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TEMPORARY ADMINISTRATIVE RULES

Oregon Health Authority, Health Systems Division:
Medical Assistance Programs

410

Agency and Division

Administrative Rules Chapter Number

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Upon filing.

Adopted on

05/01/2016 thru 06/28/2016

Effective dates

RULE CAPTION

Amending PDL November 19, 2015, January 28, 2016 DUR/P&T Action

Not more than 15 words

RULEMAKING ACTION

ADOPT:

AMEND: 410-121-0030

SUSPEND:

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, and 414.316

Other Auth.:

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, and 414.354

RULE SUMMARY

The Pharmaceutical Services Program administrative rules (Division 121) govern Division payments for services provided to certain clients. The Division needs to amend rules as follows:

410-121-0030:

Preferred:

Budesonide

Exenatide Pen Injector

Guaifenesin (Mucinexâ,,ç)

Daclatasvir Dihydrochloride

Elviteg/ Cobi/ Emtric/ Tenofo Ala (Genvoyaâ,,ç)

Rivaroxaban (Xareltoâ,,ç)

Insulin Lispro Protamin / Lispro

Non-Preferred:

Ciclesonide Nasal Spray/ Pump

Ombita/ Paritap/ Riton/ Dasabuvir (Viekira Pakâ,,ç)

Amantadine HCL

Rimantadine HCL

Bupropion HCL

Amphetamine Sulfate

Tobramycin

TOBI

Due to changes in supplemental rebate contracts, the following changes were made:

Removed Pegasysâ,,ç

Added Sovaldiâ,,ç

Added Evotazâ,,ç

Added Eliquisâ,,ç

Added Pradaxaâ,,ç

Removed Androgelâ,,ç

Added Janumetâ,,ç

Removed Humalogâ,,ç

Removed Humalog Mix 50/50â,,ç

Removed Humalog Mix 75/25â,,ç

Removed Humulin Râ,,ç

Removed Humulin Nâ,,ç

Removed Humulin 70/30â,,ç

Removed Makenaâ,,ç

Removed Aprisoâ,,ç

Removed Exelonâ,,ç

Removed Capaxoneâ,,ç

Removed Avonexâ,,ç

Removed Betaseronâ,,ç

Removed Stalevoâ,,ç

Removed Zubsolvâ,,ç

Removed Bethkisâ,,ç

Added Renagelâ,,ç

Clerical - Various clerical changes were made to system class, drug and form names.

STATEMENT OF NEED AND JUSTIFICATION

The amendment of OAR 410-121-0030

In the Matter of

Or Law 2011, chapter 720 (HB 2100):
http://www.oregon.gov/pers/docs/2011_legislation/hb2100.en.pdf

Documents Relied Upon, and where they are available

The Pharmaceutical Services Program administrative rules (division 121) govern Division payments for services provided to certain clients. The Division needs to amend 410-121-0030 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the November 19, 2015, and January 28, 2016, meeting. The Authority needs to implement changes to the Preferred Drug List to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

410-121-0030:

Preferred:

Budesonide

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Removed Humalog[®]

Removed Humalog Mix 50/50[®]

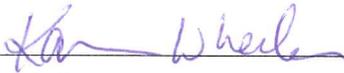
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Removed Humulin Râ„¢
Removed Humulin Nâ„¢
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Clerical - Various clerical changes were made to system class, drug and form names.

Need for the Temporary Rule(s)

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and clients enrolled in Oregon's Medicaid program by delaying the reassessment and update of preferred drug lists and prior authorization requirements. These rules need to be adopted promptly so the Authority can ensure the safe and appropriate use of Medicaid covered drugs.

Justification of Temporary Rules



Authorized Signer

Karen Wheeler

Printed Name

4/28/16

Date

Authorization Page replaces the ink signature on paper filings. Have your authorized signer sign and date, then scan and attach it to your filing. You must complete this step before submitting your Permanent and Temporary filings.

STATEMENT OF NEED AND JUSTIFICATION

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Authority, Health Systems Division, Medical Assistance Programs

410

Agency and Division

Administrative Rules Chapter Number

Rule Caption: Amending PDL November 19, 2015, January 28, 2016 DUR/P&T Action

In the Matter of: The amendment of OAR 410-121-0030

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

Other Authority: None

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354

Need for the Temporary Rule(s): The Pharmaceutical Services Program administrative rules (division 121) govern Division payments for services provided to certain clients. The Division needs to amend 410-121-0030 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the November 19, 2015, and January 28, 2016, meeting. The Authority needs to implement changes to the Preferred Drug List to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

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Rivaroxaban (Xarelto™)

Insulin Lispro Protamin / Lispro

Non-Preferred:

Ciclesonide Nasal Spray/ Pump

Ombitasvir/ Paritapiravir/ Ritonavir/ Dasabuvir (Viekira Pak™)

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Amphetamine Sulfate

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TOBI

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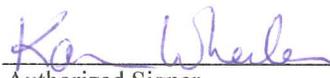
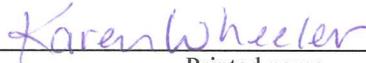
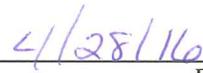
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Documents Relied Upon, and where they are available: Or Law 2011, chapter 720 (HB 2100):
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Justification of Temporary Rule(s): The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and clients enrolled in Oregon's Medicaid program by delaying the reassessment and update of preferred drug lists and prior authorization requirements. These rules need to be adopted promptly so the Authority can ensure the safe and appropriate use of Medicaid covered drugs.

Authorized Signer Printed name Date
Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.

410-121-0030

Practitioner-Managed Prescription Drug Plan

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that OHP fee-for-service clients have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price:

(a) Licensed health care practitioners who are informed by the latest peer reviewed research make decisions concerning the clinical effectiveness of the prescription drugs;

(b) Licensed health care practitioners also consider the client's health condition, personal characteristics, and the client's gender, race, or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool the Division uses to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;

(b) The PDL contains a list of prescription drugs that the Division, in consultation with the Drug Use Review (DUR)/Pharmacy & Therapeutics Committee (P&T), has determined represent the most effective drugs available at the best possible price;

(c) The PDL shall include drugs that are Medicaid reimbursable and the Food and Drug Administration (FDA) has determined to be safe and effective.

(3) PMPDP PDL Selection Process:

(a) The Division shall utilize the recommendations made by the P&T that result from an evidence-based evaluation process as the basis for selecting the most effective drugs;

(b) The Division shall ensure the drugs selected in section (3)(a) that are available for the best possible price and shall consider any input from the P&T about other FDA-approved drugs in the same class that are available for a lesser relative price. The Division shall determine relative price using the methodology described in section (4);

(c) The Division shall evaluate selected drugs for the drug classes periodically:

(A) The Division may evaluate more frequently if new safety information or the release of new drugs in a class or other information makes an evaluation advisable;

(B) New drugs in classes already evaluated for the PDL shall be non-preferred until the new drug has been reviewed by the P&T;

(C) The Division shall make all revisions to the PDL using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules website.

(4) Relative cost and best possible price determination:

(a) The Division shall determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective;

(b) The Division may also consider dosing issues, patterns of use, and compliance issues. The Division shall weigh these factors with any advice provided by the P&T in reaching a final decision.

(5) Pharmacy providers shall dispense prescriptions in the generic form unless:

(a) The practitioner requests otherwise pursuant to OAR 410-121-0155;

(b) The Division notifies the pharmacy that the cost of the brand name particular drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.

(6) The exception process for obtaining non-preferred physical health drugs that are not on the PDL shall be as follows:

(a) If the prescribing practitioner in their professional judgment wishes to prescribe a physical health drug not on the PDL, they may request an exception subject to the requirements of OAR 410-121-0040;

(b) The prescribing practitioner must request an exception for physical health drugs not listed in the PDL subject to the requirements of OAR 410-121-0060;

(c) Exceptions shall be granted when:

(A) The prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Call Center; or

(B) Where the prescriber requests an exception subject to the requirement of section (6)(b) and fails to receive a report of PA status within 24 hours, subject to OAR 410-121-0060.

(7) Table 121-0030-1, PMPDP PDL dated ~~January~~May 1, 2016, is adopted and incorporated by reference and is found at: www.orpdl.org.

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354