CA

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

(a)

Health plans that utilize a prescription drug prior authorization or step therapy exception process shall use and accept only the Prescription Drug Prior Authorization or Step Therapy Exception Request Form, numbered 61-211 (Revised 12/16), which is incorporated by reference and referred to hereafter in this section as "Form 61-211." This section does not apply to the following except as further specified in this regulation: (1) Contracted physician groups described in Section 1367.241, subdivision (f)(1)-(3) of the Act. (2) Health plans or their affiliated providers if the health plan owns or operates its pharmacies and does not utilize prescription prior authorizations for prescription drugs. (3) Physicians or physician groups that have been delegated the financial risk for prescription drugs by a health care service plan and that do not use a prior authorization process.

(1)

Contracted physician groups described in Section 1367.241, subdivision (f)(1)-(3) of the Act.

(2)

Health plans or their affiliated providers if the health plan owns or operates its pharmacies and does not utilize prescription prior authorizations for prescription drugs.

(3)

Physicians or physician groups that have been delegated the financial risk for prescription drugs by a health care service plan and that do not use a prior authorization process.

(b)

Contracted physician groups specified in subdivision (a)(1) shall comply with the following provisions of this regulation: subdivisions (e)(3), (e)(4), (k), (l), (m)(1), (m)(2) and (m)(3).

(c)

(1) A prescribing provider may use an electronic prior authorization system compliant with the SCRIPT standard as described in Health and Safety Code Section 1367.241, subdivision (e), in place of Form 61-211. (2) A prescribing provider may submit prescription drug 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.

(1)

A prescribing provider may use an electronic prior authorization system compliant with the SCRIPT standard as described in Health and Safety Code Section 1367.241, subdivision (e), in place of Form 61-211.

(2)

A prescribing provider may submit prescription drug 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.

(d)

A health plan 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

61-211, except as specified in subdivision (c) of this regulation.

(e)

Beginning January 1, 2018, a health plan that maintains the financial risk for prescription drug or step therapy exception benefits and its contracted pharmacy benefit managers shall do the following: (1) Make Form 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, that information shall be submitted as part of section 3. of Form 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 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 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.

(1)

Make Form 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, that information shall be submitted as part of section 3. of Form 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 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 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.

(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 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.

(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.

(h)

A health plan 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 61-211 or a form or process compliant with subdivision (c) of this regulation.

(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.

(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.

(k)

In the event the prescribing provider's prescription drug prior authorization or step therapy exception request is disapproved pursuant to (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)(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.

(l)

In the event the health plan or contracted physician group fails to send the notice of disapproval, consistent with the requirements of subdivisions (e) and (c), to the prescribing provider 24 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.

(m)

Review and Enforcement. (1) A health plan or physician group 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 Act and this regulation. (2) A health plan or contracted physician group 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 pharmacy benefit managers comply with section 1367.241 of the Act and this regulation. (3) The obligation of the health plan or contracted physician group to comply with section 1367.241 of the Act and this regulation shall not be deemed to be waived when the health plan or contracted physician group contracts with a pharmacy benefit manager to conduct prescription drug prior authorization or step therapy exception services except as otherwise specified under this regulation. (4) A health plan 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 shall subject the health plan to all civil, criminal, and administrative remedies available under the Act. (5) Failure of a health plan or a contracted pharmacy benefit manager to comply with the requirements of section 1367.241 of the 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 Act, including section 1394.

(1)

A health plan or physician group 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 Act and this regulation.

(2)

A health plan or contracted physician group 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 pharmacy benefit managers comply with section 1367.241 of the Act and this regulation.

(3)

The obligation of the health plan or contracted physician group to comply with section 1367.241 of the Act and this regulation shall not be deemed to be waived when the health plan or contracted physician group contracts with a pharmacy benefit manager to conduct prescription drug prior authorization or step therapy exception services except as otherwise specified under this regulation.

(4)

A health plan 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 shall subject the health plan to all civil, criminal, and administrative remedies available under the Act.

(5)

Failure of a health plan or a contracted pharmacy benefit manager to comply with the requirements of section 1367.241 of the 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 Act, including section 1394.