PROPOSED RULE MAKING



matters: None

CR-102 (June 2024) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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DATE: September 10, 2024

TIME: 10:26 AM

WSR 24-19-032

Agency: Health Care Authority							
⊠ Original Notice							
☐ Supplemental Noti	ce to WSR						
□ Continuance of WSR							
☐ Expedited Rule MakingProposed notice was filed as WSR; or							
☐ Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or							
□ Proposal is exempt under RCW							
Title of rule and other identifying information: (describe subject) 182-530-7150, Reimbursement – Compounded prescriptions; 182-530-8150, Reimbursement – Automated maximum allowable cost (AMAC)							
Hearing location(s):							
Date:	Time:	Location: (be specific)		Comment:			
October 22, 2024	10:00 AM	The Health Care Authority		To attend the virtual public hearing,			
		public hearings virtually with physical meeting place	nout a	you must register in advance:			
		priysical meeting place		https://us02web.zoom.us/webinar/register/ WN_icWpKqAQTxyCXgTcltuVgA			
				If the link above opens with an error message, please try using a different browser. After registering, you will receive a confirmation email containing information about joining the public hearing			
		ooner than October 23, 2024	<u>4</u>	Note: This is NOT the effective date)			
Submit written comm			Assistance for persons with disabilities:				
Name HCA Rules Coordinator			Contact Johanna Larson				
Address PO Box 42716, Olympia WA 98504-2716			Phone 360-725-1349				
Email arc@hca.wa.gov			Fax 360-586-9727				
Fax 360-586-9727			TTY Telecommunication Relay Service (TRS): 711				
Other		Email Johanna.Larson@hca.wa.gov					
Beginning (date and	time) <u>Sept</u> e	5111561 111, 202 1, 0.00 7 tivi	Other				
By (date and time) October 22, 2024 by 11:59 PM By (date) October 11, 203							
Purpose of the proposal and its anticipated effects, including any changes in existing rules: The agency is removing all instances of "automated maximum allowable cost" and "AMAC" from WAC 182-530-7150 and repealing WAC 182-530-8150. The agency no longer uses AMAC as a reimbursement method.							
Reasons supporting proposal: See Purpose							
Statutory authority for adoption: RCW 41.05.021, 41.05.160							
Statute being implemented: RCW 41.05.021, 41.05.160							
Is rule necessary because of a:							
Federal Law?				☐ Yes ⊠ No			
Federal Court Decision?				☐ Yes ⊠ No			
State Court Decision? □ Yes ☑ No If yes, CITATION:							
Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal							

Name of proponent: (person or organization) Health Care Authority Type of proponent: □ Private. □ Public. ☒ Governmental.						
Name of agency personnel responsible for:						
	Name	Office Location	Phone			
Drafting	Brian Jensen	PO Box 42716, Olympia, WA 98504-2716	360-725-0815			
Implementation	Wendy Steffens	PO Box 45500, Olympia, WA 98504-5500	360-725-5145			
Enforcement	Wendy Steffens	PO Box 45500, Olympia, WA 98504-5500	360-725-5145			
Is a school district If yes, insert staten		nired under <u>RCW 28A.305.135</u> ?	☐ Yes ⊠ No			
The public may Name Address Phone Fax TTY Email Other	obtain a copy of the school dist	rict fiscal impact statement by contacting:				
Is a cost-benefit a	nalysis required under RCW :	34.05.328?				
Name Address Phone Fax TTY Email Other ⊠ No: Pleas Administrative F	Rules Review Committee or app	not apply to Health Care Authority rules unless req lied voluntarily.	uested by the Joint			
Regulatory Fairness Act and Small Business Economic Impact Statement Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.						
(1) Identification of exemptions: This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption.guide.published.by.orial . Please check the box for any applicable exemption(s):						
☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted. Citation and description:						
 □ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule. □ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum. 						

	This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:						
		RCW 34.05.310 (4)(b)		RCW 34.05.310 (4)(e)			
		(Internal government operations)		(Dictated by statute)			
		RCW 34.05.310 (4)(c)		RCW 34.05.310 (4)(f)			
		(Incorporation by reference)		(Set or adjust fees)			
		RCW 34.05.310 (4)(d)		RCW 34.05.310 (4)(g)			
		(Correct or clarify language)		((i) Relating to agency hearings; or (ii) process			
				requirements for applying to an agency for a license or permit)			
\boxtimes	This rule	proposal, or portions of the proposal, is exemp	t under <u>F</u>	RCW 19.85.025(4). (Does not affect small businesses).			
		proposal, or portions of the proposal, is exemp					
				rule: The proposed rule removes references to an			
		mbursement method and does not impose any	costs on	businesses.			
		f exemptions: Check one.	mntions i	dentified above apply to all portions of the rule proposal			
	 ☑ The rule proposal: Is fully exempt. (Skip section 3.) Exemptions identified above apply to all portions of the rule proposal. ☐ The rule proposal: Is partially exempt. (Complete section 3.) The exemptions identified above apply to portions of the rule 						
	proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):						
	The rule	proposal: Is not exempt. (Complete section 3.)	No exem	ptions were identified above.			
(3)	Small bu	usiness economic impact statement: Comple	ete this se	ection if any portion is not exempt.			
If any portion of the proposed rule is not exempt , does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?							
	□ No	• • •	alysis and	how the agency determined the proposed rule did not			
	•	nore-than-minor costs.					
	☐ Yes			e-than-minor cost to businesses and a small business			
	economi	c impact statement is required. Insert the requir	eu Siliali	business economic impact statement here.			
The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:							
	Na	ame					
	Address						
	Phone						
	Fax						
	TTY						
		nail					
		her	C: aus of				
Date: September 10, 2024		Signat	10110				
Name: Wendy Barcus			Mondy Borons				
Title: HCA Rules Coordinator			0				

- WAC 182-530-7150 Reimbursement—Compounded prescriptions. (1) The medicaid agency does not consider reconstitution to be compounding.
- (2) The agency covers a drug ingredient used for a compounded prescription only when the manufacturer has a signed rebate agreement with the federal Department of Health and Human Services (DHHS).
 (3) The agency considers bulk chemical supplies used in compoun-
- (3) The agency considers bulk chemical supplies used in compounded prescriptions as nondrug items, which do not require a drug rebate agreement. The agency covers such bulk chemical supplies only as specifically approved by the agency.
- (4) The agency reimburses pharmacists for compounding drugs only if the client's drug therapy needs are unable to be met by commercially available dosage strengths or forms of the medically necessary drug.
- (a) The pharmacist must ensure the need for the adjustment of the drug's therapeutic strength or form is well-documented in the client's file.
- (b) The pharmacist must ensure that the ingredients used in a compounded prescription are for an approved use as defined in "medically accepted indication" in WAC 182-530-1050.
- (5) The agency requires that each drug ingredient used for a compounded prescription be billed to the agency using its eleven-digit national drug code (NDC) number.
 - (6) Compounded prescriptions are reimbursed as follows:
- (a) The agency allows only the lowest cost for each covered ingredient, whether that cost is determined by actual acquisition cost (AAC), federal upper limit (FUL), maximum allowable cost (MAC), ((automated maximum allowable cost (AMAC),)) or amount billed.
- (b) The agency applies current prior authorization requirements to drugs used as ingredients in compounded prescriptions, except as provided under (c) of this subsection. The agency denies payment for a drug requiring authorization when authorization is not obtained.
- (c) The agency may designate selected drugs as not requiring authorization when used for compounded prescriptions. For the list of selected drugs, refer to the agency's prescription drug program billing instructions.
- (d) The agency pays a professional dispensing fee as described under WAC 182-530-7050 for each drug ingredient used in compounding when the conditions of this section are met and each ingredient is billed separately by the eleven-digit NDC.
 - (e) The agency does not pay a separate fee for compounding time.
- (7) The agency requires pharmacists to document the need for each inactive ingredient added to the compounded prescription. The agency limits reimbursement to the inactive ingredients that meet the following criteria. To be reimbursed by the agency, each inactive ingredient must be:
 - (a) A necessary component of a compounded drug; and
 - (b) Billed by an eleven-digit national drug code (NDC).

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 182-530-8150 Reimbursement—Automated maximum allowable cost (AMAC).