

Title 28. Managed Health Care
Division 1. The Department of Managed Health Care
Chapter 2. Health Care Service Plans
Article 7. Standards

§ 1300.67.241. Prescription Drug Prior Authorization or Step Therapy Exception Request Form Process.

(a) ~~Health plans, risk-bearing organizations, physicians or physician groups that maintain or are delegated the financial risk for prescription drug benefits and~~ utilize a prescription drug prior authorization or step therapy process shall use and accept only the Prescription Drug Prior Authorization or Step Therapy Exception Request Form, numbered 61-211 (~~New 08/13, Revised 04/16~~), which is incorporated herein by reference, and referred to hereafter in this section as “Form No. 61-211-” or an electronic prior authorization form or process described in subdivision (c)(1) of this regulation. Contracted physician groups described in section 1367.241, subdivision (f)(1)-(3) of the Act shall comply with this regulation including, but not limited to, subdivisions (e)(3) and (e)(4), but are exempted from this subdivision (a) regarding the use and acceptance of the prescription drug prior authorization or step therapy process.

(b) This regulation shall not apply to a health plan that owns and operates its pharmacies and does not use a prior authorization or step therapy process for prescription drugs.

(c)(1) A prescribing provider may use an electronic prior authorization system described in section 1367.241, subdivision (e) of the Act.

(2) A prescribing provider may submit prescription prior authorization or step-therapy exception requests using the contracted physician group’s process for those groups described in section 1367.241, subdivision (f)(1)-(3) of the Act.

~~(b) (d) A H~~health plan, risk-bearing organizations, physicians or physician groups that maintain or are delegated the financial risk for prescription drug benefits that contracts with a pharmacy benefit manager to conduct prescription drug prior authorization or step therapy exception request services; shall require their pharmacy benefit manager to use and accept only Form No. 61-211, or as specified in subdivision (c) of this regulation.

~~(e) (e) No earlier than July 1, 2017, or later than six months after the effective date of the regulation, whichever is later, the a health plans, risk-bearing organizations, physicians, or physician groups, that maintains or are delegated the financial risk for prescription drug or step therapy benefits and their its contracted pharmacy benefit managers shall do the following:~~

(1) Make Form No. 61-211 electronically available on their websites.

(2) Accept Form 61-211 or a form or a process compliant with subdivision (c) of this regulation through any reasonable means of transmission, including, but not limited to, paper, electronic transmission, telephone, web portal, or another mutually agreeable accessible method of transmission.

(3) Request from the prescribing provider only the minimum amount of material information necessary to approve or disapprove the prescription drug prior authorization or step therapy exception request. If state or federal law requires additional information for dispensing restricted prescription drugs ~~is required by state or federal law~~, that information ~~must~~ shall be submitted as part of section 3. of Form No. 61-211 or as specified in subdivision (c) of this regulation.

(4) Notify the prescribing provider and the enrollee or the enrollee's designee within ~~two (2) business days~~ 24 hours for exigent circumstances or 72 hours for non-urgent requests of receipt of a prescription drug prior authorization or step therapy exception request, including requests submitted pursuant to subdivision (c) of this regulation, that either:

(A) The prescribing provider's request is approved; or

(B) The prescribing provider's request is disapproved as not medically necessary or not a covered benefit; or

(C) The prescribing provider's request is disapproved as missing material information necessary to approve or disapprove the prescription drug prior authorization or step therapy exception request; or

(D) The patient is no longer eligible for coverage; or

(E) The prescription drug prior authorization or step therapy exception request was not submitted on the required form. Please resubmit your request on the attached Form No. 61-211 or on a form or process compliant with subdivision (c) of this regulation.

(F) This subdivision (e)(4) shall not apply to Medi-Cal managed care contracts or any contracts entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

(f) Definitions. The following definitions are applicable for this regulation:

(1) Exigent circumstances shall mean the circumstances described in section 1367.241, subdivision (h) of the Act.

(2) Step therapy exception is the exception to the step therapy process and the determination of whether the exception shall be granted, taking into consideration the enrollee's needs and medical circumstances, along with the professional judgment of the enrollee's provider.

(3) Electronic I.D. Verification shall mean a unique identification number that clearly identifies the prescribing provider on the prescription drug prior authorization or step therapy exception request to allow verification by the health plan or pharmacy benefit manager.

(g) For nonformulary prescription drug exception requests and subsequent coverage, the health plan or its contracted pharmacy benefits manager shall comply with 45 C.F.R. 156.122(c). This subdivision (g) shall not apply to Medi-Cal managed care contracts or any contracts entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

~~(d) (h) A H~~health plans, risk-bearing organizations, physicians or physician groups that maintain or are delegated the financial risk for prescription drug benefits that offers a prescription drug prior authorization or step therapy exception process telephonically or through a web portal, shall not require the prescribing provider to provide more information than is required by Form No. 61-211 or a form or process compliant with subdivision (c) of this regulation.

~~(e) (i)~~ Notices to the prescribing provider required under this regulation shall be delivered in the same manner as the prescription drug prior authorization or step therapy exception request was submitted, or another mutually agreeable accessible method of notification.

~~(f) (j)~~ “Minimum Amount of Material Information” means the information generated by or in the possession of the prescribing provider related to the patient's clinical condition that enables an individual with the appropriate training, experience, and competence in prescription drug prior authorization processing to determine if the prescription drug prior authorization or step therapy exception request should be approved or disapproved.

~~(g) (k)~~ In the event the prescribing provider's prescription drug prior authorization or step therapy exception request is disapproved pursuant to ~~(e)(e)~~(4)(B), the notice of disapproval shall contain an accurate and clear written explanation of the specific reason(s) for disapproving the prescription drug prior authorization or step therapy exception request. In the event the prescribing provider's prescription drug prior authorization or step therapy exception request is disapproved pursuant to ~~(e)(e)~~(4)(C), the notice of disapproval shall contain an accurate and clear written explanation of the specific material information that is necessary to approve the request.

~~(h) (l)~~ In the event the health plan or contracted physician group fails to send the notice of disapproval, consistent with the requirements of subdivision ~~(g)(e)~~ and (c), to the prescribing provider within two (2) business days24 hours for exigent circumstances or 72 hours for non-urgent requests, the prescription drug prior authorization or step therapy exception request shall be deemed approved. This subdivision (l) shall not apply to Medi-Cal managed care contracts or any contracts entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

~~(i) (m)~~ Review and Enforcement.

~~(l)~~ Health plans that delegate the financial risk for prescription drugs to a risk-bearing organization, physician or physician group, shall include a provision in the contract requiring the risk-bearing organization, physician or physician group to comply with section 1367.241 of the Knox Keene Act and this regulation.

(2) (1) ~~A H~~health plans, ~~risk-bearing organizations, physicians or physician groups~~ that contracts with a pharmacy benefit manager to conduct prescription drug prior authorization or step therapy exception services shall include a provision in the contract requiring the pharmacy benefit manager to comply with section 1367.241 of the ~~Knox-Keene~~ Act and this regulation.

(3) (2) ~~A H~~health plans, ~~that delegate the financial risk for prescription drugs to a risk-bearing organization, physician or physician group, or~~ that contracts with a pharmacy benefit manager to conduct prescription drug prior authorization or step therapy exception services shall have written policies and procedures in place to ensure that the contracted ~~risk-bearing organizations, physicians, physician groups and~~ pharmacy benefit managers comply with section 1367.241 of the ~~Knox-Keene~~ Act and this regulation.

(4) (3) The obligation of the health plan or physician group to comply with section 1367.241 of the ~~Knox-Keene~~ Act and this regulation shall not be deemed to be waived when the health plan delegates the financial risk for prescription drug benefits to a risk-bearing organization, physician or physician group, or when the health plan or physician group contracts with a pharmacy benefit manager to conduct prescription prior authorization drug or step therapy exception services except as otherwise specified under this regulation.

(5) (4) ~~A H~~health plans, ~~risk-bearing organizations, physicians or physician groups, or contracted pharmacy benefit manager that requires a prescribing provider to utilize a prescription drug prior authorization or step therapy exception form or process in violation of this regulation drug specific form other than Form No. 61-211 or require information in excess of the information required by Form No. 61-211~~ shall be subject the health plan to all civil, criminal, and administrative remedies available under the ~~Knox-Keene~~ Act.

(6) (5) Failure of a health plan, ~~risk-bearing organization, physician or physician group, or a contracted pharmacy benefit manager to comply with the requirements of section 1367.241 of the Knox-Keene Act and this regulation may constitute a basis for disciplinary action against the health plan. The Director shall have the civil, criminal, and administrative remedies available under the Knox-Keene Act, including section 1394.~~

Note: Authority cited: Sections 1341.9, 1344, 1367.24, and 1367.241 and 1367.244, Health and Safety Code. Reference: Sections 1367.24, ~~and 1367.241 and 1367.244~~, Health and Safety Code.

PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

Plan/Medical Group Name: _____ Plan/Medical Group Phone#: (_____) _____
 Plan/Medical Group Fax#: (_____) _____ Non-Urgent Urgent (Exigent Circumstances)

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step-therapy request. **Information contained in the form must be HIPAA compliant.**

Patient Information- This must be filled out completely to ensure HIPAA compliance

First Name:	Last Name:	MI:	Phone Number:
Address:		City:	State: Zip Code:
Date of Birth:	<input type="checkbox"/> Male <input type="checkbox"/> Female	Circle unit of measure Height (in/cm): _____ Weight (lb/kg): _____	Allergies:
Patient's Authorized Representative (if applicable):		Authorized Representative Phone Number:	

Insurance Information

Primary Insurance Name:	Patient ID Number:
Secondary Insurance Name:	Patient ID Number:

Prescriber Information

First Name:	Last Name:	Specialty:
Address:		City: State: Zip Code:
Requestor (if different than prescriber):		Office Contact Person:
NPI Number (individual):		Phone Number:
DEA Number (if required):		Fax Number (in HIPAA compliant area):
Email Address:		

Medication / Medical and Dispensing Information

Medication Name:			
<input type="checkbox"/> New Therapy <input type="checkbox"/> Renewal <input type="checkbox"/> Step Therapy Exception Request			
If Renewal: Date Therapy Initiated:		Duration of Therapy (specific dates):	
How did the patient receive the medication?			
<input type="checkbox"/> Paid under Insurance Name: _____		Prior Auth Number (if known): _____	
<input type="checkbox"/> Other ((explain): _____			
Dose/Strength:	Frequency:	Length of Therapy/#Refills:	Quantity:
Administration:			
<input type="checkbox"/> Oral/SL <input type="checkbox"/> Topical <input type="checkbox"/> Injection <input type="checkbox"/> IV <input type="checkbox"/> Other:			
Administration Location:		<input type="checkbox"/> Patient's Home <input type="checkbox"/> Long Term Care <input type="checkbox"/> Physician's Office <input type="checkbox"/> Home Care Agency <input type="checkbox"/> Other (explain): _____ <input type="checkbox"/> Ambulatory Infusion Center <input type="checkbox"/> Outpatient Hospital Care	

PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

Patient Name:	ID#:
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Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step therapy exception request.

1. Has the patient tried any other medications for this condition? <input type="checkbox"/> YES (if yes, complete below) <input type="checkbox"/> NO

Medication/Therapy (Specify Drug Name and Dosage)	Duration of Therapy (Specify Dates)	Response/Reason for Failure/Allergy

2. List Diagnoses:	ICD-9/ICD-10:
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3. <u>Required clinical information</u> - Please provide all relevant clinical information to support a prior authorization or <u>step therapy exception</u> review.

Please provide symptoms, lab results with dates and/or justification for initial or ongoing therapy or increased dose and if patient has any contraindications for the health plan/insurer preferred drug. Lab results with dates must be provided if needed to establish diagnosis, or evaluate response. Please provide any additional clinical information or comments pertinent to this request for coverage, including information related to exigent circumstances (e.g. formulary tier exceptions), or required under state and federal laws.

Attachments

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification: _____ **Date:** _____

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Plan/Insurer Use Only: Date/Time Request Received by Plan/Insurer: _____ Date/Time of Decision: _____

Approved Denied Comments/Information Requested: _____