains to controlled substance prescribing and dispensing.

Effective August 27, 2013, practitioners will be required, with limited exceptions, to check the PMP Registry prior to writing a prescription for a controlled substance in schedule II, III, and IV for a patient. Pharmacists will have access to the PMP Registry after this date as well.

Q: Will pharmacists see the same information seen by practitioners?
A: Yes, if the pharmacist has an individual HCS account, he or she can access the same information when that patient presents a prescription for a controlled substance to the pharmacy.

Q: What are the benefits of the PMP Registry?
A: • The program allows for better understanding of a patient’s controlled substance utilization based on recent controlled substance prescription history.
  • Provides a quick, confidential online report to the practitioner and the pharmacist.
  • Available 24 hours a day, 7 days a week.
  • Information is based on controlled substance prescription data from nearly 5,000 pharmacies.
  • No cost to the practitioner or pharmacist.

Q: My patient appears on the Prescription Monitoring Program (PMP). Does this mean my patient is a “Doctor Shopper”?
A: Not necessarily. A PMP registry report indicates that your patient has received controlled substance prescriptions in the past six months. This report is intended to provide you access to your patient’s controlled substance prescription history for purposes of making treatment decisions. The information in this report is provided to help reasonably inform a practitioner when he or she is deciding whether or not to prescribe or dispense a controlled substance.

Q: Who can access the PMP Registry?
A: Any New York State licensed prescriber, excluding veterinarians, may access the PMP Registry. Each prescriber must have an individual Health Commerce System Account (HCS) to gain access. The application to establish an account for a licensed professional is available on the following website: https://hcsteamwork1.health.state.ny.us/pub/top.html

Important Note: Effective August 27, 2013, pharmacists will have access to the program and will need their own HCS accounts.

Q: I submitted for an HCS account, what happens next?
A: New accounts are usually established within two weeks. Once your application is processed you will be e-mailed documents. They must be printed, notarized and received by the Department of Health for your user ID to be issued. For account information or help with your HCS Account please contact Commerce Account Management Unit (CAMU) at 1-866-529-1890, option 1.

Q: I have an HCS account but do not know my user ID or password. Who should I contact?
A: For account information or help with your HCS Account please contact CAMU at 1-866-529-1890, option 1.

Q: My password expired, who should I contact?
A: For expired passwords please contact CAMU at 1-866-529-1890, option 1.

Q: Once I established an HCS account how do I access the PMP Registry?
A: • Go to the HCS at: https://commerce.health.state.ny.us
• Log onto the system with your user ID and password (If you can’t remember your password, call the Commerce Account Management Unit at 1-866-529-1890, Option 1, for assistance).
• Click on the NYS PMP Registry campaign button on the home page or select “Applications” at the top of the page. Click on the letter “P”.
• Scroll down to “Prescription Monitoring Program Registry”.

Q: Are any practitioners excluded from the requirement to consult the PMP prior to dispensing or prescribing?
A: Veterinarians are excluded. In addition, practitioners who are not veterinarians may be excluded if they meet the criteria defined within Section 3343-a Article 33 of the Public Health Law. Please review this section of the law, which may be accessed from the Bureau of Narcotic Enforcement’s web page; www.nyhealth.gov/
professionals/narcotic. Click on the link on the left hand side of the page for “Laws and Regulations” and follow the instructions on this page to get to Article 33.

Q: I am a practitioner working in a hospital that is licensed as a Class 3 Institutional Dispenser. Am I exempt from consulting the PMP?
A: The duty to consult the PMP Registry shall not apply to a practitioner prescribing or ordering a controlled substance for use on the premises of an institutional dispenser pursuant to Article 33.

Q: I am a practitioner working in a Nursing Home, Adult Home, Adult Assisted Living, correctional facility, etc. that is licensed as a Class 3A Institutional Dispenser Limited. Am I exempt from consulting the PMP?
A: The duty to consult the PMP Registry shall not apply to a practitioner prescribing or ordering a controlled substance for use on the premises of an institutional dispenser limited pursuant to Article 33.

Q: Do I need to consult the PMP Registry if the prescription was dispensed for administration on the premises of an institutional dispenser limited, but the patient leaves the premises at any time with that medication?
A: If the patient would be consuming the medication, at any time, off the premises then the PMP Registry must be consulted.

Q: My patient is under the care of hospice, am I exempt?
A: Yes, the duty to consult the PMP Registry shall not apply to a practitioner prescribing or ordering a controlled substance to a patient under the care of hospice.

Q: What if the power goes out? Am I limited to write for only a five-day supply of controlled substance?
A: No. You will conduct business as usual and document the relevant information in the patient’s chart, as required. The duty to consult the PMP Registry shall not apply to a situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure, as set forth in the regulations.

Q: If the power goes out am I required to document in the patient’s chart that I was unable to consult the PMP Registry?
A: Yes. All relevant information related to the technological failure must be documented in the patient’s chart.

Q: Are refills and partial-filled prescriptions listed in the report?
A: Yes. Dispensers are required to report refills and partial-filled prescriptions to the Department of Health.

Q: How current will the data be that is reflected on the PMP when the practitioner is required to consult the PMP?
A: Effective August 27, 2013, the data will be submitted to the Bureau on a “real time” basis as defined by the commissioner within the regulations.

Q: Why are my patients’ prescriptions not showing up on the PMP Registry?
A: The PMP Registry is based on controlled substance data submitted by pharmacies and dispensing practitioners. It may take up to 24 hours for the prescription to be visible in the PMP Registry. Please note: Section 80.73 Title 10 Rules and Regulations define the dispensing data that must be filed with the Bureau. Data may not display as expected in the PMP Registry due to the following factors:

- There could be a delay in the pharmacy or dispensing practitioner’s submission of data to the Bureau.
- There may have been errors generated during the pharmacy or dispensing practitioner’s data submissions, which require correction before the data will be displayed in the PMP Registry.
- The patient did not fill the prescription.
- The practitioner’s search criteria for the patient demographics (last name, first name, sex and DOB) does not match the pharmacy’s data submission for that patient.

Please note: when entering patient information on the PMP Registry, enter FIRST NAME then LAST NAME.

Q: Do I have to report to the Department that I reviewed my patient’s controlled substance history?
A: No.

Q: What is the “Drug Listing”? A: The “Drug Listing” tab in the horizontal menu at the top of the screen provides a reference of the brand names that are associated with the drug names shown on the Patient Search Results and lists the controlled substance schedule in New York State. Schedules of controlled substances are defined within section 3306 Article 33 of the Public Health Law. This information may be accessed from the Bureau of Narcotic Enforcement’s web page; www.nyhealth.gov/professionals/narcotic. Click on the link on the left hand side of the page for “Laws and Regulations” and follow the instructions on this page to get to Article 33.

Q: After reviewing the PMP for a patient, what do I do if I suspect diversion?
A: Please note a link on the bottom of the Confidential Drug Utilization Report to report a prescription discrepancy, or to send questions or comments about the report to the Bureau of Narcotic Enforcement. You may also contact the Bureau of Narcotic Enforcement office in your area to speak to a narcotic investigator.

- Albany/Central Office: (866) 811-7957 Opt. #2
- Western Area Regional Office (Buffalo Area): (716) 847-4532
- Rochester Office: (585) 423-8043
- Syracuse Office: (315) 477-8459
- New York City Metropolitan Area Regional Office: (212) 417-4103

Q: My patient is claiming identity theft. How should I direct him or her?
A: Identity theft should be reported to the local police department.

Q: How do I assist patients who want help for an addiction problem?
A: Treatment program information is available from the NYS Office of Alcoholism and Substance Abuse Services at www.oasas.ny.gov or by calling 1-877-846-7369. You may also access the Substance Abuse and Mental Health Services Administration (SAMHSA) website at www.buprenorphine.samhsa.gov to locate a participating opioid addiction physician in your area.

Q: As a physician, how do I become eligible to prescribe buprenorphine for opioid addiction?
A: You must qualify for a Drug Enforcement Administration (DEA) waiver. You can obtain more information at the Center for Substance Abuse Treatment (CSAT) at 1-866-287-2728 or www.buprenorphine.samhsa.gov.
Q: I have patients who receive Schedule II prescriptions which require a new prescription with each fill. Do I have to consult the PMP for the same patient each month when writing the same prescription?
A: Effective August 27, 2013, the duty to consult the PMP is required of the practitioner prior to prescribing or dispensing any controlled substance listed on schedule II, III or IV, regardless if it is the same patient being prescribed a controlled substance each month.

Q: Is there a distinction between immediate release and extended release products when viewing drugs on the PMP?
A: The PMP will display the drug and strength, but does not specify the dosage form.

Q: How can I integrate the PMP into our electronic health record or electronic prescribing software?
A: At this time, the PMP must be accessed through the Health Commerce System. The Department of Health is actively working on solutions to integrate the PMP Registry into electronic medical records.

Q: What is the difference between the “Printer Friendly” and “Extended” options for the Data Detail Level?
A: The “Printer-Friendly” level is intended to be printable in landscape mode on 8.5” x 11” paper. When the “Extended” option is selected, additional fields are included in the search results; including the Payment Method and the Dispenser. The results area can be scrolled horizontally and there is no guarantee regarding printability.

Q: What is the purpose of the “My DEA Numbers” tab?
A: The “My DEA Numbers” tab provides the option of entering one or more DEA numbers associated with the practitioner. It allows for separation of prescriptions associated with any of the entered DEA numbers from all other results on the Patient Search Results page. (My Prescriptions versus Other’s Prescriptions)

Q: Which DEA number should I use if I hold multiple registration numbers?
A: The DEA number associated with your prescriptions is the number that the dispenser submitted to the Department. You may enter all of your DEA numbers under the DEA listing tab. Patient Search results will be sorted by DEA number.

Q: What is the difference between “other’s prescriptions” and “my prescriptions”?
A: “Other’s prescriptions” reflect prescriptions written by another prescriber (other than you).

Q: Who do I contact if I didn’t write the prescription shown under “My Prescriptions”?
A: Use the link on the page to report a prescription error to the Bureau of Narcotic Enforcement. The link is located below your patient’s prescription information.

Q: How do I contact the other physician(s) for a consultation?
A: Practitioner information is public and can be researched from the following web site: http://www.nydoctorprofile.com/

Q: What will happen if I do not enter my DEA number in the “MY DEA Numbers” tab?
A: If you do not enter DEA number in the “MY DEA Numbers” tab, there will be no separation of prescriptions you wrote from prescriptions other prescribers wrote.

Q: Do I need to rerun the patient search after I enter my DEA number(s)?
A: Only if you want to see your prescriptions separate from other prescribers. The same data will be displayed; just the format of the data displayed will change.

Q: I entered my DEA number on the My DEA Numbers page, but made an error. Can I modify the entry?
A: Click on the check box next to your DEA Number and then click on “Remove”. Then enter the correct DEA number in the “Enter your DEA number” field.

Q: I changed my DEA number, how do I update this data in my HCS account?
A: To remove a DEA Number, click the check box next to it and click the “Remove” button. Multiple DEA numbers may be removed at the same time.

Q: Will the PMP display a patient’s controlled substance records for doctors within the same practice together?
A: No. The PMP will display a patient’s controlled substance records for the practitioner under “My Prescriptions”, provided that the practitioner entered his or her DEA number(s) using the “My DEA Numbers” menu option. The “My DEA Numbers” link is located in the horizontal menu at the top of the screen. All other controlled substance records for a patient, including records of prescriptions written by practitioners within the same practice, are grouped into “Other’s Prescriptions” on the PMP display.

Q: What is the “Update Personal Info” menu option for?
A: It is used to update Business contact information, emergency contact information, and professional information.

Q: Can I update my Physician Profile from the HCS account?
A: Yes, select the Applications Tab at the top of the page, select the letter “P” and scroll down to Physician Profile System.

Q: I received an “Access Denied” message with a link to Update Personal Info. Why am I being denied access to the PMP application?
A: The system was not able to validate your license number to allow access to the application because your license number is either missing from your HCS personal account information or your current license number needs to be added to your HCS personal account information. Please click on the link and update your license information. Once updated, you should be able to access the PMP application.

Q: I received an “Access Denied” message with a System Error Code of BNE8937. Why am I being denied access to the PMP application?
A: You are currently not allowed to access the PMP application because either your NYS license has expired or your license has an administrative action code on it. The PMP relies upon licensing data provided by the New York State Education Department (NYSED). Questions regarding the status of your license should be directed to NYSED.

Q: Why does my patient’s prescription information appear in ‘blocks’ or ‘groups’ on the Drug Utilization Review Screen?
A: The PMP utilizes matching criteria to determine if records for people with slight differences in demographic data could be for the same individual. The dispensed prescriptions are shown based on variations in the name, date of birth and address. Practitioners should compare patient name, date of birth and address in determining whether or not the different groups represent the same individual. For example, an address for the same patient may be similar, but the information will be grouped separately.
For example, information dispensed under an address of 33-33 Main St., may appear in a separate grouping from information dispensed under the address of 3333 Main St. Also note that if you entered your DEA numbers on the ‘My DEA Numbers’ tab, you will see the prescriptions you wrote for that patient grouped first, followed by those written by others, if any.

Q: How is the prescription data sorted?
A: Within each grouping, the information is sorted by date dispensed.

Q: Will I have to attest every time I access a patient’s information?
A: By clicking “Yes” on the Patient Search screen to advance the search, you are attesting to abide by the guidelines for use of the PMP in accordance with the New York State Public Health Law. You may view the guidelines by clicking the link at the top of the Patient Search screen.

Q. Where can I find the guidelines that I am attesting to?
A: The guidelines or attestation is accessible via a link on the Patient Search page.

Q. What is the purpose of the Search Terms Review page?
A: The Search Terms Review page allows you to review the entered search criteria and ensure its accuracy. You can choose either to complete the search by pressing “Continue”, or to fix any mistakes by pressing “Revise Search Terms”.

Q: What is the System Alert Message?
A: The System Alert Message will allow announcements to be made regarding

Source: Prescription Monitoring Program (PDF, 290KB) Frequently Asked Questions For The NYS PM Prescription Monitoring Program Registry Revised: February 2014
MANDATORY ELECTRONIC PRESCRIBING
EFFECTIVE MARCH 27, 2016

Practitioners are mandated to electronically prescribe both controlled and non-controlled substances effective March 27, 2016. However, there are a number of exceptions in which a practitioner may issue anOfficial New York State prescription (ONYSRx) form, oral prescription or a fax of an ONYSRx.

GENERAL INFORMATION: Amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances have been adopted and became effective as final regulations on March 27, 2013. The amendments authorize a practitioner to issue an electronic prescription for controlled substances in Schedules II through V and allow a pharmacist to accept, annotate, dispense and electronically archive such prescriptions.

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES REQUIREMENTS EPCS REQUIREMENTS
The amendments require the following:

- Computer applications utilized must meet federal security requirements. The federal requirements are included in the Drug Enforcement Administration Interim Final Rule regarding Electronic Prescriptions for Controlled Substances. The rule may be accessed via the U.S. Department of Justice DEA Office of Diversion Control website. Contact your software vendor to determine if your application meets the above-mentioned requirements. Click here for DEA Audit and Certification FAQs.
- Computer applications meeting federal security requirements must be registered with the Department of Health, Bureau of Narcotic Enforcement.
- To meet the New York State Public Health Law data submission requirements for electronic prescribing of controlled substances, the pharmacy must submit controlled substance dispensing data to the Department of Health, Bureau of Narcotic Enforcement, using the American Society for Automation in Pharmacy (ASAP) format Version 4.2 or greater.
- Pursuant to Public Health Law section 3302(37), an electronic prescription for controlled substances may only be issued in accordance with Department of Health regulations, as well as NYS Education Department regulations and federal requirements. NYS Education Department regulations may be accessed electronically.

On March 13, 2015, Governor Andrew M. Cuomo and the New York State Legislature amended the Public Health Law and the Education Law to extend the implementation date for mandatory electronic prescribing to March 27, 2016.

PRACTITIONER REGISTRATION FOR EPCS
If you have met all federal security requirements and would like to register the application with the Bureau of Narcotic Enforcement, access the online application called ROPES.
- Online registration process for practitioners (ROPES)
- Physician Assistant EPCS Registration (DOH-5121) (PDF)
- Instructions for Physician Assistant EPCS registration form

HOSPITAL REGISTRATION FOR EPCS
- Online registration process for hospitals (ROPES)
- Electronic Prescribing Important Notification to Hospitals — February 2015 (PDF)

PHARMACY REGISTRATION FOR EPCS
If you have met all federal security requirements and would like to register the application with the Bureau of Narcotic Enforcement, access the online application called ROPES.
- Online registration process for pharmacies (ROPES)
- Electronic Prescribing Important Notification to Pharmacies — October 2016 (PDF)

ELECTRONIC PRESCRIBING WAIVERS OR CERTIFICATIONS
WAIVER INFORMATION: Practitioners unable to electronically prescribe can either request a waiver from the requirement or submit a certification depending on their circumstance. Public Health Law (PHL) Section 281 (3) (c) states a waiver, or a renewal thereof, may be granted for a specified period determined by the Commissioner, not to exceed one year.

CERTIFICATION INFORMATION: Public Health Law (PHL) Section 281 (7) states a certification, or a renewal thereof, may be submitted by a practitioner issuing 25 prescriptions or less during a twelve month period.

EXCEPTIONS TO ELECTRONIC PRESCRIBING
The following circumstances allow a practitioner to issue an ONYSRx or oral prescription, for controlled or non-controlled substances. NOTE: The practitioner is not required to indicate the circumstance on the written or oral prescription. The pharmacist is not required to verify the reason for a written or oral prescription.

- Approved waiver from electronic prescribing+
- Nursing home or RHCF defined in Article 2801 of the Public Health Law
- Complicated directions
- Directions longer than 140 characters
- Compounded prescriptions containing two (2) or more products
- Compounded infusion prescriptions containing two (2) or more products
- A prescription containing certain elements required by the Federal Food and Drug Administration (FDA), such as an attachment
- Approved protocols under expedited partner therapy
- Approved protocols under collaborative drug management
- Response to a public health emergency that would allow a non-patient specific prescription
- Approved research protocol
- A non-patient specific prescription for an opioid antagonist
- Veterinarian
- Temporary technical failure
- Temporary electronic failure
- The prescription will be dispensed out-of-state, including federal installations such as Veteran Administration Facilities, Fort Drum & West Point
- Patient harm If the practitioner determines that an electronic prescription cannot be issued in a timely manner and that the patient’s condition is at risk

ADDITIONAL INFORMATION
- Letter from the NYS Commissioner of Health to practitioners and pharmacist regarding a blanket waiver for additional exceptional circumstances related to electronic prescribing – March 2, 2017
- Practitioner Notification Process — Use of an Electronic Prescribing Exception (Revised September 30, 2016)
Electronic Prescribing Exceptions – Dispensing Clarification for Pharmacists - April 2016

Letter from the NYS Commissioner of Health to practitioners and pharmacists regarding a blanket waiver for additional exceptional circumstances related to electronic prescribing – March 16, 2016 (PDF)

Letter to Practitioners Regarding Electronic Prescribing Mandate – November 2015 (PDF)

FAQs (PDF) - Updated November 2016 - Update to Practitioner Reporting Requirements 136-145

Information regarding e-prescribing of non-controlled substances – NYSED

New York State Regulations related to Electronic Prescribing of Controlled Substances

Specific regulations pertaining to issuing electronic prescriptions for controlled substances may be accessed in 10 NYCRR 80.64

U.S. Department of Justice DEA Office of Diversion Control website.

NYS Education Department regulations

SOURCE: https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/
Revised: March 2017
Q1: What is Electronic Prescribing of Controlled Substances or EPCS?
A1: Amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances have been adopted and became effective as final regulations on March 27, 2013. The amendments authorize a practitioner to issue an electronic prescription for controlled substances in Schedules II through V and allow a pharmacist to accept, annotate, dispense and electronically archive such prescriptions. A definition of an electronic prescription can be found in Section 3302 Article 33 Public Health Law. Click on the following link for Section 3302; Section 3302 Article 33 Public Health Law.

Q2: Is Electronic Prescribing mandatory for New York State practitioners?
A2: As of March 27, 2016 it will be mandatory for practitioners, excluding veterinarians, to issue electronic prescriptions for controlled and non-controlled substances. Electronic prescribing of controlled substances will require additional security features and registration of the certified software application with the Bureau of Narcotic Enforcement.

Q3: Why will electronic prescribing of controlled and non-controlled substances be mandatory effective March 27, 2016?
A3: New York Education Law Article 137 §6810 requires that all prescriptions be transmitted electronically three years from the Department of Health’s promulgating regulations allowing for the electronic prescribing of controlled substances. These regulations became effective on March 27, 2013. Utilizing modern prescribing technology has the potential to minimize medication errors for patients in New York State. Electronic prescribing also allows for the integration of prescription records directly into the patient’s electronic medical record. Electronic prescribing has the potential to reduce prescription theft and forgery.

Q4: Will the use of Official New York State Prescription forms be prohibited as of March 27, 2016?
A4: Official New York State Prescription forms may be used in the event of a power outage or technical failure, or by practitioners who meet one of the exceptions listed in Article 2A - Section 281 or Title 10 Part 80 Section 80.64. Please review this section of the law and regulations, which may be accessed from the following links: Article 2A - Section 281 and Title 10 Part 80 Section 80.64.

Q5: Should I return all of my unused Official New York State Prescription forms to BNE?
A5: Not necessarily. Under limited circumstances, the use of an Official NYS Prescription form will still be allowed, including events of a power outage or technological failure. However, it is unlikely that practitioners and institutions will need to continue to keep a similar inventory as in the past. Please consider the amount of prescription paper you will need to keep on hand, safeguard any stored Official New York State Prescription forms and return unneeded or unwanted forms to the Bureau of Narcotic Enforcement at 150 Broadway, Albany, NY 12204. The Bureau of Narcotic Enforcement will continue to supply Official New York State Prescription forms to practitioners and institutions.

Q6: I currently electronically prescribe non-controlled substances. Are there any additional steps I need to complete in order to electronically prescribe controlled substances?
A6: Yes.
- First, the software you currently use must meet all the federal security requirements for EPCS, which can be found on the Drug Enforcement Agency’s (DEA) web page. http://www.deadiversion.usdoj.gov/eComm/e_rx/
- Note that federal security requirements include a third party audit or DEA certification of the software.
- Second, you must complete the identity proofing process as defined in the federal requirements.
- Third, you must obtain a two-factor authentication as defined in the federal requirements.
- Fourth, you must register your DEA certified EPCS software with the Bureau of Narcotic Enforcement (BNE). Registration instructions are included in the FAQs.

Q7: Can I electronically prescribe controlled substances before it becomes mandated on March 27, 2016?
A7: EPCS became permissible in NYS on March 27, 2013. Practitioners can electronically prescribe controlled substances if:
- The EPCS software application meets all of the federal security requirements for EPCS, which can be found on the DEA’s web page. http://www.deadiversion.usdoj.gov/eComm/e_rx/
- Note that federal security requirements include a third party audit or DEA certification of the software.
- The practitioner has completed identity proofing as defined in the federal requirements and
- The practitioner has obtained a two-factor authentication as defined in the federal requirements and
- The practitioner has registered their DEA certified EPCS software application with the Bureau of Narcotic Enforcement (BNE). Please refer to the Registration instructions included below in the section titled “Registration for Official Prescriptions and E-prescribing Systems” or “Physician Assistant and Pharmacy EPCS Registration Form”, whichever is applicable.

Q8: If only 5 days or less of a controlled substance is prescribed, does the prescription need to be transmitted electronically?
A8: Yes. Any amount of controlled substances being prescribed requires the prescription to be transmitted electronically. An exception to this is that a paper or oral prescription may be issued for a controlled substance, that does not exceed a 5 day supply, ONLY if the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, AND such delay would adversely impact the patient’s medical condition.

Q9: Can a prescriber fax a prescription to a pharmacy after March 27, 2016?
A9: Yes, under very limited circumstances defined in Public Health Law (PHL) Section 281 (3) and The Commissioner of Health’s Letter, provided that the following criteria are met:
- a. Must be a fax of an original hard copy prescription;
- b. Must be manually signed by the prescriber; and
- c. If issued in NY, must be on an Official New York State Prescription form.
In most instances, faxed prescriptions for controlled substances must comply with requirements for oral prescriptions for controlled substances, including issuance of the follow-up prescription. A facsimile is not an electronic prescription and must bear a manual signature.
Q10: Will it be permissible for a NY practitioner to fax a prescription for a 30 day supply of a controlled substance for a patient in a Hospice Program or a RHCF to a NY pharmacy once e-prescribing becomes mandatory?
A10: No, unless the prescription is issued pursuant to one of the exceptions in the regulation, 10NYCRR Sec. 80.64. Fax ed prescriptions are not considered electronic prescriptions.

Q11: Is an electronic facsimile of a prescription considered an electronic prescription?
A11: No. A definition of an electronic prescription can be found in Section 3302 Article 33 Public Health Law and specifically states that a prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription. Click on the following link for Section 3302: Section 3302 Article 33 Public Health Law.

Q12: Is it permissible for an intermediary to convert an electronic prescription for a controlled substance to an electronic fax in the event of a transmission failure?
A12: At no time may an intermediary convert an electronic prescription for a controlled substance to facsimile for transmission to the pharmacy if the electronic transmission fails.

Q13: Is it permissible for an intermediary to convert a non-controlled substance prescription to an electronic fax in the event of a transmission failure of the electronic prescription?
A13: At no time may an intermediary convert an electronic prescription to a facsimile prescription for transmission to the pharmacy if the electronic transmission fails. Education Law, Section 6802 specifically excludes facsimiles from the definition of an electronic prescription. In order to be an acceptable prescription a facsimile must be issued on the Official New York State Prescription and contain a manual signature. In the event of a transmission failure, an intermediary may send a facsimile notification to the pharmacy. This notification will be for informational purposes only and is not considered a valid prescription.

Q14: I work for the Department of Veterans Affairs on federal property. Do I need to register my certified EPCS software application with BNE?
A14: No, practitioners who practice on federal property do not fall under the jurisdiction of New York State. However, a practitioner working on federal property who also practices off of federal property within New York State, the EPCS software application that is used off of federal property must be registered with BNE.

Q15: Can a practitioner who prescribes controlled substances electronically from multiple practice sites change the practice site address on the prescribing software or choose from multiple practices site addresses within the software to transmit the correct practice site address to the pharmacy?
A15: Practitioners should speak to their software vendor regarding the functionality around practice site addresses.

Q16: Will practitioners be required to issue electronic prescriptions for compounds containing a controlled substance ingredient as of March 27, 2016?
A16: BNE is aware that there may be system limitations due to the NCPDP script standard. Please monitor BNE’s webpage for more information.

Q17a: Will practitioners be required to electronically prescribe non-prescription items, including durable medical equipment?
A17a: No, an electronic prescription will not be required. Section 281 (1) of the Public Health Law specifically references the use of electronic prescriptions for prescription drugs only.

Q17b: If a third party payor requires a prescription for payment of non-prescription items, including durable medical equipment, can it be electronically prescribed?
A17b: Consult with your electronic prescribing software vendor to ascertain if the e-prescribing software is capable of transmitting these items correctly. If not, a written ONYSRx, manually signed, is permissible. A “failover” electronic fax is never permissible. The only acceptable facsimile is a manually signed ONYSRx.

Q18: Can an agent or employee of the prescriber create or prepare an electronic prescription?
A18: Yes. Education law 6802 and Sections 80.67 and 80.69 of Title 10 NYCRR Part 80 do not prohibit an agent of the practitioner from preparing an electronic prescription for his or her review and electronic signature.

Q19: Can an agent or employee of the prescriber electronically sign an electronic prescription?
A19: No. Practitioners are authorized to prescribe by virtue of his or her license to practice medicine or dentistry. Therefore, only the practitioner may review and sign the prescription.

Q20: Can an agent or employee of the prescriber transmit an electronic prescription to the pharmacy?
A20: The signing and transmission of an electronic prescription are two distinct actions. Only the practitioner may review and electronically sign the prescription. Once signed, an agent or employee of the practitioner may transmit the prescription on behalf of the practitioner. The act of transmission must be independent of the review and signature process.

Q21: Can a Physician Assistant electronically prescribe controlled and non-controlled substances?
A21: Yes. All electronic prescriptions issued and signed by a Physician Assistant must contain the name of their supervising physician.

Q22: Is the supervising physician’s name required on an electronic prescription issued by a physician assistant?
A22: Yes, the supervising physician’s name is required on all prescriptions (controlled and non-controlled substances) issued by a physician assistant, including electronic prescriptions, handwritten official prescriptions, and official prescriptions generated on an EMR system.

Q23: Can a physician assistant register for EPCs if their supervising physician does not?
A23: Yes. The supervising physician is not required to register for EPCs if they have no intention of electronically prescribing controlled substances. Note: Both the supervising physician and physician assistant must maintain active registrations for the Official Prescription Program.
Q24: Can an unlicensed resident, intern or foreign physician electronically prescribe controlled and non-controlled substances?  
A24: Yes. Please refer to 10 NYCRR 80.75 for further information.

Q25: Is a resident, intern or foreign physician's supervising physician/attending's name or signature required to be on an electronic prescription?  
A25: BNE does not require the supervising physician/attending’s name or signature to be on an electronic prescription, however third party payors or government programs may have additional requirements.

Q26: Are residents, interns and foreign physicians required to provide their DEA suffix when prescribing electronically?  
A26: Yes. 10 NYCRR Part 80 §80.75(e) provides the authority for residents, interns and foreign physicians to use the DEA registration number of the institution by whom they are employed and they must include the suffix assigned by the institution to prescribe and dispense controlled substances (may be up to 21 characters).

Q27: Is an attending physician that oversees residents, foreign physicians, and interns required to register for EPCS?  
A27: The attending physician is not required to register for EPCS if they have no intention of electronically prescribing controlled substances.

Q28: Are unlicensed medical residents required to register their EPCS software with BNE?  
A28: No. The facility must maintain a current list of unlicensed residents with prescriptive privileges within the facility who have been authorized to access the facility’s EPCS software. This information must be available to BNE upon request.

Q29: Does a practitioner still have to consult the Prescription Monitoring Program (PMP) Registry when e-prescribing?  
A29: Yes. The practitioner must consult the PMP Registry prior to prescribing a controlled substance in Schedules II-IV regardless of how the prescription is issued.

Q30: I am not licensed or practicing in New York, but have a patient who uses a pharmacy in New York. Do I have to register my certified EPCS software application with BNE to send electronic prescriptions for controlled substances to pharmacies in the state of New York?  
A30: Practitioners who are not practicing in New York State are not required to register their certified EPCS software application with BNE. They must follow the state’s law and regulations.

Q31: Can I send an electronic prescription for a controlled substance to an out-of-state pharmacy?  
A31: You may or may not be able to depending upon the laws of that state. The pharmacy must dispense the prescription following the laws of the state in which the prescription is being dispensed.

Q32: I don't have a DEA number, therefore, I don't prescribe controlled substances. Do I have to register the software application used to electronically prescribe non-controlled substances with BNE?  
A32: There is no current requirement to register E-prescribing software applications that only transmit non-controlled substance prescriptions. However, all prescriptions must be issued electronically unless an exception applies.

Q33: I am a veterinarian and would like to electronically prescribe controlled substances. What should I do?  
A33: Practitioners issuing electronic prescriptions for controlled substances must use a software application that meets all DEA (federal) security requirements, which includes a third party audit or DEA certification indicating that all federal requirements are met. The New York State Department of Health requires practitioners licensed in New York State issuing electronic prescriptions for controlled substances to register their certified EPCS software application with BNE.

Q34: Regulations (Title 10 NYCRR Part 80 §§80.67 and §80.69 ) require that the quantity of the dosage units must be indicated in both numerical and written word form on an Official New York State prescription (ONYSRx). Does this pertain to electronic prescriptions as well?  
A34: No. While a quantity is required on all prescriptions, both the “numerical and written word form” are required to be on the ONYSRx form only. The intention of including both formats on the ONYSRx is to prevent alteration of the quantity on a written prescription.

Q35: Regulations (Title 10 NYCRR Part 80 §§80.67 and §80.69 ) allow a practitioner to issue a prescription for greater than a 30 day supply of a controlled substance for certain conditions by specifying either the name of the condition, or the condition code, in accordance with codes designated in these sections, on the prescription. Is it mandatory for pharmacies to receive electronic prescriptions for emergency oral prescriptions for a schedule II controlled substance?  
A35: A practitioner may use the notes field on the electronic prescription to indicate an approved condition or its corresponding code. A practitioner may also name the condition as part of the directions to the patient (sig. field).

Q36: Is the phrase “Authorization for Emergency Dispensing” required on the follow-up prescription for an emergency oral prescription for a schedule II controlled substance?  
A36: Both 21 CFR Part 1300 §1306.11 (d) (4) and New York Public Health Law Article 33 §3334(3) require the phrase “Authorization for Emergency Dispensing” on follow-up prescriptions for emergency oral prescriptions for Schedule II controlled substances.

Q37: Does an electronic prescription for a controlled substance require a written follow-up prescription to be sent to the pharmacy?  
A37: No. The electronic prescription is the prescription and does NOT require a hard copy follow up prescription.

Q38: Is it mandatory for pharmacies to receive electronic prescriptions for controlled substances?  
A38: No. However, it will be mandatory for practitioners, with some exceptions, to issue electronic prescriptions for both controlled and non-controlled substances effective March 27, 2016.
Q39: What are the practitioner and pharmacist responsibilities in the event of a transmission failure of an electronic prescription for a controlled substance?
A39: The responsibilities of the practitioner and the pharmacist with regard to failed transmission of an electronic controlled substance prescription may be found in detail in 10 NYCRR Part 80 Sections 80.67, 80.69, 80.73 and 80.74.

Q40: What should I do if I am notified that the security of my certified EPCS software application is noncompliant with federal requirements?
A40: If your EPCS software application no longer meets federal security requirements, your software shall NOT be used to process electronic prescriptions for controlled substances until your software is in compliance with DEA requirements and you re-register the software application with BNE.

Q41: What should I do if my credentials used to sign electronic prescriptions have been lost, stolen or compromised?
A41: In addition to any federal requirements, practitioners must immediately notify BNE that his or her credentials have been lost, stolen or compromised. Please send an email to narcotic@health.state.ny.us with the subject of credentials lost, stolen or compromised or call BNE’s toll free number (866-811-7957, Option 1).

Q42: What should I do if I suspect or am notified of a security breach with my certified EPCS software application?
A42: If there has been a security breach, you may not process electronic prescriptions for controlled substances. You must notify the DEA and BNE. After security has been restored, you must re-register the certified software application with BNE.

Q43: What is the difference between the third party audit or certification required by the DEA and the registration that BNE requires?
A43: Practitioners and pharmacies processing electronic prescriptions for controlled substances must use a software application that meets all DEA (federal) security requirements, which includes a third party audit or DEA certification indicating that all federal requirements are met. The New York State Department of Health does not certify software applications. However, practitioners and pharmacies licensed in New York State processing electronic prescriptions for controlled substances are required to register their certified EPCS software application with BNE.

Q44: Why do I need to register my certified EPCS software application with the Bureau of Narcotic Enforcement (BNE)? My software vendor already notified BNE.
A44: Each individual practitioner and pharmacy, not the software vendor, is required by regulation to register their certified EPCS software application with BNE.

Q45: My pharmacy is NOT physically located in New York, however, it is registered with the New York State Board of Pharmacy. Are we required to register our certified pharmacy software application with BNE to process electronic prescriptions for controlled substances received from practitioners in the state of New York?
A45: Yes, non-resident pharmacies registered with the New York State Board of Pharmacy must register their certified pharmacy software application with BNE to receive electronic prescriptions for controlled substances.

Q46: My pharmacy is NOT located in New York. We are NOT registered with the New York State Board of Pharmacy. Do we have to register our certified pharmacy software application with BNE to process electronic prescriptions for controlled substances received from practitioners in the state of New York?
A46: No, pharmacies located outside of New York State that are NOT registered with the New York State Board of Pharmacy are not required to register their certified software applications with BNE.

Q47: If a pharmacy does not dispense controlled substances, does their computer system have to be certified to meet the DEA security standards?
A47: No. Computer systems only need to be certified that they meet the DEA security standards if they will be used to dispense controlled substances.

Q48: Can pharmacies receive electronic prescriptions for controlled substances from practitioners before it becomes mandated on March 27, 2016?
A48: Yes, EPCS became permissible in New York State on March 27, 2013. The pharmacy can receive electronic prescriptions for controlled substances provided that it has met the following requirements:
• The pharmacy software application meets all of the federal security requirements included in the DEA’s Interim Final Rule.
• The pharmacy can submit controlled substance prescription data to BNE using ASAP version 4.2.
• The certified pharmacy software application is registered with BNE.

Q49: Can I accept an out-of-state electronic prescription for a controlled substance?
A49: A pharmacist may dispense a controlled substance medication pursuant to an out-of-state electronic prescription as defined in Section 80.78 Title 10 Part 80 Rules and Regulations on controlled substances. Electronic prescriptions may be created, signed and transmitted from another state, provided the practitioner complies with all requirements, state and federal, for issuing controlled substance prescriptions electronically. It is prudent on the part of the pharmacist to verify the authenticity of any controlled substance prescription presented to them.

Q50: Is the prescription valid for dispensing if the practitioner has not registered their certified EPCS application with BNE?
A50: Yes. The prescription is valid for dispensing if the practitioner has not registered their certified EPCS software application with BNE and the prescription meets all other federal and State requirements. Pharmacists are not expected to verify that a practitioner has registered their application with BNE.

Q51: Can a pharmacy accept an electronic prescription as a follow-up to an oral prescription?
A51: Yes. A pharmacy may accept an electronic prescription as a follow-up to an oral prescription. It is incumbent on the pharmacist to know the limitations of their software application and if it can accurately accept and archive an electronic follow-up prescription. If the software application cannot do this, a paper prescription is necessary and permissible. This should be communicated to the practitioner at the time the prescription is called in, and the need for the follow-up is discussed.
Q52: Certain elements may be changed or added to a controlled substance prescription by a pharmacist with practitioner authorization. If a prescription is sent electronically that requires information to be added or changed, how should the information be added to the electronic prescription?
A52: Information added/changed on an electronic prescription must be annotated and maintained electronically. Pharmacists should consult their software vendor or corporate headquarters for guidance to ensure annotation meets all federal requirements. The process of annotating a prescription may vary based on the software used.

Q53: How does a pharmacist annotate an electronic prescription?
A53: Pharmacists should consult their software vendor or corporate headquarters for guidance to ensure annotation meets all federal requirements. The process of annotating a prescription may vary based on the software used.

Q54: Certain elements may NOT be changed or added to a controlled substance prescription. If a prescription is sent electronically that requires correction that cannot be made by a pharmacist with practitioner authorization, and the patient has an immediate need for the controlled substance, can the prescriber call in a 5 day emergency supply?
A54: In instances where the pharmacist may NOT add or change information, the pharmacist may use their professional judgment and call the practitioner to obtain an oral prescription, or request a new electronic prescription with the correct information after first canceling the incorrect original prescription. Click here for a reference regarding what a pharmacist may add/change on a controlled substance prescription.

Q55: Can a pharmacist add or clarify a condition code by calling the prescriber?
A55: Yes. The pharmacist shall write the date he or she received the oral authorization on the prescription and affix his or her signature. In the event of an electronic prescription, the pharmacist shall annotate and retain the same information in the electronic record.

Q56: Can a pharmacist fill a prescription for a controlled substance that does not contain the maximum daily dose (MDD)?
A56: Pharmacists must exercise professional judgement when determining if clarification from the practitioner is necessary when a MDD is not included on a prescription. Pharmacists may call the practitioner and add the MDD to the prescription with practitioner authorization. However, omission of the MDD does not render the prescription invalid for dispensing.

Q57: May a pharmacist accept an Official New York State Prescription written prior to March 27, 2016?
A57: Yes. The prescription is written on an Official New York State Prescription form prior to the effective date of the statute.

Q58: May a pharmacist dispense an authorized refill from an Official New York State Prescription issued prior to March 27, 2016?
A58: Yes. The prescription, issued on an Official New York State Prescription form, with refills was written prior to the effective date of the statute.

Q59: Is a pharmacist who is presented with a prescription issued on Official New York State Prescription form after March 27, 2016 required to verify that the practitioner properly falls under one of the exceptions from the requirement to electronically prescribe?
A59: No. However, a corresponding liability for the proper prescribing and dispensing of controlled substances rests with the pharmacist who fills the prescription.
LIMIT INITIAL OPIOID PRESCRIBING TO A 7 DAY SUPPLY FOR ACUTE PAIN

NEW LEGISLATION ENACTED TO LIMIT INITIAL OPIOID PRESCRIBING TO A SEVEN DAY SUPPLY FOR ACUTE PAIN

To further reduce overprescribing of opioid medications, effective July 22, 2016, initial opioid prescribing for acute pain is limited to a seven (7) day supply. A practitioner may not initially prescribe more than a 7-day supply of an opioid medication for acute pain. Acute pain is defined as pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. This rule shall not include prescribing for chronic pain, pain being treated as a part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices. Upon any subsequent consultations for the same pain, the practitioner may issue, in accordance with existing rules and regulations, any appropriate renewal, refill, or new prescription for an opioid.

The Department of Health will communicate a date in the near future when this will be systematically enforced by the Medicaid Fee-for-Service Program. The following procedure is being put in place until such time that the Department is able to implement an automated solution to exempt copayments for such subsequent opioid prescriptions.

If a prescriber initiates a subsequent prescription for the same pain medication within 30 days of the initial 7-day supply, and the pharmacist is notified and/or confirms this upon reviewing the patient’s prescription history or utilizing ProDUR editing, the following may be used to exempt copayments for such subsequent opioid prescriptions.

- In NCPDP field 461-EU, enter a value “04” (Exempt Copay and/or Coinsurance)

Although pharmacists should continue to use all of the tools at their disposal when dispensing opioid prescriptions, pharmacists are not required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with the above-referenced statutory requirements. Pharmacists may continue to dispense opioids as prescribed, consistent with current laws, regulations, and Medicaid policies. For guidance regarding a pharmacist’s ability to add/change information on a controlled substance prescription, see 10 NYCRR 80.677 and 80.69 @ http://www.health.ny.gov/professionals/narcotic/laws_and_regulations/

Additional information on opioids and this legislation can be found at the Bureau of Narcotic Enforcement website at: https://www.health.ny.gov/professionals/narcotic/ or by contacting the Bureau of Narcotic Enforcement at 1-866-811-7957. For billing questions please contact the eMedNY Call Center at 1-800-343-9000. Questions specific to Medicaid Fee-For-Service policy can be directed to ppno@health.ny.gov or by calling 518-486-3209.

LIMITED INITIAL OPIOID PRESCRIBING - FAQ

Q. Are all opioid prescriptions limited to a seven-day supply?
A. No. Effective July 22, 2016, the 7-day supply limit applies to opioid prescriptions at an initial consultation or treatment for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue, in accordance with existing rules and regulations, any appropriate renewal, refill or new prescription for an opioid.

Q. How is acute pain defined?
A. Acute pain is defined as “pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. Such term shall not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices.”

Q. Does the 7-day supply opioid prescribing limit apply to patients suffering from chronic pain?
A. No. The limited quantity for opioid prescribing affects acute pain not chronic pain.

Q. Can a pharmacist dispense/fill a prescription for a 30-day supply of an opioid?
A. Yes. Although pharmacists may continue to use all of the tools at their disposal when dispensing opioid prescriptions, pharmacists are not required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with statutory requirements. Pharmacists may continue to dispense opioids as prescribed, consistent with current laws and regulations. Within the scope of the practitioner’s professional opinion or discretion, the limited quantity for opioid prescribing affects the initial consultation or treatment for acute pain only. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill or new prescription for the opioid or any other drug.

Q. How will a pharmacist know that a 30-day supply opioid prescription is not for initial treatment of acute pain?
A. The pharmacist may not know. It is within the scope of the practitioner’s professional opinion or discretion to prescribe a limited quantity of an opioid for the initial consultation or treatment for acute pain. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill or new prescription for the opioid or

Q. Is it necessary for the patient to visit the practitioner after receiving the initial 7-day supply for acute pain, if an additional prescription is necessary to continue treatment?
A. No. After the initial examination of the patient has been completed, the frequency and necessity for future examinations, prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient’s condition, history and disposition toward the use of controlled substances.

Q. Are refills allowed on the initial 7-day supply prescription for a schedule CIII, CIV or CV opioid that was issued for acute pain?
A. Yes. The new legislation does not prohibit refills for the initial prescription for schedules CIII, CIV or CV.

Q. Where does a pharmacist obtain educational material regarding the dangers of misuse, and the potential for addiction to prescription controlled substances, treatment resources available, and the proper way to dispose of unused prescription controlled substances to provide to the patient?
A. This section of the law becomes effective October 20, 2016 (120 days), please monitor the Bureau’s web page for updates.

Q. Where should questions regarding insurance co-payments pertaining to follow-up prescriptions for the initial 7-day supply be directed?
A. Questions regarding commercial insurance should be referred to the New York State Department of Financial Services (DFS) at 1-800-342-3736 or http://www.dfs.ny.gov/about/contact.htm
KEY FINDINGS

DELIVERY OF PERSON-CENTERED, FAMILY-ORIENTED CARE

- People nearing the end of life often experience multiple transitions between health care settings—including high rates of apparently preventable hospitalizations—which can fragment the delivery of care and create burdens for patients and families.
- Demand for family caregiving is increasing, and the types of tasks performed by family caregivers are expanding from personal care and household tasks to include medical and nursing tasks, such as medication management.
- Palliative care is associated with a higher quality of life, including better understanding and communication, access to home care, emotional and spiritual support, well-being and dignity, care at time of death, and lighter symptom burden. Some evidence suggests that, on average, palliative care and hospice patients may live longer than similarly ill patients who do not receive such care.
- Although professional guidelines and expert advice increasingly encourage oncologists, cardiologists, and other disease-oriented specialists to counsel patients about palliative care, widespread adoption of timely referral to palliative care appears slow.

CLINICIAN–PATIENT COMMUNICATION AND ADVANCE CARE PLANNING

- Most people nearing the end of life are not physically, mentally, or cognitively able to make their own decisions about care. The majority of these patients will receive acute hospital care from physicians who do not know them. Therefore, advance care planning is essential to ensure that patients receive care reflecting their values, goals, and preferences.
- Of people who indicate end-of-life care preferences, most choose care focused on alleviating pain and suffering. However, because the default mode of hospital treatment is acute care, advance planning and medical orders are needed to ensure that these preferences are honored.
- Frequent clinician–patient conversations about end-of-life care values, goals, and preferences are necessary to avoid unwanted treatment. However, most people—particularly younger, poorer, minority, and less-educated individuals, do not have these conversations. Clinicians need to initiate conversations about end-of-life care choices and work to ensure that patient and family decision making is based on adequate information and understanding.
- Incentives, quality standards, and system support are needed to promote improved clinician communication skills and more frequent and productive clinician–patient conversations.

PROFESSIONAL EDUCATION AND DEVELOPMENT

- The establishment of specialty practice in hospice and palliative medicine is a major improvement in the education of health professionals. Three problems remain: (1) insufficient attention to palliative care in medical and nursing school curricula; (2) educational silos that impede the development of interprofessional teams; and (3) deficits in equipping physicians with sufficient communication skills.
- Health professionals are not always adequately prepared to deliver “basic” or “primary” palliative care to patients who are not currently hospitalized or do not require specialty palliative care.

POLICIES AND PAYMENT SYSTEMS

- Incentives under fee-for-service Medicare result in more use of services (hospital days, intensive care, emergency care), more transitions among care settings, and late enrollment in hospice, all of which jeopardize the quality of end-of-life care and add to its costs. In addition, payment silos contribute to fragmentation of care, hinder coordination across providers, and encourage inappropriate utilization.
- Programs that integrate health care and long-term social services may reduce hospitalizations and health care costs while improving patients’ quality of life. Successful models of these programs, including methods for ensuring financial sustainability, need to be implemented more broadly.
- Palliative care services, including hospice, improve patient outcomes and may reduce health care costs by lessening use of acute care services. Changes are needed throughout the health care system to incentivize provision of comprehensive palliative care.
- Quality standards and measures are needed to ensure that changes in payment systems, particularly those occurring under the Patient Protection and Affordable Care Act, do not adversely affect quality of care for patients at the end of life.

PUBLIC EDUCATION AND ENGAGEMENT

- Need for public education and engagement about end-of-life care issues is manifest at the societal, community/family, and individual levels. Not only do most Americans lack knowledge about end-of-life care choices, but the health community and other leaders also have not fully utilized strategies to make that knowledge available, meaningful, and relevant across diverse population groups.
- Efforts are needed to normalize conversations about death and dying. Several social trends suggest that the time is right for a national dialogue on this issue, including health care consumers’ motivation to pursue high-quality care for themselves and their loved ones; a growing willingness to share stories about end-of-life care experiences that resonate across diverse groups; and emerging leadership in local communities as well as national coalitions and collaborations.

RECOMMENDATIONS

RECOMMENDATION 1: DELIVERY OF CARE

Government health insurers and care delivery programs, as well as private health insurers, should cover the provision of comprehensive care for individuals with advanced serious illness who are nearing the end of life. Comprehensive care should

- be seamless, high-quality, integrated, patient-centered, family-oriented, and consistently accessible around the clock;
- consider the evolving physical, emotional, social, and spiritual needs of individuals approaching the end of life, as well as those of their family and/or caregivers;
- be competently delivered by professionals with appropriate expertise and training;
- include coordinated, efficient, and interoperable information transfer across all providers and settings; and
- be consistent with individuals’ values, goals, and informed preferences.

Health care delivery organizations should take the following steps to provide comprehensive care:

- All people with advanced serious illness
should have access to skilled palliative care or, when appropriate, hospice care in all settings where they receive care (including health care facilities, the home, and the community).

- Palliative care should encompass access to an interdisciplinary palliative care team, including board-certified hospice and palliative medicine physicians, nurses, social workers, and chaplains, together with other health professionals as needed (including geriatricians). Depending on local resources, access to this team may be on site, via virtual consultation, or by transfer to a setting with these resources and expertise.

- The full range of care that is delivered should be characterized by transparency and accountability through public reporting of aggregate quality and cost measures for all aspects of the health care system related to end-of-life care. The committee believes that informed individual choices should be honored, including the right to decline medical or social services.

**RECOMMENDATION 2: CLINICIAN–PATIENT COMMUNICATION AND ADVANCE CARE PLANNING**

Professional societies and other organizations that establish quality standards should develop standards for clinician–patient communication and advance care planning that are measurable, actionable, and evidence based. These standards should change as needed to reflect the evolving population and health system needs and be consistent with emerging evidence, methods, and technologies. Payers and health care delivery organizations should adopt these standards and their supporting processes, and integrate them into assessments, care plans, and the reporting of health care quality. Payers should tie such standards to reimbursement, and professional societies should adopt policies that facilitate tying the standards to reimbursement, licensing, and credentialing to encourage

- all individuals, including children with the capacity to do so, to have the opportunity to participate actively in their health care decision making throughout their lives and as they approach death, and receive medical and related social services consistent with their values, goals, and informed preferences;
- clinicians to initiate high-quality conversations about advance care planning, integrate the results of these conversations into the ongoing care plans of patients, and communicate with other clinicians as requested by the patient; and
- clinicians to continue to revisit advance care planning discussions with their patients because individuals’ preferences and circumstances may change over time.

**RECOMMENDATION 3: PROFESSIONAL EDUCATION AND DEVELOPMENT**

Educational institutions, credentialing bodies, accreditating boards, state regulatory agencies, and health care delivery organizations should establish the appropriate training, certification, and/or licensure requirements to strengthen the palliative care knowledge and skills of all clinicians who care for individuals with advanced serious illness who are nearing the end of life. Specifically,

- all clinicians across disciplines and specialties who care for people with advanced serious illness should be competent in basic palliative care, including communication skills, interprofessional collaboration, and symptom management;
- educational institutions and professional societies should provide training in palliative care domains throughout the professional’s career;
- accreditating organizations, such as the Accreditation Council on Graduate Medical Education, should require palliative care education and clinical experience in programs for all specialties responsible for managing advanced serious illness (including primary care clinicians);
- certifying bodies, such as the medical, nursing, and social work specialty boards, and health systems, should require knowledge, skills, and competency in palliative care;
- state regulatory agencies should include education and training in palliative care in licensure requirements for physicians, nurses, chaplains, social workers, and others who provide health care to those nearing the end of life;
- entities that certify specialty-level health care providers should create pathways to certification that increase the number of health care professionals who pursue specialty-level palliative care training; and
- entities such as health care delivery organizations, academic medical centers, and teaching hospitals that sponsor specialty level training positions should commit institutional resources to increasing the number of available training positions for specialty-level palliative care.

**RECOMMENDATION 4: POLICIES AND PAYMENT SYSTEMS**

Federal, state, and private insurance and health care delivery programs should integrate the financing of medical and social services to support the provision of quality care consistent with the values, goals, and informed preferences of people with advanced serious illness nearing the end of life. To the extent that additional legislation is necessary to implement this recommendation, the administration should seek and Congress should enact such legislation. In addition, the federal government should require public reporting on quality measures, outcomes, and costs regarding care near the end of life (e.g., in the last year of life) for programs it funds or administers (e.g., Medicare, Medicaid, the Department of Veterans Affairs). The federal government should encourage all other payment and health care delivery systems to do the same. Specifically, actions should

- provide financial incentives for medical and social support services that decrease the need for emergency room and acute care services,
- coordination of care across settings and providers (from hospital to ambulatory settings as well as home and community), and
- improved shared decision making and advance care planning that reduces the utilization of unnecessary medical services and those not consistent with a patient’s goals for care;
- require the use of interoperable electronic health records that incorporate advance care planning to improve communication of individuals’ wishes across time, settings, and providers, documenting (1) the designation of a surrogate/decision maker, (2) patient values and beliefs and goals for care, (3) the presence of an advance directive, and (4) the presence of medical orders for life-sustaining treatment for appropriate populations; and
- encourage states to develop and implement a Physician Orders for Life-Sustaining Treatment (POLST) paradigm program in accordance with nationally standardized core requirements.
Medical and social services provided should accord with a person’s values, goals, informed preferences, condition, circumstances, and needs, with the expectation that individual service needs and intensity will change over time. High-quality, comprehensive, person-centered, and family-oriented care will help reduce preventable crises that lead to repeated use of 911 calls, emergency department visits, and hospital admissions, and if implemented appropriately, should contribute to stabilizing aggregate societal expenditures for medical and related social services and potentially lowering them over time.

**RECOMMENDATION 5: PUBLIC EDUCATION AND ENGAGEMENT**

Civic leaders, public health and other governmental agencies, community-based organizations, faith-based organizations, consumer groups, health care delivery organizations, payers, employers, and professional societies should engage their constituents and provide fact-based information about care of people with advanced serious illness to encourage advance care planning and informed choice based on the needs and values of individuals. Specifically, these organizations and groups should

- use appropriate media and other channels to reach their audiences, including underserved populations;
- provide evidence-based information about care options and informed decision making regarding treatment and care;
- encourage meaningful dialogue among individuals and their families and caregivers, clergy, and clinicians about values, care goals, and preferences related to advanced serious illness; and
- dispel misinformation that may impede informed decision making and public support for health system and policy reform regarding care near the end of life.

In addition,

- health care delivery organizations should provide information and materials about care near the end of life as part of their practices to facilitate clinicians’ ongoing dialogue with patients, families, and caregivers;
- government agencies and payers should undertake, support, and share communication and behavioral research aimed at assessing public perceptions and actions with respect to end-of-life care, developing and testing effective messages and tailoring them to appropriate audience segments, and measuring progress and results; and
- health care professional societies should prepare educational materials and encourage their members to engage patients and their caregivers and families in advance care planning, including end-of-life discussions and decisions.

All of the above groups should work collaboratively, sharing successful strategies and promising practices across organizations.
NOTES
NYS DOH PALLIATIVE CARE
PALLIATIVE CARE INFORMATION ACT

INTRODUCTION
Effective February 9, 2011, Chapter 331 of the Laws of 2010 (commonly known as the Palliative Care Information Act) amends the Public Health Law by adding section 2997-c, which requires physicians and nurse practitioners to offer terminally-ill patients information and counseling concerning palliative care and end-of-life options. Under the law, information and counseling concerning palliative care and end-of-life options must be offered only to patients with an illness or condition that is reasonably expected to cause death within six months. Palliative care, as defined by the law, is “health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient’s quality of life, including hospice care.”

The law is intended to ensure that patients are fully informed of the options available to them when they are faced with a terminal illness or condition, so that they are empowered to make choices consistent with their goals for care, and wishes and beliefs, and to optimize their quality of life. The law is not intended to limit the options available to terminally-ill patients. Nor is it intended to discourage conversations about palliative care with patients whose life expectancy exceeds six months. As discussed below, it is often appropriate to discuss palliative care with patients earlier in the disease progression.

PLEASE NOTE: The Palliative Care Information Act has been amended. Effective January 14, 2013, “attending health care practitioners” will be required to offer to provide information and counseling to terminally ill patients regarding “other appropriate treatment options should the patient wish to initiate or continue treatment.” This is in addition to the current requirement to offer to provide information and counseling regarding prognosis; the range of options, including palliative care and end-of-life options, appropriate to the patient; risks and benefits of options; and pain management. Please review the questions and answers below for further information.

SUMMARY OF THE LAW
Public Health Law section 2997-c requires the “attending health care practitioner” to offer to provide patients with a terminal illness with information and counseling regarding palliative care and end-of-life options appropriate to the patient, including:

- Prognosis;
- Range of options appropriate to the patient;
- Risks and benefits of various options;
- Patient’s “legal rights to comprehensive pain and symptom management at the end of life.”

The information and counseling may be provided orally or in writing.

- The attending health care practitioner may arrange for information and counseling under this section to be provided by another professionally qualified individual.
- If the attending health care practitioner is “not willing to provide the patient with information and counseling,” he/she must arrange for another physician or nurse practitioner to do so, or must “refer or transfer the patient to another physician or nurse practitioner.”

When the patient lacks medical decision-making capacity, the information and counseling must be provided to the person who has authority to make health care decisions for the patient.

DEFINITIONS

“APPROPRIATE” means consistent with applicable legal, health and professional standards; the patient’s clinical and other circumstances; and the patient’s reasonably known wishes and beliefs.

“ATTENDING HEALTH CARE PRACTITIONER” means a physician or nurse practitioner who has primary responsibility for the care and treatment of the patient. Where more than one physician or nurse practitioners share that responsibility, each of them has responsibility under this section, unless they agree to assign that responsibility to one of them.

“PALLIATIVE CARE” means health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient’s quality of life, including hospice care under article forty of [the Public Health Law].

“TERMINAL ILLNESS OR CONDITION” means an illness or condition which can reasonably be expected to cause death within six months, whether or not treatment is provided.

PALLIATIVE CARE ACCESS ACT
Palliative Care Requirements for Hospitals, Nursing Homes, Home Care and Assisted Living Residences (Enhanced and Special Needs)

INTRODUCTION
On April 1, 2011, Governor Cuomo signed into law Chapter 59 of the Laws of 2011, which added Section 2997-d to the Public Health Law, now commonly known as the Palliative Care Access Act (“PCAA”). It imposes certain requirements on hospitals, nursing homes, home care agencies and two types of assisted living residences (enhanced and special needs) regarding palliative care. It becomes effective on September 27, 2011.

The PCAA expands upon the requirements of the Palliative Care Information Act (“PCIA”) which took effect on February 1, 2011. The PCAA requires physicians and nurse practitioners to offer information and counseling about palliative care to patients with a terminal illness.

THE “PCAA” BUILDS UPON THE “PCIA” IN THE FOLLOWING WAYS:

1. It applies directly to health care facilities, home care agencies, and assisted living residences, as well as individual practitioners;
2. It applies to patients/residents with “advanced life limiting conditions or illnesses who might benefit from palliative care” and not just those who are terminally ill;
3. It requires, not only an offer of information and counseling, but also that the covered health care provider or residence “facilitate access to appropriate palliative care consultation and services, including associated pain management consultations and services.”

Like the PCIA, the PCAA is intended to ensure that patients are fully informed of the options available to them when they are faced with a serious illness or condition, so that they are empowered to make choices consistent with their goals for care, and wishes and beliefs, and to optimize their quality of life. The law is not intended to limit the options available to patients. Nor is it intended to discourage conversations about palliative care with patients who have distressing symptoms and serious conditions, but do not technically fall within the law’s requirements. Patients and providers should recognize that palliative care and disease-modifying therapies are not mutually
exclusive. Patients may opt to pursue palliative care while also pursuing aggressive treatment. Palliative care may be provided together with life-prolonging or curative care or as the main focus of care.

**SUMMARY OF THE LAW**

Public Health Law section 2997-d requires that hospitals, nursing homes, home care agencies, special needs assisted living residences, and enhanced assisted living residences, provide access to information and counseling regarding options for palliative care appropriate to patients with advanced life limiting conditions and illnesses. These providers and residences must also facilitate access to appropriate palliative care consultation and services, including associated pain management consultation and services, consistent with the patient needs and preferences. When the patient or resident lacks capacity to make medical decisions, the provider or residence must have policies so that access to such information and counseling will be provided to the persons who are legally authorized to make medical decisions on behalf of such patients or residents.

**STATUTORY DEFINITIONS**

“**APPROPRIATE**” means consistent with applicable legal, health and professional standards; the patient’s clinical and other circumstances; and

“**Palliative care**” means health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient’s quality of life, including hospice care under article forty of [the Public Health Law].

**LINKS FOR NEW YORK STATE PALLIATIVE CARE**

- Palliative Care
- Palliative Care Information Act (PDF, 19KB, 3pg.)
- Questions and Answers About Palliative Care, Hospice, and the Palliative Care Information Act
- Resources for Practitioners
- Palliative Care Access Act (PHL Section 2997-d): Palliative Care Requirements for Hospitals, Nursing Homes, Home Care and Assisted Living Residences (Enhanced and Special Needs)
MOLST is generally for patients with serious health conditions. Physicians should consider consulting with the patient about completing a MOLST form if the patient:
- Wants to avoid or receive life-sustaining treatment.
- Resides in a long-term care facility or requires long-term care services.
- Might die within the next year.

These instructions and checklists are intended to assist health care professionals in completing the MOLST form with adult patients and/or the patients’ authorized health care decision-makers. They are NOT intended for use with minor patients, or patients with developmental disabilities who lack medical decision-making capacity, or patients with mental illness in a mental hygiene facility.

GENERAL INSTRUCTIONS

The MOLST form must be completed based on the patient’s current medical condition, values, wishes, and these MOLST instructions. Completion of the MOLST begins with a conversation or a series of conversations between the patient, the health care agent or the surrogate, and a qualified, trained health care professional that defines the patient’s goals for care, reviews possible treatment options on the entire MOLST form, and ensures shared, informed medical decision-making. The conversation should be documented in the medical record. The patient or other medical decision-maker must consent to the MOLST orders, with the exception of patients covered by Checklist #4 (for adult hospital or nursing home patients without medical decision-making capacity who do not have a health care proxy or a Public Health Law surrogate).

Although the conversation(s) about goals and treatment options may be initiated by any qualified and trained health care professional, a licensed physician must always, at a minimum: (i) confer with the patient and/or the patient’s health care agent or surrogate about the patient’s diagnosis, prognosis, goals for care, treatment preferences, and consent by the appropriate decision-maker, and (ii) sign the orders derived from that discussion. If the physician is licensed in a border state, the physician must insert the abbreviation for the state in which he/she is licensed, along with the license number.

Completion of both the first and second pages of the MOLST form is strongly encouraged. However, the patient or decision-maker (i.e., a health care agent or surrogate) may not be physically or emotionally prepared to reach a decision concerning every treatment option on the form in a single meeting. Completion of only page 1 of the MOLST form (concerning CPR/DNR) is permissible, and page 2 (Section E) may be completed at a later time. If a patient or decision-maker can reach a decision on one or more treatment options, but not others, on page 2, the physician may cross out the portion of the form with the treatment option(s) for which there is no decision and write “Decision Deferred” next to those treatment option(s). If the patient or decision-maker reaches a decision concerning that treatment option(s) at a later time, a new form must be completed and signed by a physician, indicating all of the patient’s or decision-maker’s decisions.

Verbal orders are acceptable with a follow-up signature by a NYS licensed physician or a border state physician in accordance with facility/community policy. Verbal orders must be authenticated within 48 hours under Medicare and Medicaid hospital conditions of participation.

Printing the form on bright “pulsar” pink, heavy stock paper is strongly encouraged. When EMS personnel respond to an emergency call in the community, they are trained to check whether the patient has a pink MOLST form before initiating life-sustaining treatment. They might not notice a MOLST form on plain white paper. However, white MOLST forms and photocopies, faxes, or electronic representations of the original, signed MOLST are legal and valid.

MOLST orders completed in accordance with New York law remain valid when the patient transitions from one health care setting to another. Non-hospital DNR orders must be reviewed by a physician at least every 90 days. In addition, all MOLST orders must be reviewed consistent with facility policy and when the patient transitions between care settings, when there is a major change in health status, and when the patient or other health care decision-maker changes his/her mind about treatment.

Decision-making standards, procedures and statutory witness requirements for decisions to withhold or withdraw life-sustaining treatment, including DNR, vary depending on who makes the decision and where the decision is made.
Accordingly, there are different checklists for different types of decision-makers and settings.

Please note: There are 5 different checklists for adult patients:

**CHECKLIST #1** - Adult patients with medical decision-making capacity (any setting)

**CHECKLIST #2** - Adult patients without medical decision-making capacity who have a health care proxy (any setting)

**CHECKLIST #3** - Adult hospital or nursing home patients without medical decision-making capacity who do not have a health care proxy, and decision-maker is Public Health Law Surrogate (surrogate selected from the surrogate list)

**CHECKLIST #4** - Adult hospital or nursing home patients without medical decision-making capacity who do not have a health care proxy and for whom no surrogate from the list is available

**CHECKLIST #5** - Adult patients without medical decision-making capacity who do not have a health care proxy, and the MOLST form is being completed in the community

Choose the correct checklist. Then, complete the clinical steps and legal requirements based on who makes the decision and the setting. The checklists can be found on the Department of Health’s website at: http://www.nyhealth.gov/professionals/patients/patient_rights/molst/.

**REVIEW AND RENEWAL OF MOLST ORDERS**

The physician must review the MOLST form from time to time as the law requires, and also:

- If the patient moves from one location to another to receive care; or
- If the patient has a major change in health status (for better or worse); or
- If the patient or other decision-maker changes his or her mind about treatment.

If the patient lacks capacity to make health care decisions, the Health Care Agent or Surrogate may request a change in the MOLST and must be consulted about any changes recommended by the patient’s health care provider when any of the above circumstances arise.

**DNR/ALLOW NATURAL DEATH ORDERS:** Public Health Law requires the physician to review non-hospital DNR orders and record the review at least every 90 Days. In hospitals and nursing homes, MOLST orders must be reviewed regularly in accordance with facility policies.

**LIFE-SUSTAINING TREATMENT ORDERS:**

- If the patient has a major change in health status, medical decision-making capacity, goals for care or preferences that results in a change in MOLST orders, write “VOID” in large letters on pages 1 and 2, and complete a new form, in accordance with NYS Public Health Law decision-making standards and procedures. Check box marked “FORM VOID, new form completed”. (RETAIN voided MOLST form in chart, medical record, or electronic registry as required by law.)
- If there is no change in the patient’s health status, medical decision-making capacity or preferences, sign, date and check the “No Change” box.
- If there is a substantial change in patient’s health status, medical decision-making capacity, goals for care or preferences that results in a change in MOLST orders, write “VOID” in large letters on pages 1 and 2, and complete a new form, in accordance with NYS Public Health Law decision-making standards and procedures. Check box marked “FORM VOID, new form completed”. (RETAIN voided MOLST form in chart, medical record, or electronic registry as required by law.)

**GLOSSARY**

“Adult” means any person 18 or older or any person who has married.

“Clear and convincing evidence” is evidence that the patient held a firm and settled commitment to the withholding of life-sustaining treatment in the event of circumstances like the patient’s current medical condition. The evidence may be in a written living will, and/or previous oral statements indicating the patient’s wishes, considering the circumstances under which such statements were made and to whom. In order to decide whether the evidence of the patient’s wishes is clear and convincing, consideration should be given to:

- whether the statements were general or specific;
- whether the statements were about specific circumstances (for example, terminal illness, persistent vegetative state) that are similar to the patient’s current medical condition;
- the intensity, frequency, consistency, and seriousness of such statements;
- whether the statements tended to show that the patient held a firm and settled commitment to certain treatment decisions under circumstances like those presented;
- whether the strength and durability of the patient’s religious and moral beliefs make a more recent change of heart unlikely; and
- whether the statements were made to one person only or to more than one person close to the patient.

“Close friend” is any person 18 or older who is a friend or relative of the patient. This person must have maintained regular contact with the patient; be familiar with the patient’s activities, health, and religious or moral beliefs; and present a signed statement to that effect to the attending doctor.

“Community” means not in a hospital or nursing home.

“Domestic partner” means a person who:
- has entered into a formal domestic partnership recognized by a local, state or national government; or
- has registered as a domestic partner with a registry maintained by the government or an employer; or
- is covered as a domestic partner under the same employment benefits or health insurance; or
- shares a mutual intent to be a domestic partner with the patient, considering all the facts and circumstances, such as:
  - They live together.
  - They depend on each other for support.
  - They share ownership (or a lease) of their
- home or other property.
- They share income or expenses.
- They are raising children together.
- They plan on getting married or becoming formal domestic partners.
- They have been together for a long time.

The following may not be a “domestic partner:”
- A parent, grandparent, child, grandchild, brother, sister, uncle, aunt, nephew or niece of the patient or the patient’s spouse.
- A person who is younger than 18.

“Health or social service practitioner” means a registered professional nurse, nurse practitioner, physician, physician assistant, psychologist or licensed clinical social worker, licensed or certified pursuant to the Education Law and acting within his or her scope of practice. A health or social service practitioner who determines that a patient lacks medical decision-making capacity must be competent to do so, based on his/her experience and training.

“Hospital” means a general hospital as defined in subdivision ten of section twenty-eight hundred one of the Public Health Law, excluding a ward, wing, unit or other part of a general hospital operated for the purpose of providing services for persons with mental illness pursuant to an operating certificate issued by the New York State Office of Mental Health; or a hospice as defined in Public Health Law Article 40, without regard to where the hospice care is provided.

“Life-sustaining treatment” means any medical treatment or procedure without which the patient will die within a relatively short time, as determined by an attending physician to a reasonable degree of medical certainty. Cardiopulmonary resuscitation (CPR) is presumed to be life-sustaining treatment without the necessity of a determination by an attending physician.

“Mental hygiene facility” means, for purposes of these checklists, a facility operated or licensed by the Office of Mental Health (OMH) or the Office for People With Developmental Disabilities (OPWDD) as defined in subdivision six of section 1.03 of the Mental Hygiene Law; i.e., any place in which services for the mentally disabled are provided and includes but is not limited to a psychiatric center, developmental center, institute, clinic, ward, institution or building, except that in the case of a hospital as defined in article 28 of the Public Health Law it shall mean only a ward, wing, unit, or part thereof which is operated for the purpose of providing services for the mentally disabled. A mental hygiene facility also includes a community residence operated by or subject to licensure by OMH or OPWDD (MHL § 1.03 (28)).

“Nursing home” means a residential health care facility as defined in subdivision three of section twenty-eight hundred one of the Public Health Law.

“Physician” means a licensed physician.

“Qualified psychiatrist” means a physician licensed to practice medicine in New York State, who is a diplomate or eligible to be certified by the American Board of Psychiatry and Neurology or who is certified by the American Osteopathic Board of Neurology and Psychiatry or is eligible to be certified by that board.

“Reasonably available” means that a person to be contacted, can be contacted with diligent efforts by an attending physician, another person acting on behalf of an attending physician, or the hospital or nursing home.
NOTES
VERIFIED CERTIFICATES AND LEARNER RECORDS

1. **Important:** To ensure accurate record keeping and reporting, your personal information entered at the beginning of the assessment should match your license record.

2. **Why we collect this info:** We use this information to uniquely identify each individual who successfully completes our activities and verify learner records for professional credentialing.

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REMINDER TO NOTIFY THE DEPARTMENT OF HEALTH WHEN YOU COMPLETE THE COURSE:

Please note Practitioners must notify the Department that they have completed the educational requirement by submitting an attestation form. The form, as well as FAQs and additional information, will soon be available on the BNE website.

SOME FREQUENTLY ASKED QUESTIONS

MANDATORY PRESCRIBER EDUCATION

Attestation of Completion to DOH (NEAT)

**QUESTION:** How will the Department of Health (DOH) know the required course work or training has occurred?

**ANSWER:** Prescribers must attest to the completion of a minimum three hours of course work or training in all eight topic areas. A prescriber with a Health Commerce System (HCS) account will attest online using the Narcotic Education Attestation Tracker (NEAT) application. Prescribers without an HCS account may obtain one by visiting https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/docs/hcs_application_instructions.pdf. Prescribers that do not have access to a computer can request a paper attestation form by calling the Bureau of Narcotic Enforcement (BNE) toll-free at 1-866-811-7957. They may then complete the form and return it by mail to the address provided.

**QUESTION:** When does the attestation for the completion of course work or training for the mandatory education need to be submitted to DOH?

**ANSWER:** Prescribers must attest to the completion of the course work or training by July 1, 2017, and again every three years thereafter.

**QUESTION:** Can the mandatory course work or training in pain management, palliative care, and addiction count towards the continuing education required by the New York State Education Department (SED)?

**ANSWER:** The mandatory course work or training in pain management, palliative care, and addiction requirement may possibly count towards the continuing education required for registration in your specific profession. Please reference the SED website http://www.op.nysed.gov/prof/ for your specific profession.

**QUESTION:** How often is a prescriber required to complete course work or training in pain management, palliative care, and addiction?

**ANSWER:** A prescriber must complete course work or training in pain management, palliative care, and addiction every three years after the first attestation.

**QUESTION:** Are veterinarians licensed in New York and who have a DEA registration number to prescribe controlled substances required to complete course work or training in pain management, palliative care, and addiction?

**ANSWER:** No, veterinarians licensed and who have a DEA registration number to prescribe controlled substances in New York are not required by PHL §3309-a to complete course work or training in pain management, palliative care, and addiction. Veterinarians may have other educational or training requirements. For more information, please contact the New York State Education Department, Office of the Professions, State Board of Veterinary Medicine at vetmedbd@nysed.gov.

Additionally, all prescribers should be sure to check for updates @:

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement
www.health.ny.gov/professionals/narcotic
SELF-ASSESSMENT ANSWER SHEET

NEW YORK MANDATORY PRESCRIBER EDUCATION COURSE

To Receive Credit: Please ensure information entered matches your license record and all required fields are accurately completed. For help see the previous page.

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SPECIALTY: 

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☐ OR 

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PRESCRIBER EDUCATION FOR EXTENDED-RELEASE AND LONG-ACTING OPIOID ANALGESICS (42-43)


Turn information in online or by following these easy steps:

1. Complete the customer information and self assessment on this page
2. Complete the survey on the backside of this page
3. Tear out page and mail this sheet in the self-addressed envelope find inside program

IMPORTANT
PLEASE REMEMBER TO COMPLETE SURVEY ON THE BACK OF THIS FORM

PROGRAM CODE: NY3CME 

For internal use only

Phone: 1-800-237-6999 • Fax: 1-800-647-1356
ACTIVITY EVALUATION(S)

For each of the objectives determine if the activity increased your:  A Competence  B Performance  C Outcome  D No Change

PRESCRIBER EDUCATION FOR EXTENDED-RELEASE AND LONG-ACTING OPIOID ANALGESICS:

1. Assessing Patients for Treatment with ER/LA Opioid Analgesic Therapy ........................................... A B C D
2. Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioid Analgesics .......................................................... A B C D
3. Managing Therapy with ER/LA Opioid Analgesics .......................................................... A B C D
4. Counseling Patients and Caregivers about the Safe Use of ER/LA Opioid Analgesics .......................................................... A B C D
5. General Drug Information for ER/LA Opioid Analgesic Products .......................................................... A B C D
6. Specific Drug Information for ER/LA Opioid Analgesic Products .......................................................... A B C D
7. Have you prescribed ER/LA opioids in the past twelve months? .......................................................... Y N
8. Please identify a specific change, if any, you will make in your practice related to prescribing ER/LA opioid analgesics?

________________________________________________________________________

9. What do you see as a barrier to making these changes?

________________________________________________________________________

PROGRAM EVALUATION:

10. The program was balanced, objective & scientifically valid .......................................................... A B C D
11. Do you feel the program was scientifically sound & free of commercial bias or influence? .......................................................... A B C D
12. How can this program be improved?

________________________________________________________________________

13. Based on your educational needs, please provide us with suggestions for future program topics & formats

________________________________________________________________________

NYS INFECTION CONTROL MANDATORY TRAINING:

For individuals who are required by law to report their completion of approved course work in infection control and barrier precautions:

14. Have you Completed Approved course work during your current 4 year licensure period? .......................................................... Y N
15. What type of course format do you prefer for this type of training? .......................................................... DISTANT LEARNING L LIVE
16. If you would like us to provide you with approved course material via mail or email, please indicate here:

☐ Yes, please send me Approved Course material for Infection Control training.

PROGRAM CODE: NY3CME
CUSTOMER SERVICE

We maintain a fully-staffed educational service center that physicians and course participants can contact Monday through Friday, 8:30 AM to 5:30 PM (EST) by calling toll-free at 1-800-237-6999. Physicians can speak directly with our educational support personnel to request course materials, have tests graded, receive interactive training and interpretation of course materials, request duplicate certificates and resolve problems.

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MANDATORY PRESCRIBER EDUCATION COURSE
3 HOUR REQUIREMENT IN PAIN MANAGEMENT, PALLIATIVE CARE, AND ADDICTION

Must be completed within 12 months of DEA registration for NYS Prescribers