



State of Utah
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

160 East 300 South, P.O. Box 146741
Salt Lake City, Utah 84114-6741
Telephone (801) 530-6628
www.dopl.utah.gov

**CONTROLLED SUBSTANCE PRESCRIBERS CONTINUING EDUCATION COURSE APPROVAL
REQUEST**

(Note: Microsoft Word users can fill in the blanks, print the form and save it for their records)

COURSE INFORMATION		
Course Name:		
Institute Providing Course:		
Mailing Address:		
City:	State:	Zip:
Phone #:	E-Mail:	

CONTACT PERSON INFORMATION		
Contact Person:		Telephone:
Address of Contact Person:		
City:	State:	Zip:
Alternate Contact Person:		Telephone:
Address of Contact Person:		
City:	State:	Zip:

AFFIDAVIT	
I attest the Course meets and educates in all content areas of the State of Utah and REMS required criteria.	
I attest the Course requires and provides the full time frame of 3.5 hours of education for prescribing practitioners.	
I attest the Course requires and provides the full time frame of 2 hours of education for Dentists.	
I attest the examination cannot be taken until the full time frame of educational hours has been taught.	
Signature of Applicant:	Date:

ACCREDITATION – Submit copy of all accreditations.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Course is designated for AMA PRA Category 1 credit.
If no, list Accreditation Provider:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Course meets other prescribing practitioner professions continuing education guidelines and has been accredited.

DO NOT WRITE IN THIS SECTION - FOR DIVISION USE ONLY
Course Approved: _____
Date Approved/Denied: ___/___/___ by _____
Reason for Denial/Other Comments: _____

UTAH COURSE REQUIREMENTS	
Please provide proof your program meets the State of Utah required criteria	
<i>Page #/ Section</i>	<i>In the Box to the left of the required information, list the page number or section where the information is found in your Course.</i>
	Program begins after January 1, 2014.
	Are prepared and presented by individuals who are qualified by education, training and experience to provide the controlled substance Prescribers continuing education.
	Program provides a method of verification of attendance and maintains records for future verification of course completion.
	Includes a post course knowledge assessment and examination.
The Controlled Substance Prescribing Course addresses:	
	The scope of the controlled substance abuse problem in Utah and the nation.
	Content about opioid narcotics, hypnotic depressants, and psychostimulants.
	All elements of the FDA Blueprint for Prescribers Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published July 9, 2012, or as it may be subsequently revised.
	The national and Utah-specific resources available to Prescribers to assist in appropriate controlled substance and opioid prescribing.
	Patient record documentation for controlled substance and opioid prescribing.
	Office policies, procedures, and implementation.
The Controlled Substance Prescribing Course:	
	Has a pain specialist which helped developed the educational content for the program?
	Name of pain specialist:
	Is an in-person course.
	Is an on-line course.

REMS COURSE REQUIREMENTS	
Please provide proof your program meets the REMS required criteria	
<i>Page #/ Section</i>	<i>In the Box to the left of the required information, list the page number or section where the information is found in your Course.</i>
I. Assessing Patients for Treatment with ER/LA Opioid Analgesic Therapy	
	Prescribers should consider risks involved with ER/LA opioid analgesics and balance these against potential benefits. Risks include:
	1. Overdose with ER/LA formulations, as most dosage units contain more opioid than immediate-release formulations.
	2. Abuse by patient or household contacts.
	3. Misuse and addiction.
	4. Physical dependence and tolerance.
	5. Interactions with other medications and substances (See REMS table in Section VI for specific information).
	6. Inadvertent exposure by household contacts, especially children.
	Prescribers should assess each patient's risk of abuse, including substance use and psychiatric history. Prescribers should:
	1. Obtain a complete history and conduct a complete physical examination, including assessment of family history of substance abuse and psychiatric disorders, as well as special considerations for the elderly and children. A history of substance abuse does not prohibit treatment with ER/LA opioid analgesics but may require additional monitoring and expert consultation.
	2. Be knowledgeable about risk factors for opioid abuse.
	3. Understand and appropriately use screening tools for addiction or abuse to help assess potential risks associated with chronic opioid therapy and to help manage patients using ER/LA opioid analgesics (e.g., structured interview tools).
	4. Adequately document all patient interactions and treatment plans.
	Prescribers should understand when to appropriately refer high risk patients to pain management specialists.
	Prescribers should understand opioid tolerance criteria as defined in the product labeling.
	Prescribers should know which products and which doses are indicated for use only in opioid tolerant patients. (See REMS table in Section VI for specific information).

II. Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioid Analgesics	
	Prescribers should have awareness of federal and state regulations on opioid prescribing.
	Prescribers should be aware that:
	1. Dose selection is critical, particularly when initiating therapy in opioid non-tolerant patients.
	2. Some ER/LA Opioid analgesics are only appropriate for opioid-tolerant patients.
	3. Dosage should be individualized in every case.
	4. Titration should be based on efficacy and tolerability.
	Prescribers should be knowledgeable about when and how to supplement pain management with immediate-release analgesics, opioids and non-opioids.
	Prescribers should be knowledgeable about converting patients from immediate-release to ER/LA opioid products and from one ER/LA opioid product to another ER/LA opioid product.
	Prescribers should understand the concept of incomplete cross-tolerance when converting patients from one opioid to another.
	Prescribers should understand the concepts and limitations of equianalgesic dosing and follow patients closely during all periods of dose adjustment.
	Prescribers should understand the warning signs and symptoms of significant respiratory depression from opioids.
	Prescribers should understand that tapering the opioid dose is necessary to safely discontinue treatment with ER/LA opioid analgesics when therapy is no longer needed.
III. Managing Therapy with ER/LA Opioid Analgesics	
	Prescribers should establish analgesic and functional goals for therapy and periodically evaluate pain control, functional outcomes, side-effect frequency and intensity, and health-related quality of life.
	Prescribers should be aware of the existence of Patient Prescribers Agreements (PPAs).
	1. PPAs are documents signed by both Prescriber and patient at the time an opioid is prescribed.
	2. PPAs can help ensure patients and caregivers understand the goals of treatment, the risks, and how to use the medications safely.
	3. PPAs can include commitments to return for follow-up visits, to comply with appropriate monitoring (such as random drug testing), and to safeguard the medication.
	Prescribers should monitor patient adherence to the treatment plan, especially with regard to misuse and abuse by:
	1. Recognizing, documenting, and addressing aberrant drug-related behavior.
	2. Utilizing state Prescription Drug Monitoring Programs, where practical, to identify behaviors that may represent abuse.
	3. Understanding the utility and interpretation of drug testing (e.g., screening and confirmatory tests), and using it as indicated.
	4. Screening and referring for substance abuse treatment as indicated.
	5. Performing medication reconciliation as indicated.
	Prescribers should understand how to anticipate and manage adverse events associated with ER/LA opioid analgesics.
	Prescribers treating patients with ER/LA opioid analgesics should periodically assess benefits and side effects of these drugs, and the continued need for opioid analgesics.
	Prescribers should understand the need for reevaluation of patient's underlying medical condition if the clinical presentation changes over time.
	Prescribers should be familiar with referral sources for the treatment of abuse or addiction that may arise from the use of ER/LA opioid analgesics.
IV. Counseling Patients and Caregivers about the Safe Use of ER/LA Opioid Analgesic.	
	Prescribers should use the Patient Counseling Document as part of the discussion when prescribing opioid analgesics.
	Prescribers should explain product-specific information about the prescribed ER/LA opioid analgesic.
	Prescribers should explain how to take the ER/LA opioid analgesic as prescribed.

	Prescribers should explain the importance of adherence to dosing regimen, how to handle missed doses, and to contact their prescriber should pain not be controlled.
	Prescribers should inform patients and caregivers to read the specific ER/LA opioid analgesic Medication Guide they receive from the pharmacy.
	Prescribers should warn patients that under no circumstances should an oral ER/LA opioid analgesic be broken, chewed or crushed, and patches should not be cut or torn prior to use, as this may lead to rapid release of the ER/LA opioid analgesic causing overdose and death. When 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.
	Prescribers should caution patients that the use of other CNS depressants such as sedative-hypnotics and anxiolytics, alcohol, or illegal drugs with ER/LA opioid analgesics can cause overdose and death. Patients should be instructed to only use other CNS depressants, including other opioids, under the instruction of their prescriber.
	Prescribers should instruct patients to tell all of their doctors about all medications they are taking.
	Prescribers should warn patients not to abruptly discontinue or reduce their ER/LA opioid analgesic and discuss how to safely taper the dose when discontinuing.
	Prescribers should caution patients that ER/LA opioid analgesics can cause serious side effects that can lead to death. Prescribers should counsel patients and caregivers on the risk factors, signs, and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions.
	Prescribers should counsel patients and caregivers on the most common side effects of ER/LA opioid analgesics, and about the risk of falls, working with heavy machinery, and driving.
	Patients should call their prescriber for information about managing side effects.
	Prescribers should explain that sharing ER/LA opioid analgesics with others may cause them to have serious side effects including death, and that selling or giving away ER/LA opioid analgesics is against the law.
	Prescribers should counsel patients to store their ER/LA opioid analgesic in a safe and secure place away from children, family members, household visitors, and pets.
	Prescribers should warn patients that ER/LA opioid analgesics must be protected from theft.
	Prescribers should counsel patients to dispose of any ER/LA opioid analgesics when no longer needed and to read the product-specific disposal information included with the ER/LA opioid analgesic product.
	Prescribers should counsel patients and caregivers to inform them about side effects.
	Adverse events should be reported to the FDA at 1-800-FDA-1088 or via http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf .
V. General 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. For example:
	ER/LA opioid analgesic products are scheduled under the Controlled Substances Act and can be misused and abused.
	Respiratory depression is the most important serious adverse effect of opioids as it can be immediately life-threatening.
	Constipation is the most common long-term side effect and should be anticipated.
	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.
	1. Central nervous system depressants (alcohol, sedatives, hypnotics, tranquilizers, tricyclic antidepressants) can have a potentiating effect on the sedation and respiratory depression caused by opioids.
	2. 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.
	3. Using opioids with monoamine oxidase inhibitors (MAOIs) may result in possible increase in respiratory depression. Using certain opioids with MAOIs may cause serotonin syndrome.
	4. Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone (ADH).
	5. Some opioids (methadone, buprenorphine) can prolong the QTc interval.

	6. 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. (See table in Section VI for specific information).
	Tolerance to sedating and respiratory-depressant effects of opioids is critical to the safe use of certain products, certain dosage unit strengths, or certain doses of some products.
	1. Patients must be opioid tolerant before using any strength of Transdermal fentanyl, or ER hydromorphone.
	2. For other ER products, patients must be opioid tolerant before using certain strengths, or certain daily doses.
	3. Education addresses REMS Section VI for specific drug information.
	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.
	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.
VI. 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 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. The attached table 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 .

Course Program and Examination: Please provide a copy of your course program. Additionally provide final examination questions and the area the questions correspond to in the REMS and State of Utah criteria.

Mail Complete Approval Request to:

By U.S. Mail

Division of Occupational & Professional Licensing

P.O. Box 146741

Salt Lake City, Utah 84114-6741

By Delivery or Express Mail

Division of Occupational & Professional Licensing

160 East 300 South, 1st Floor Lobby

Salt Lake City, Utah 84111

Telephone Numbers:

(801) 530-6628

(866) 275-3675 – Toll-free in Utah