



RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Department of Labor & Industries (L&I)

Permanent Rule Only

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) July 1, 2013 (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

Yes No If Yes, explain:

Purpose The purpose of this rulemaking is to ensure safe, appropriate and effective drug therapy designed to improve clinical outcomes and to support a successful return to work. The adopted rule language updates the coverage of and payment for prescription drugs and describes specific authorization requirements for the payment of opioids. Authorization requirements for opioids are based on best practices and will improve the care for injured workers and help save lives.

Washington is among those states with the highest rate of prescription opioid-related deaths in the United States. This now exceeds both motor-vehicle accidents and firearms as the leading cause of injury-related death.

Citation of existing rules affected by this order:

Repealed: WACs 296-20-03016, 296-20-03019, 296-20-03020, 296-20-03021, 296-20-03022, 296-20-03023, and 296-20-03024
Amended: WACs 296-20-03010, 296-20-03011, 296-20-03012, 296-20-03015, and 296-20-03101
Suspended: 0

Statutory authority for adoption: RCW 51.04.020 and RCW 51.04.030

Other authority :

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 13-07-058 on March 19, 2013.

Describe any changes other than editing from proposed to adopted version:

Clarifying language was added to the following WAC sections: WAC 296-20-03011, WAC 296-20-03050, WAC 296-20-03055, WAC 296-20-03058, WAC 296-20-03060, WAC 296-20-03065, WAC 296-20-03070, and WAC 296-20-03075.

Please see the Concise Explanatory Statement for details.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: _____ phone () _____
Address: _____ fax () _____
e-mail _____

Date adopted: May 28, 2013

NAME (TYPE OR PRINT)

Joel Sacks

SIGNATURE

TITLE

Director

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 28, 2013

TIME: 3:18 PM

WSR 13-12-024

(COMPLETE REVERSE SIDE)

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in the agency's own initiative:

New	<u>16</u>	Amended	<u>5</u>	Repealed	<u>7</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>16</u>	Amended	<u>5</u>	Repealed	<u>7</u>
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	_____	Repealed	_____

Concise Explanatory Statement (CES)

This CES refers to comments made in response to proposed rules related to the coverage of and payment for prescription drugs. Rules are necessary to ensure safe, appropriate and effective drug therapy designed to improve clinical outcomes and to support a successful return to work.

AMENDED SECTIONS:

- WAC 296-20-03010 What are the general principles the department uses to determine coverage on drugs and medications?
- WAC 296-20-03011 What general limitations are in place for medications?
- WAC 296-20-03012 Where can I find the department's outpatient drug and medication coverage decisions?
- WAC 296-20-03015 What steps may the department or self-insurer take when concerned about the amount or appropriateness of drugs and medications prescribed to the injured worker?
- WAC 296-20-06101 What reports are health care providers required to submit to the insurer?

NEW SECTIONS:

- WAC 296-20-03030 Definitions associated with opioid authorization and payment
- WAC 296-20-03035 Checking the prescription monitoring program data base
- WAC 296-20-03040 Administering urine drug testing
- WAC 296-20-03045 Tracking function and pain
- WAC 296-20-03050 Preinjury opioid use
- WAC 296-20-03055 Opioid authorization requirement for the acute phase (0-6 weeks)
- WAC 296-20-03056 Opioid authorization requirement for the subacute phase (6-12 weeks)
- WAC 296-20-03057 Opioid authorization requirement for the chronic phase (> 12 weeks)
- WAC 296-20-03058 Opioid authorization requirement for ongoing chronic opioid therapy
- WAC 296-20-03059 Opioid authorization requirement for catastrophic injuries
- WAC 296-20-03060 Episodic care for pain
- WAC 296-20-03065 Managing surgical pain in workers on opioid therapy
- WAC 296-20-03070 When opioid prescribing is not proper and necessary care
- WAC 296-20-03075 When to discontinue opioids
- WAC 296-20-03080 Weaning or detoxification
- WAC 296-20-03085 Addiction treatment

REPEALED SECTIONS:

- WAC 296-20-03016 Is detoxification and/or chemical dependency treatment covered?
- WAC 296-20-03019 Under what conditions will the department or self-insurer pay for oral opioid treatment for chronic, noncancer pain?
- WAC 296-20-03020 What are the authorization requirements for treatment of chronic, noncancer pain with opioids?
- WAC 296-20-03021 What documentation is required to be submitted for continued coverage of opioids to treat chronic, noncancer pain?
- WAC 296-20-03022 How long will the department or self-insurer continue to pay for opioids to treat chronic, noncancer pain?
- WAC 296-20-03023 When may the department or self-insurer deny payment of opioid medications used to treat chronic, noncancer pain?

WAC 296-20-03024 Will the department or self-insurer pay for nonopioid medications for the treatment of chronic, noncancer pain?

I. Purpose of this rulemaking:

Why is this rulemaking being adopted?

The purpose of this rulemaking is to ensure safe, appropriate and effective drug therapy designed to improve clinical outcomes and to support a successful return to work. Primarily, this rulemaking is necessary to support key concepts in the Department of Labor & Industries' (L&I) new guideline for Prescribing Opioids to Treat Pain in Injured Workers, ensure consistency with the Department of Health's (DOH) pain management rules and reverse the trend of prescription opioid-related death and disability. This rulemaking also includes:

- Clarifying payment for prescription drugs to those approved by the Food and Drug Administration (FDA) or other similar regulatory agencies outside the United States, to address treatment of workers who live in other countries, and
- Allowing claims that are held open for life-sustaining treatment and pensioners with ongoing medical treatment the convenience of receiving a 90-day supply of prescription drugs via mail-order to improve customer service and implement the State Auditor's Office (SAO) Prescription Drug Audit recommendation.

The date of adoption is May 28, 2013.

The effective date for this rule is July 1, 2013.

II. Purpose of the concise explanatory statement:

The purpose of this document is to respond to the oral and written comments directly related to the proposed rule language, received through the public comment period and a public hearing. The public comment period for this rulemaking began March 19, 2013, and ended noon April 26, 2013.

III. Public hearing:

A public hearing was held to receive comments from interested parties regarding this rulemaking. The hearing took place on April 23, 2013, at the L&I regional service location in Tukwila.

No one attended the hearing. The written comment deadline as published in the CR-102 was April 23, 2013 at 5 p.m. The deadline for L&I to receive written comments was extended to noon April 26, 2013 during the public hearing in compliance with RCW 34.05.325. The extension of the written comment period was also communicated in a department press release and as an addendum to the April 2013 Provider Newsletter.

IV. Summary of comments received directly related to this rulemaking, including department responses and, where applicable, changes to the rule:

The department received five written comments on this rulemaking. In general, commenters supported the proposed rule language with some requests for clarification. One commenter was opposed to the documentation requirements.

General Comments

Comments received: Commenter expressed support in closing down clinics with questionable practice but asked the department to consider that most patients are not abusing or selling their medications and require them to live a full life.

Department Response: The rules support the use of best practices necessary to safely and effectively prescribe opioids to treat patients with chronic non-cancer pain. Effective chronic opioid therapy should result in improved work capacity or the ability to progress in vocational retraining or a successful return to work.

Rule change: No changes were made in response to this comment.

WAC 296-20-03010 What are the general principles the department uses to determine drug coverage?

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: Editing changes were made to this WAC.

WAC 296-20-03011 What general limitations are in place for drugs?

Comments received: Commenter recommended changing a limitation on the amount dispensed for drugs from a 30-day to 28-day supply to ensure the next refill date falls on a day of the week when the prescriber is usually in the office.

Department Response: Changing the limitation on the amount dispensed to a 28-day supply would affect all drug therapy not just opioids, and result in additional cost because of one extra dispensing fee per year. Currently, billing edits prevent billing of prescription with more than a 30-day supply, but does not prevent providers from writing prescription with less than a 30-day supply.

Rule change: No changes were made to this WAC in response to this comment. The department may implement a billing edit to prevent opioid prescriptions with more than a 28-day supply.

Department Comment: The department has moved proposed language within this WAC section to clarify the availability of a ninety-day supply of drugs for workers.

Rule change: Clarifying language has been added to WAC 296-20-03011 as stated in part, “(1) **Amount dispensed.** The department or self-insurer will pay for no more than a thirty-day supply of a ((medication)) drug dispensed at any one time except in pension cases (see subsection (6) of this section) and claims that are held open for life-sustaining treatment. In these cases, up to a ninety-day supply of the drug is payable when:

- Coverage has been authorized; and

- The drug is not a controlled substance; and
- The drug is obtained through a designated provider...

WAC 296-20-03012 Where can I find the department's outpatient drug coverage decisions?

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: No changes were made to this WAC.

WAC 296-20-03015 What steps may the department or self-insurer take when concerned about the amount or appropriateness of drugs prescribed for the injured worker?

Comment received: Commenter asked if the Attending Provider (AP) continues to prescribe opioids after L&I terminates payment, at low morphine equivalent dose (MED) which does not meet the "risk of harm" definition, whether the provider would still be at risk from penalties including removal from the network?

Department response: Once opioids are denied on a claim prescribing low dose opioids doesn't meet the risk of harm definition and will not place the prescriber at risk for penalties. This would only occur if the prescriber continues to prescribe opioids after the development of a severe adverse event which would meet the "risk of harm" definition or opioid use is itself a barrier to recovery.

Rule change: No changes were made to this WAC in response to this comment.

Rule change: Editing changes were made to this WAC.

WAC 296-20-03030 Definitions associated with opioid authorization and payment

Comments received: Commenter asked to clarify the definition of baseline, how is a baseline determined, what if you are not the provider who initially assessed baseline function and pain status and if workers have a year to file for an injury and two years for occupational disease, where does baseline begin?

Department response: These scenarios exist with the current authorization process. As part of the implementation, the department is planning to create a new "identifier" for documents relating to opioid authorization that can be accessed by providers and staff via the Claimant Account Center. The new guideline recommends baseline measures of function and pain within two weeks of filing a claim. In addition, the baseline is required before opioid coverage is extended through the subacute and chronic phase, so this should be available in the record.

Rule change: No changes were made to this WAC.

WAC 296-20-03035 Checking the prescription monitoring program data base

Comments received: Commenter urged the department to make checking the state's prescription monitoring program mandatory before providers prescribe opioids for new injuries in order to identify potential red flags early in the claim.

Department response: The proposed rule language is consistent with L&I's new Guideline for Prescribing Opioids to Treat Pain in Injured Workers. There are circumstances which make checking the prescription monitoring program on new injuries challenging and making this a requirement would not allow flexibility in these circumstances.

Rule change: No changes were made to this WAC.

WAC 296-20-03040 Administering urine drug testing

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: No changes were made to this WAC.

WAC 296-20-03045 Tracking function and pain

Comments received: Commenter did not like this WAC and as a board-certified doctor, she didn't need one more thing to do to be compliant with the rule.

Department response: The department currently requires tracking of function and pain at least every 60 days during chronic opioid therapy. The new rule requires function and pain to be assessed earlier to obtain a baseline, but otherwise decreases tracking of function and pain to every 90 days during chronic opioid therapy.

Rule change: No changes were made to this WAC.

WAC 296-20-03050 Preinjury opioid use

Comments received: Commenter asked if increased opioids are indicated beyond six weeks for an industrial injury above the pre-opioid MED, why would the increase above baseline not be covered by the department?

Department response: *The intent is to discourage continued escalating doses after the acute phase. The department agrees that severe injuries may need more than six weeks to return to preinjury status, thus language will be added to this WAC to clarify that coverage may be extended through the subacute phase for severe injuries or beyond for catastrophic injuries.*

Rule change: *“The department or self-insurer is not responsible for the continuation of preinjury opioid use or any adverse outcomes which may result. For workers with preinjury chronic opioid therapy, payment for opioids beyond the acute phase will not be authorized except:*

- *For catastrophic injuries (See WAC 296-20-03059), and*
- *For severe injuries, coverage may be extended through the subacute phase.”*

WAC 296-20-03055 Opioid authorization requirement for the acute phase (0-6 weeks)

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: *The department made a clarifying change to this WAC.*

“The department or self-insurer may cover opioids for up to six weeks when prescribed to treat pain from the acute industrial injury or after an authorized surgery.”

WAC 296-20-03056 Opioid authorization requirement for the subacute phase (6-12 weeks)

Comments received: *Commenter recommended the department require providers to document all non-opioid therapies attempted along with outcomes during the subacute phase. In addition, the department should require providers to document a treatment plan that includes a proposed timeline for weaning if clinically meaningful improvement in function was not achieved and information on non-opioid and non-pharmacologic therapies during and following the weaning process.*

Department response: *The proposed rule language requires providers to document that reasonable alternatives to opioids have been tried and have failed as one of the criteria during the subacute phase. In addition, the timeline for weaning is specified under WAC 296-20-03030, step 1 and 2 taper.*

Rule change: *No changes were made to this WAC.*

WAC 296-20-03057 Opioid authorization requirement for the chronic phase (>12 weeks)

Comments received: Commenter recommended the department require providers to document a treatment plan that includes a proposed timeline for weaning if clinically meaningful improvement in function was not achieved and information on non-opioid and non-pharmacologic therapies during and following the weaning process.

Department response: The timeline for weaning is specified under WAC 296-20-03030, step 1 and 2 taper as well as adjuvant treatment to aid with the weaning process under WAC 296-20-03080.

Rule change: No changes were made to this WAC in response to this comment.

Rule change: Editing changes were made to this WAC.

WAC 296-20-03058 Opioid authorization requirement for ongoing chronic opioid therapy

Comments received: Commenter asked which function scale are you using?

Department response: The department is referencing the two item graded chronic pain scale and will clarify this in the WAC language.

Rule change: The department made clarifying changes to this WAC.

“Before the department or self-insurer authorizes continued payment for chronic opioid therapy, the provider must routinely, at least every ninety days or more frequently, according to the worker's risk, review the effects of opioids to determine whether therapy should continue and document the following best practices:

- Clinically meaningful improvement in function or pain interference with function score of ≤ 4 on the two item graded chronic pain scale is maintained with stable dosing. See WAC 296-20-03030 for the definition of clinically meaningful improvement in function.”...

Rule change: The department made clarifying changes to this WAC.

“...Workers receiving chronic opioid therapy should be managed by a single prescribing provider. If the prescribing provider is unavailable, then refills should be addressed by the covering provider and allowed on a limited basis only. See WAC 296-20-03060, Episodic care for pain, regarding unscheduled refills from visits to emergency departments or urgent care facilities for pain management.

WAC 296-20-03059 Opioid authorization requirement for catastrophic injuries

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: Editing changes were made to this WAC.

WAC 296-20-03060 Episodic care for pain

Comments received: Commenter asked for a definition of urgent care visit.

Department response: The intent is to limit unscheduled visits to other than the usual place of care for pain management. The department will clarify the language in this WAC.

Rule change: “The department or self-insurer may pay for one pain-related emergency or urgent care visit related to the accepted condition for a worker already receiving opioid therapy, but payment for additional emergency or urgent care visits may be denied. Urgent care visit includes any unscheduled visit to other than the usual place of care for pain management. Workers receiving opioid therapy should be managed by a single prescriber.”

WAC 296-20-03065 Managing surgical pain in workers on opioid therapy

Comments received: Commenter recommended changing the language to be consistent with the L&I Opioid Guideline.

Department response: The intent is to discourage continued escalating doses after surgery. The department will clarify the language in this WAC.

Rule change: “The provider ~~must~~should taper the worker's total opioids to the preoperative dose or lower by six weeks after surgery. Upon request, and depending on the complexity of the surgery, the department or self-insurer may authorize an additional six weeks for the provider to taper opioids to the preoperative or lower dose.”

WAC 296-20-03070 When opioid prescribing is not proper and necessary care

Comments received: Commenter asked what are the consequences of a provider choosing to prescribe opioids not covered by L&I for palliative purposes, e.g. Vicodin at bedtime?

Department response: Once opioids are denied on a claim, prescribing low dose opioids doesn't meet the “risk of harm” definition and will not place the prescriber at risk for penalties. The provider's prescribing practices would meet the definition of “risk of harm” only if the prescriber continues to prescribe opioids after the development of a severe adverse event or opioid use is itself a barrier to recovery. The department will reference the definition for proper and necessary and clarify applicability to the workers' compensation system.

Rule change: “Continuing to prescribe opioids in the absence of clinically meaningful improvement in function or after the development of a severe adverse outcome, or prescribing opioids in escalating doses to the point of the worker developing opioid use disorder is not considered proper and necessary care in the Washington state's workers' compensation system (See WAC 296-20-01002 for the definition of proper and necessary care). Further coverage of opioids under these circumstances is not payable.”

WAC 296-20-03075 When to discontinue opioids

Comments received: Commenter suggested changing language to be consistent with the guideline and to clarify when the worker's risk from continued treatment outweighs the benefit. In addition, commenter has suggested clarifying attending provider's request for an opioid wean to include concern for potential adverse outcomes and to change wean to discontinuation.

Department response: Language is already included in this WAC to cover the situation when the treating provider feels continued opioid therapy is not warranted for any reason. There is also flexibility so that this determination can be made by the treating provider, attending provider or department's medical staff. In response to request for clarifying language regarding the attending provider and changing wean to discontinuation, the department will revise the language for clarification.

Rule change: WAC 296-20-03075 states in part, "The prescriber must discontinue opioids under the following circumstances:

- ~~The worker or attending provider requests opioid wean~~ discontinuation; or
- The attending provider, because of concern for potential adverse outcomes, requests opioid discontinuation..."

Rule change: Editing changes were made to this WAC.

WAC 296-20-03080 Weaning or detoxification

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: No changes were made to this WAC.

WAC 296-20-03085 Addiction treatment

No comments were received suggesting changes to the proposed amendments to this WAC.

Rule change: No changes were made to this WAC.

WAC 296-20-06101 What reports are health care providers required to submit to the insurer?

Comments received: Commenter asked if the Activity Prescription Form (APF) currently replaced the Loss of Earning Power (LEP) and Doctor's estimate of physical capacity form?

Department response: Although the APF has information on LEP and the Doctor's estimate of physical capacity, the department still uses both forms for other purposes.

Rule change: No changes were made to this WAC.

Repealer

WAC 296-20-03016 Is detoxification and/or chemical dependency treatment covered?

WAC 296-20-03019 Under what conditions will the department or self-insurer pay for oral opioid treatment for chronic non-cancer pain?

WAC 296-20-03020 What are the authorization requirements for treatment of chronic, noncancer pain with opioids?

WAC 296-20-03021 What documentation is required to be submitted for continued coverage of opioids to treat chronic, noncancer pain?

WAC 296-20-03022 How long will the department or self-insurer continue to pay for opioids to treat chronic, noncancer pain?

WAC 296-20-03023 When may the department or self-insurer deny payment of opioid medications used to treat chronic, noncancer pain?

WAC 296-20-03024 Will the department or self-insurer pay for nonopioid medications for the treatment of chronic, noncancer pain?

No comments were received suggesting changes to the proposed repeal WACs.

Rule change: No changes were made to these WACs.