

REGULAR

STATE OF CALIFORNIA—OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2013-0115-04	REGULATORY ACTION NUMBER 2014-0110-055	EMERGENCY NUMBER
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ENDORSED FILED
IN THE OFFICE OF

2014 FEB 25 PM 1:51

Debra Bowen
DEBRA BOWEN
SECRETARY OF STATE

For use by Office of Administrative Law (OAL) only	
NOTICE	REGULATIONS

2014 JAN 10 PM 3:49
OFFICE OF
ADMINISTRATIVE LAW

AGENCY WITH RULEMAKING AUTHORITY Department of Insurance	AGENCY FILE NUMBER (if any) REG-2012-00015
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A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input checked="" type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	NOTICE REGISTER NUMBER 2013-42	PUBLICATION DATE 1-25-2013

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Prescription Drug Prior Authorization Requests	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT Section 2218.30 AMEND REPEAL
TITLE(S) 10	

3. TYPE OF FILING			
<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
First 15-Day Notice: 10/18/2013 - 11/04/2013. Second 15-Day Notice: 11/15/2013 - 12/02/2013.

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)
 Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))
 Effective on filing with Secretary of State
 \$100 Changes Without Regulatory Effect
 Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input checked="" type="checkbox"/> Other (Specify) <u>Department of Managed Health Care</u>		

7. CONTACT PERSON Julia Yee	TELEPHONE NUMBER (916) 492-3592	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional) Julia.Yee@insurance.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Geoffrey Margolis</i>	DATE 01/10/2014
TYPED NAME AND TITLE OF SIGNATORY Geoffrey Margolis, Deputy Commissioner and Special Counsel to the Commissioner	

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ENDORSED APPROVED

FEB 25 2014

Office of Administrative Law

STATE OF CALIFORNIA
DEPARTMENT OF INSURANCE
300 Capitol Mall, 17th Floor
Sacramento, CA 95814

TEXT OF MODIFIED REGULATIONS

TITLE 10. INVESTMENT
Chapter 5. Insurance Commissioner
Proposed Regulations

Date: November 15, 2013

CDI File No. REG-2012-00015

PRESCRIPTION DRUG PRIOR AUTHORIZATION REQUESTS

The proposal as revised October 18, 2013 is in single underline. Changes are illustrated by double underline for proposed additions, and by strikeout for proposed deletions.

Article 1.2. Prescription Drug Prior Authorization Requests

Section 2218.30. Prescription Drug Prior Authorization Requests; Form and Procedure

(a) Definitions. The following definitions shall apply to this section:

(1) "Request Form" means the Prescription Drug Prior Authorization Request Form set forth in subdivision (j) of this section.

(2) "Material information" means information that is:

(A) related to the patient's clinical condition sufficient to enable an individual with the appropriate training and experience to determine whether the prescription authorization request should be approved or disapproved; or

(B) required by state or federal law for dispensing restricted prescription drugs.

(b) Health insurers that utilize a prior authorization process for prescription drug benefits shall utilize only the Request Form. Health insurers shall not utilize or accept any prescription drug prior authorization form other than the Request Form.

(c) On or before ~~April~~ October 1, 2014, health insurers shall do the following:

(1) Make the Request Form electronically available on their websites.

(2) Accept the Request Form through any reasonable means of transmission, including, but not limited to, paper, electronic, 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 request.

(4) Notify the prescribing provider within two business days of receipt of a completed Request Form that:

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

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

(C) The prescribing provider's request is disapproved as missing material information necessary to approve or disapprove the request; ~~or~~

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

(E) The request was not submitted on the required form, and must be resubmitted using the approved Request Form.

(d) Notices to the prescribing provider required under this section shall be delivered in the same manner as the Request Form was submitted, or another mutually agreeable accessible method of notification.

(e) Prescription drug prior authorization procedures conducted telephonically, through a web portal, or any other manner of transmission, shall not require the prescribing provider to provide more information than is required by the Request Form.

(f) In the event that the prescribing provider's prior authorization request is disapproved:

(1) Pursuant to subparagraph (c)(4)(B) or (c)(4)(C), the notice of disapproval shall contain an accurate and clear written explanation of the specific reasons for disapproving the prior authorization request.

(2) Pursuant to subparagraph (c)(4)(C), the notice of disapproval shall contain an accurate and clear written explanation that specifically identifies the missing material information that is necessary to approve or disapprove the prior authorization request.

(g) In the event that the notice of disapproval is not sent to the prescribing provider within two business days of receipt of a completed Request Form, or if a health insurer or its third party administrator either fails to utilize only the Request Form, or accepts any prescription drug prior authorization form other than the Request Form, the prescription drug prior authorization request shall be deemed approved.

(h) If a health insurer contracts with a third party administrator to conduct prior prescription authorization services, failure by the third party administrator to comply with the requirements of this section or of Insurance Code section 10123.191 shall subject the health insurer to the remedies available under Insurance Code section 10123.191 and this regulation.

(i) Review and Enforcement.

(1) Every health insurer that contracts with a third party administrator to conduct prior prescription authorization services shall include a provision in its contract with the third party administrator requiring the third party administrator to comply with the requirements of Insurance Code section 10123.191 and this regulation.

(2) Every health insurer, and any third party administrator that conducts prescription drug prior authorizations shall have written policies and procedures in place to ensure that the insurer and its contracting entities comply with the requirements of Insurance Code section 10123.191 and this regulation.

(3) Utilizing or accepting a drug specific form other than the Request Form shall constitute a violation of subdivision (b).

(4) Requiring information in excess of the minimum material information specified by the Request Form shall constitute a failure to utilize only the Request Form, in violation of subdivision (b). An insurer may not disapprove a Request Form on grounds of missing information pursuant to subparagraph (c)(4)(C) if the form provides the minimum amount of material information pursuant to paragraph (c)(3).

(j) Prescription Drug Prior Authorization Request Form.

PRESCRIPTION DRUG PRIOR AUTHORIZATION REQUEST FORM

Plan/Medical Group Name: _____ Plan/Medical Group Phone#: (_____) _____
Plan/Medical Group Fax#: (_____) _____

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 request.					
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					
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 _____			

New 08/13

PRESCRIPTION DRUG PRIOR AUTHORIZATION 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 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:

3. <u>Required clinical information</u> - Please provide all relevant clinical information to support a prior authorization 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 (e.g. formulary tier exceptions) or required under state and federal laws.
<input type="checkbox"/> 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: _____ **Date:** _____

Confidentiality Notice: The documents accompanying this transmission contain confidential health information that is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately (via return FAX) and arrange for the return or destruction of these documents.

Plan Use Only:	Date of Decision: _____
<input type="checkbox"/> Approved <input type="checkbox"/> Denied	Comments/Information Requested: _____

New 08/13

Note: Authority cited: Insurance Code section 10123.191. Reference: Insurance Code section 10123.191.