DEPARTMENT OF MANAGED HEALTH CARE
OFFICE OF PLAN MONITORING
DIVISION OF PLAN SURVEYS

TECHNICAL ASSISTANCE GUIDE

RX DRUG TAG MODULE

ROUTINE MEDICAL SURVEY

OF

PLAN NAME

DATE OF SURVEY:

PLAN COPY

Issuance of this June 1, 2020 Technical Assistance Guide renders all other versions obsolete.

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PRESCRIPTION DRUG REQUIREMENTS

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Requirement RX-001: Prior Authorization and Step Therapy Exception Requests Review Process

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy

DOCUMENTS TO BE REVIEWED

- Pharmacy management procedures
- Policies and procedures for reviewing requests for prior authorization for prescription drugs
- Policies and procedures for reviewing requests for an exception to the Plan's step therapy process for prescription drugs
- Delegate contracts (if the plan delegates financial risk and/or utilization management functions for prescription drug benefits)
- Policies and procedures for delegate oversight (if the plan delegates financial risk and/or utilization management functions for prescription drug benefits)
- Provider Manual
- The Plan's Web site
- The Plan's contracting Pharmacy Benefit Manager (PBM) Web site (if applicable)

RX-001 - Key Element 1:

1. **The Plan has a process for providers to obtain prior authorization for requests for prescription drugs and exceptions to the Plan's step therapy process. CA Health and Safety Code section 1367.241(a)-(c), (e)-(f), and (h); CA Health and Safety Code section 1367.244(a); 28 CCR 1300.67.241(a)-(c), (e)-(f), (h)-(i), and (m)(1)-(2).**

Assessment Questions	
1.1	Do the Plan's policies and procedures require providers to use Form No. 61-211 to submit prior authorization requests for prescription drugs?
1.2	Does the Plan allow providers to submit prior authorization requests for prescription drugs using an electronic prior authorization system?
1.3	Does the Plan utilize a step therapy process for prescription drugs?
1.3.1	If yes, does the Plan require providers to use Form No. 61-211 to submit step therapy exception requests?

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1.3.2	Do the Plan's policies and procedures treat and respond to step therapy exception requests in the same manner as requests for prior authorization for prescription drugs?
1.3.3	Does the Plan have an expeditious process in place to authorize exceptions to step therapy when medically necessary?
1.4	Do the Plan's policies and procedures require a response to exigent prior authorization and step therapy exception requests within 24 hours?
1.4.1	If yes, do the Plan's policies specify that, if the Plan fails to respond to the request within this timeframe, the request be deemed granted?
1.5	Do the Plan's policies and procedures require a response to non-urgent prior authorization and step therapy exception requests within 72 hours?
1.6	Does the Plan make Form 61-211 electronically available on its website(s)?
1.7	Does the Plan contract with a PBM to conduct prescription drug prior authorization or step therapy exception services?
1.7.1	If yes, the Plan have written policies and procedures in place to ensure that the PBM complies with section 1367.241 of the KKA and Rule 1300.67.241?
1.7.2	Does the PBM make Form 61-211 electronically available on its website(s)?
1.8	Does the Plan: a. delegate financial risk for prescription drugs to a contracted physician group; b. contract with a physician group that uses its own internal prior authorization process; or c. delegate utilization management concerning any prescription drug, regardless of the delegation of financial risk, to a contracted physician group?
1.8.1	If yes, does the Plan's contract require the contracted physician group to comply with Rule 1300.67.241, subdivision (b)?

End of Requirement RX-001: Prior Authorization and Step Therapy Exception Requests Review Processes

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Requirement RX-002: Formulary Exception Request Authorization

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy

DOCUMENTS TO BE REVIEWED

- Policies and procedures for reviewing formulary exception requests, including pharmacy management procedures
- Formulary disclosures
- Evidence of Coverage
- Provider Manual
- The Plan's Web site
- The PBM's Web site (if applicable)
- Sample of formulary exception denial files to be reviewed on site
- Sample of external exception request review files to be reviewed on site, if applicable
- Formulary exception denial template letters

RX-002 - Key Element 1:

1. **The Plan provides an expeditious process for providers to obtain authorization for medically necessary non-formulary prescription drugs. CA Health and Safety Code section 1342.71(c); CA Health and Safety Code section 1367.01(e); CA Health and Safety Code section 1367.22(a); CA Health and Safety Code sections 1367.24(a)-(d) and (k); CA Health and Safety Code section 1367.241(h)(2); CA Health and Safety Code section 1368.01(a) and (c); 45 CFR 156.122(c)(1)-(4).**

Assessment Questions	
1.1	Do the Plan's policies and procedures provide an expeditious process for providers to obtain authorization for medically necessary non-formulary prescription drugs?
1.2	If the Plan offers any individual, small group, or large group product lines, do the Plan's policies and procedures require the Plan to respond to formulary exception requests within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist? *Does not apply to Medi-Cal plans*

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1.3	Do the Plan's policies and procedures require that, if the Plan grants a formulary exception request, the Plan not limit or exclude coverage if the prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition?
1.3.1	If the Plan offers any individual, small group, or large group product lines, do the Plan's policies and procedures require that, if the Plan grants a standard formulary exception request, the Plan provide coverage of the nonformulary drug for the duration of the prescription, including refills? *Does not apply to Medi-Cal plans.*
1.3.2	If the Plan offers any individual, small group, or large group product lines, do the Plan's policies and procedures require that, if the Plan grants an expedited formulary exception request, the Plan provide coverage of the nonformulary drug for the duration the exigency? *Does not apply to Medi-Cal plans.*
1.4	If the Plan offers any individual, small group, or large group product lines, do the Plan's policies and procedures provide a process for an enrollee, an enrollee's designee, or a prescribing provider to request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization?[1] *Does not apply to Medi-Cal plans.*
1.4.1	Do the Plan's policies and procedures require the Plan to make its determination on the external exception review request and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than 72 hours following receipt of the request, if the original request was a standard request for nonformulary prescription drugs? *Does not apply to Medi-Cal plans.*
1.4.2	Do the Plan's policies and procedures require the Plan to make its determination on the external exception review request and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than 24 hours following receipt of the request, if the original request was an expedited formulary exception request? *Does not apply to Medi-Cal plans.*
1.4.3	Do the Plan's policies and procedures require that, if the Plan grants an external exception review request for a standard nonformulary request, the Plan provide coverage of the non-formulary drug for the duration of the prescription? *Does not apply to Medi-Cal plans.*

[1] Also known as an external exception review request.

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1.4.4	Do the Plan's policies and procedures require that, if the Plan grants an external exception review request for an expedited nonformulary request, the Plan provide coverage of the non-formulary drug for the duration of the exigency? *Does not apply to Medi-Cal plans.*
1.5	Does the Plan describe the process by which enrollees may obtain medically necessary non-formulary drugs in the Plan's evidence of coverage and disclosure forms?
1.5.1	If yes, is the information provided in the Plan's evidence of coverage and disclosure forms consistent with the Plan's policies and procedures for obtaining medically necessary nonformulary drugs?

RX-002 - Key Element 2:

2. The Plan timely reviews and responds to formulary exception requests. CA Health and Safety Code section 1367.01(e); CA Health and Safety Code sections 1367.01(e) and (h)(4); CA Health and Safety Code sections 1367.24(a), (b), and (k); CA Health and Safety Code section 1368.01(a) and (c); CA Health and Safety Code section 1368.02(b); CA Health and Safety Code section 1374.30(i); 45 CFR 156.122(c)(1)-(4); 28 CCR 1300.67.241(e)(4)(A)-(E).

Assessment Questions	
2.1	Do the Plan's denial files validate that only licensed Physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny medically necessary non-formulary drugs?
2.2	For standard formulary exception requests, does the Plan notify the enrollee or the enrollee's designee and the prescribing provider of the Plan's decision within 72 hours after the Plan receives the request? *Does not apply to Medi-Cal Plans.*
2.3	For exigent formulary exception requests, does the Plan notify the enrollee or the enrollee's designee and the prescribing provider of the Plan's coverage determination within 24 hours after the Plan receives the request? *Does not apply to Medi-Cal Plans.*
2.4	If the Plan denies a provider's formulary exception request as not medically necessary, do the Plan's denial notices include a clear and concise explanation of the reasons for the Plan's decision?
2.5	Do the Plan's denial notices include a description of the criteria and/or guidelines used for the Plan's decision?

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2.6	Do the Plan's denial notices include the clinical reasons for the denial?
2.7	Do the Plan's denial notices to the prescribing provider include the name and the direct telephone number or telephone extension of the professional that made the determination?
2.8	Do the Plan's denial notices indicate that the enrollee may file a grievance to the Plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the Plan?
2.9	Do the Plan's denial notices indicate that the enrollee may file a grievance seeking an external exception request review? *Does not apply to Medi-Cal Plans*
2.10	Do the Plan's denial notices include information as to how the enrollee may file a grievance with the Plan, including how to seek an external exception request review by an independent review organization? *Does not apply to Medi-Cal Plans*
2.11	Do the Plan's denial letters include the paragraph required by section 1368.02(b)?

RX-002 - Key Element 3:

3. The Plan provides for timely reviews of formulary exception request denials by an independent review organization.
CA Health and Safety Code section 1367.24(k); CA Health and Safety Code section 1368.01(a) and (c); 45 CFR 156.122(c)(3)(i)-(ii).

Assessment Questions	
3.1	Are all external exception request reviews completed by an independent review organization?
3.2	If the enrollee, the enrollee's designee, or the prescribing provider requests an external exception request review for a standard formulary exception request, does the Plan notify the enrollee or the enrollee's designee and the prescribing provider of the Plan's coverage determination within 72 hours after the Plan receives the request?
3.3	If the enrollee, the enrollee's designee, or the prescribing provider requests an external exception request review for an expedited formulary exception request, does the Plan notify the enrollee or the enrollee's designee and the prescribing provider of the Plan's coverage determination within 24 hours after the Plan receives the request?

End of Requirement RX-002: Formulary Exception Request Authorization

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Requirement RX-003: Plan's Obligations Relating to Drug Previously Approved for Enrollee Medical Condition

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- None

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving prescriptions previously approved for coverage by the plan for the medical condition.
- EOC sections referencing prescription coverage

RX-003 - Key Element 1:

1. The Plan does not limit or exclude coverage for a drug the Plan previously approved for an enrollee for the medical condition.
CA Health and Safety Code section 1367.22(a).

Assessment Questions	
1.1	Do the Plan's policies and procedures require coverage of a prescription previously approved for coverage by the Plan for the enrollee's medical condition if the Plan's prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition?

End of Requirement RX-003: Plan's Obligations Relating to Drug Previously Approved for Enrollee Medical Condition

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Requirement RX-004: Coverage for Pain Management Medications for Terminally Ill Patients

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving non-formulary drugs and pain management medication for the terminally ill
- Pharmacy management procedures
- EOC sections referencing prescription coverage
- Sample of prescription pain management denial files to be reviewed on site

RX-004 - Key Element 1:

1. The Plan has policies and procedures to ensure timely processing of requests for prescribed pain management for terminally ill patients.
CA Health and Safety Code section 1367.01(e); CA Health and Safety Code section 1367.215(a); CA Health and Safety Code section 1367.241(b); 28 CCR 1300.67.241(e)(4)(A)-(F), and (l).

Assessment Questions	
1.1	Do the Plan's policies and procedures specify that requests by providers for authorization of appropriately prescribed pain management medications for an enrollee who has been determined to be terminally ill shall be approved or denied in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the Plan's receipt of the information requested by the Plan to make the decision?
1.2	Do the Plan's policies and procedures specify that only licensed physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny pain management for terminally ill patients?
1.3	Do the Plan's policies and procedures stipulate that if the request is denied, or if additional information is required, the Plan is required to contact the requesting provider within one working day of the Plan's determination, with an explanation of the determination, and the reason for the denial or the need for additional information?

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1.3.1	Do the Plan's policies and procedures stipulate that if the request is denied, or if additional information is required, the Plan is required to contact the requesting provider within one working day of the Plan's determination, and no later than within 72 hours of receipt of the request (whichever is sooner), with an explanation of the determination, and the reason for the denial or the need for additional information? *Does not apply to Medi-Cal plans.*
1.3.2	Do the Plan's policies and procedures require the Plan notify the prescribing provider and the enrollee or the enrollee's designee of its decision within 24 hours of receipt of an exigent request? *Does not apply to Medi-Cal plans.*
1.3.3	Do the Plan's policies and procedures require the Plan notify the prescribing provider and the enrollee or the enrollee's designee of its decision within 72 hours of receipt of a non-urgent request? *Does not apply to Medi-Cal plans.*
1.4	Do the Plan's policies and procedures stipulate that the requested treatment shall be deemed authorized if the Plan fails to make a determination as of the expiration of the applicable timeframe?

RX-004 - Key Element 2:

2. The Plan provides coverage for appropriately prescribed pain management medication for terminally ill patients when medically necessary. CA Health and Safety Code section 1367.01(e) and (h)(3)-(4); CA Health and Safety Code section 1367.215(a); CA Health and Safety Code section 1367.241(b); 28 CCR 1300.67.241(e)(4)(A)-(E), (k) and (l).

Assessment Questions	
2.1	Does the Plan approve or deny requests by providers for authorization of appropriately prescribed pain management medication for an enrollee who has been determined to be terminally ill within 72 hours of receipt of the request? *Does not apply to Medi-Cal Plans.*
2.2	*For Medi-Cal Plans only:* does the Plan approve or deny requests by providers for authorization of appropriately prescribed pain management medication for an enrollee who has been determined to be terminally ill within 72 hours of receipt of the information requested by the Plan to make the decision?

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2.3	If additional information is required, do the Plan's files demonstrate that the Plan contacts the requesting provider within one business day of the Plan's determination, with an explanation of the determination, and the reason for the need for additional information?
2.4	If the request is denied, do the Plan's files demonstrate that the Plan contacts the requesting provider within one working day of the determination, with an explanation of the determination, and the reason for the denial?
2.4.1	Do the Plan's files demonstrate that the Plan notifies the requesting provider of its decision within 72 hours of receipt of the request? *Does not apply to Medi-Cal plans.*
2.5	Do the Plan's files demonstrate that the Plan notifies the enrollee of its decision in writing within 72 hours of receipt of the request? *Does not apply to Medi-Cal Plans.*
2.5.1	*For Medi-Cal Plans Only:* If the Plan delays, denies, and/or modifies the request, do the Plan's files demonstrate that the Plan notifies the enrollee in writing within two (2) business days?
2.6	If the Plan delays, denies, and/or modifies the request, do the Plan's written notices include a clear and concise explanation of the reasons for the Plan's decision?
2.7	If the Plan delays, denies, and/or modifies the request, do the Plan's written denials include a description of the criteria or guidelines used for the decision?
2.8	If the Plan delays, denies, and/or modifies the request, do the Plan's written denials specify the clinical reasons for the decision regarding medical necessity?
2.9	If delayed, denied, or modified, do the Plan's written notices to the requesting provider include the name and the direct telephone number or telephone extension of the professional that made the determination?
2.10	If the Plan failed to make a determination within the applicable time frame, do the Plan's files demonstrate that the Plan authorizes the requested treatment?

End of Requirement RX-004: Coverage for Pain Management Medications for Terminally Ill Patients

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Requirement RX-005: Formulary Development

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy
- Pharmacy and Therapeutics Committee Member (if feasible)
- PBM Representative, if applicable

DOCUMENTS TO BE REVIEWED

- Pharmacy management procedures
- Policies and procedures for developing and modifying the Plan's formulary
- Resumes of members of the Plan's Pharmacy and Therapeutics Committee or other formulary decision-making body
- Policies and/or procedures governing conflicts of interest on the Plan's Pharmacy and Therapeutics Committee or other formulary decision-making body
- Minutes of the Pharmacy and Therapeutics Committee or other formulary decision-making body
- Plan's Web site
- Policies and/or procedures for updating the Plan's formulary or formularies
- EOC sections referencing the Plan's formulary and prescription coverage
- Plan's formulary or formularies for nongrandfathered individual and small group products

RX-005 - Key Element 1:

1. **The Plan maintains a pharmacy and therapeutic committee responsible for developing, maintaining, and overseeing the Plan's formulary or formularies. CA Health and Safety Code section 1363.5(b); CA Health and Safety Code section 1367.41(a)-(f); CA Health and Safety Code section 1367.24(e)(2); 28 CCR 1300.67.24(b)(2) and (3).**

Assessment Questions	
1.1	Does the Plan maintain a pharmacy and therapeutics committee?
1.2	Does the membership of the Plan's pharmacy and therapeutics committee board represent a sufficient number of clinical specialties to adequately meet the needs of enrollees?
1.2.1	Does the Plan's pharmacy and therapeutics committee membership include psychiatrists, pediatricians, and/or other mental health-prescribing practitioners?

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1.3	Does the Plan's pharmacy and therapeutic committee consist of at least a majority of practicing physicians, practicing pharmacists, and other practicing health professionals licensed to prescribe drugs?
1.4	Does the Plan maintain policies and/or procedures to identify whether a member of the Plan's pharmacy and therapeutics committee has a conflict of interest with respect to a pharmaceutical drug issuer or manufacturer?
1.5	Does at least 20% of the Plan's pharmacy and therapeutics committee have no conflict of interest with respect to any pharmaceutical issuer or manufacturer?
1.6	Does the Plan maintain policies requiring a member of the pharmacy and therapeutics committee to abstain from voting on any issue in which the member has a conflict of interest with respect to a pharmaceutical issuer or manufacturer?
1.7	Does the Plan's pharmacy and therapeutics committee meet at least quarterly?
1.8	Does the Plan's pharmacy and therapeutics committee document its rationale for decisions regarding the development of, or revisions to, the Plan's formulary list?
1.9	Does the pharmacy and therapeutics committee develop and document procedures to ensure appropriate drug review and inclusion?
1.10	Does the pharmacy and therapeutics committee review policies that guide exceptions and other utilization processes, including drug utilization review, quantity limits, and therapeutic interchange?
1.11	Does the pharmacy and therapeutics committee review and analyze treatment protocols and procedures related to the Plan's formulary list at least annually?
1.12	Does the pharmacy and therapeutics committee review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to covered prescription drugs?

RX-005 - Key Element 2:

2. The Plan posts its formulary or formularies for each product on its website in a manner that is accessible and searchable by potential enrollees, enrollees, providers, the general public, the Department, and federal agencies. CA Health and Safety Code section 1367.20; CA Health and Safety Code section 1367.205(a)(1)-(3).

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Assessment Questions	
2.1	Does the Plan post its formulary or formularies for each product on its website?
2.2	Is the Plan's formulary or formularies accessible to the general public?
2.3	Are each of the Plan's formularies searchable?
2.4	Does the Plan update its formulary or formularies with any changes on a monthly basis?

End of Requirement RX-005: Formulary Development

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Requirement RX-006: Coverage for Mental Health Parity Prescriptions

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy

DOCUMENTS TO BE REVIEWED

- Policies, procedures and protocol documents related to application of limits
- Member materials regarding prescription benefit limits
- Pharmacy management procedures

RX-006 - Key Element 1:

1. The Plan provides prescription coverage for the diagnosis and medically necessary treatment of mental health parity diagnoses under the same terms and conditions applied to other medical conditions.
CA Health and Safety Code sections 1374.72(a) and (b)(4).

Assessment Questions	
1.1	Are the Plan's coverage limits and co-payments for psycho-pharmacologic drugs consistent with or not more stringent than limits for medical prescriptions?

End of Requirement RX-006: Coverage for Mental Health Parity Prescriptions

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Statutory/Regulatory Citations

CA Health and Safety Code section 1342.71(c)

(c) Nothing in this chapter shall prohibit a plan from charging a subscriber or enrollee a copayment or deductible for a prescription drug benefit or from setting forth by contract, a limitation or an exclusion from, coverage of prescription drug benefits, if the copayment, deductible, limitation, or exclusion is reported to, and found unobjectionable by, the director and disclosed to the subscriber or enrollee pursuant to the provisions of Section 1363.

CA Health and Safety Code sections 1342.71(j)

(j) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

CA Health and Safety Code section 1363.5(b)

(b) The criteria or guidelines used by plans, or any entities with which plans contract for services that include utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services shall:
(1) Be developed with involvement from actively practicing health care providers.
(2) Be consistent with sound clinical principles and processes.
(3) Be evaluated, and updated if necessary, at least annually.
(4) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee in that specified case.
(5) Be available to the public upon request. A plan shall only be required to disclose the criteria or guidelines for the specific procedures or conditions requested. A plan may charge reasonable fees to cover administrative expenses related to disclosing criteria or guidelines pursuant to this paragraph, limited to copying and postage costs. The plan may also make the criteria or guidelines available through electronic communication means.

CA Health and Safety Code section 1367.41(a)-(f)

(a) Commencing January 1, 2017, a health care service plan shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the plan delegates responsibility for the formulary to any entity, the obligation of the plan to comply with this chapter shall not be waived.
(b) The pharmacy and therapeutics committee board membership shall conform with both of the following:
(1) Represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.
(2) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.
(d) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

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(e) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding development of, or revisions to, the formulary drug list.
(f) The pharmacy and therapeutics committee shall do all of the following:
(1) Develop and document procedures to ensure appropriate drug review and inclusion.
(2) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.
(3) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.
(4) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.
(5) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.
(6) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.
(7) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.
(8) Ensure that the plan's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommend drug treatment regiments that treat all disease states and do not discourage enrollment by any group of enrollees.
(9) Ensure that the plan's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

CA Health and Safety Code section 1367.20
Every health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary of the plan by major therapeutic category, with an indication of whether any drugs on the list are preferred over other listed drugs. If the health care service plan maintains more than one formulary, the plan shall notify the requester that a choice of formulary lists is available.

CA Health and Safety Code section 1367.205(a)(1)-(3)
(a) In addition to the list required to be provided under Section 1367.20, a health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:
(1) Post the formulary or formularies for each product offered by the plan on the plan's Web site in a manner that is accessible and searchable by potential enrollees, enrollees, providers, the general public, the department, and federal agencies as required by federal law or regulations.
(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.
(3) No later than six months after the date that the standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the plan.

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CA Health and Safety Code section 1367.205(c)
(c) For purposes of this section, “formulary” means the complete list of drugs preferred for use and eligible for coverage under a health care service plan product and includes the drugs covered under the pharmacy benefit of the product.

CA Health and Safety Code section 1367.215(a)
(a) Every health care service plan contract that covers prescription drug benefits shall provide coverage for appropriately prescribed pain management medications for terminally ill patients when medically necessary. The plan shall approve or deny the request by the provider for authorization of coverage for an enrollee who has been determined to be terminally ill in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the plan's receipt of the information requested by the plan to make the decision. If the request is denied or if additional information is required, the plan shall contact the provider within one working day of the determination, with an explanation of the reason for the denial or the need for additional information. The requested treatment shall be deemed authorized as of the expiration of the applicable timeframe.

CA Health and Safety Code section 1367.22(a)
(a) A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, nor shall anything in this section be construed to prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.

CA Health and Safety Code section 1367.24(e)(2)
(e) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:
(2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

CA Health and Safety Code section 1367.24(k)
(k) For any individual, small group, or large health plan contracts, a health care service plan’s process described in subdivision (a) shall comply with the request for exception and external exception request review processes de- scribed in subdivision (c) of

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Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts as described in subdivision (l).

CA Health and Safety Code section 1367.241(a)-(c), (e)-(f), and (h)[2]

(a) Notwithstanding any other law, on and after January 1, 2013, a health care service plan that provides coverage for prescription drugs shall accept only the prior authorization form developed pursuant to subdivision (c), or an electronic prior authorization process described in subdivision (e), when requiring prior authorization for prescription drugs. This section does not apply in the event that a physician or physician group has been delegated the financial risk for prescription drugs by a health care service plan and does not use a prior authorization process. This section does not apply to a health care service plan, or to its affiliated providers, if the health care service plan owns and operates its pharmacies and does not use a prior authorization process for prescription drugs.

(b) If a health care service plan or a contracted physician group fails to respond within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization request from a prescribing provider, the prior authorization request shall be deemed to have been granted. The requirements of this subdivision shall not apply to 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. Medi-Cal managed care health care service plans that contract under those chapters shall not be required to maintain an external exception request review as provided in Section 156.122 of Title 45 of the Code of Federal Regulations.

(c) On or before January 1, 2017, the department and the Department of Insurance shall jointly develop a uniform prior authorization form. Notwithstanding any other law, on and after July 1, 2017, or six months after the form is completed pursuant to this section, whichever is later, every prescribing provider shall use that uniform prior authorization form, or an electronic prior authorization process described in subdivision (e), to request prior authorization for coverage of prescription drugs and every health care service plan shall accept that form or electronic process as sufficient to request prior authorization for prescription drugs.

(e) A prescribing provider may use an electronic prior authorization system utilizing the standardized form described in subdivision (c) or an electronic process developed specifically for transmitting prior authorization information that meets the National Council for Prescription Drug Programs' SCRIPT standard for electronic prior authorization transactions.

(f) Subdivision (a) does not apply if any of the following occurs:

(1) A contracted physician group is delegated the financial risk for prescription drugs by a health care service plan.

(2) A contracted physician group uses its own internal prior authorization process rather than the health care service plan's prior authorization process for plan enrollees.

[2] All health care service plans are required to start using Form 61-211 (Revised 12/16) by January 1, 2018. The revised form can be found here: Prescription Prior Authorization Request Form. Up until they implement the revised form, all health care service plans were required to use Form 61-211 (New 08/13).

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(3) A contracted physician group is delegated a utilization management function by the health care service plan concerning any prescription drug, regardless of the delegation of financial risk.
(h) For purposes of this section:
(1) “Prescribing provider” shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.
(2) “Exigent circumstances” exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.
(3) “Completed prior authorization request” means a completed uniform prior authorization form developed pursuant to subdivision (c), or a completed request submitted using an electronic prior authorization system described in subdivision (e), or, for contracted physician groups described in subdivision (f), the process used by the contracted physician group.

CA Health and Safety Code sections 1367.24(a)-(d) and (k)
(a) Every health care service plan that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 1999, every health care service plan that provides prescription drug benefits shall file with the department a description of its process, including timelines, for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. Each plan shall provide a written description of its most current process, including timelines, to its prescribing providers. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.
(b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the plan. The notice shall comply with subdivision (b) of Section 1368.02. Any health plan that is required to maintain an external exception request review process pursuant to subdivision (k) shall indicate in the notice required under this subdivision that the enrollee may file a grievance seeking an external exception request review.
(c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall not apply to a nonformulary drug that has been prescribed for an enrollee in conformance with the provisions of Section 1367.22.
(d) The process described in subdivision (a) by which enrollees may obtain medically necessary nonformulary drugs, including specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage

and disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1999.
(k) For any individual, small group, or large health plan contracts, a health care service plan's process described in subdivision (a) shall comply with the request for exception and external exception request review processes de- scribed in subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts as described in subdivision (l).

CA Health and Safety Code section 1367.241(b)
(b) If a health care service plan or a contracted physician group fails to respond within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization request from a prescribing provider, the prior authorization request shall be deemed to have been granted. The requirements of this subdivision shall not apply to contracts entered into pursuant to Chapter 7 (commencing with Section14000), 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. Medi-Cal managed care health care service plans that contract under those chapters shall not be required to maintain an external exception request review as provided in Section 156.122 of Title 45 of the Code of Federal Regulations.

CA Health and Safety Code section 1367.241(h)(2)
(h) For purposes of this section:
(2) "Exigent circumstances" exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

CA Health and Safety Code section 1367.244(a)
(a) A request for an exception to a health care service plan's step therapy process for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs pursuant to Section 1367.241, and shall be treated in the same manner, and shall be responded to by the health care service plan in the same manner, as a request for prior authorization for prescription drugs.

CA Health and Safety Code sections 1367.01(e) and (h)(3)
(e) No individual, other than a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, may deny or modify requests for authorization of health care services for an enrollee for reasons of medical necessity. The decision of the physician or other health care professional shall be communicated to the provider and the enrollee pursuant to subdivision (h).
(h) In determining whether to approve, modify, or deny requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, based in whole or in part on medical necessity, a health care service plan subject to this section shall meet the following requirements:

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(3) Decisions to approve, modify, or deny requests by providers for authorization prior to, or concurrent with, the provision of health care services to enrollees shall be communicated to the requesting provider within 24 hours of the decision. Except for concurrent review decisions pertaining to care that is underway, which shall be communicated to the enrollee's treating provider within 24 hours, decisions resulting in denial, delay, or modification of all or part of the requested health care service shall be communicated to the enrollee in writing within two business days of the decision. In the case of concurrent review, care shall not be discontinued until the enrollee's treating provider has been notified of the plan's decision and a care plan has been agreed upon by the treating provider that is appropriate for the medical needs of that patient.

CA Health and Safety Code sections 1367.01(e), (h)(3)-(4)
(e) No individual, other than a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, may deny or modify requests for authorization of health care services for an enrollee for reasons of medical necessity. The decision of the physician or other health care professional shall be communicated to the provider and the enrollee pursuant to subdivision (h).
(h) In determining whether to approve, modify, or deny requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, based in whole or in part on medical necessity, a health care service plan subject to this section shall meet the following requirements:
(3) Decisions to approve, modify, or deny requests by providers for authorization prior to, or concurrent with, the provision of health care services to enrollees shall be communicated to the requesting provider within 24 hours of the decision. Except for concurrent review decisions pertaining to care that is underway, which shall be communicated to the enrollee's treating provider within 24 hours, decisions resulting in denial, delay, or modification of all or part of the requested health care service shall be communicated to the enrollee in writing within two business days of the decision. In the case of concurrent review, care shall not be discontinued until the enrollee's treating provider has been notified of the plan's decision and a care plan has been agreed upon by the treating provider that is appropriate for the medical needs of that patient.
(4) Communications regarding decisions to approve requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall specify the specific health care service approved. Responses regarding decisions to deny, delay, or modify health care services requested by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall be communicated to the enrollee in writing, and to providers initially by telephone or facsimile, except with regard to decisions rendered retrospectively, and then in writing, and shall include a clear and concise explanation of the reasons for the plan's decision, a description of the criteria or guidelines used, and the clinical reasons for the decisions regarding medical necessity. Any written communication to a physician or other health care provider of a denial, delay, or modification of a request shall include the name and telephone number of the health care professional responsible for the denial, delay, or modification. The telephone number provided shall be a direct number or an extension, to allow the physician or health care provider easily to contact the professional

responsible for the denial, delay, or modification. Responses shall also include information as to how the enrollee may file a grievance with the plan pursuant to Section 1368, and in the case of Medi-Cal enrollees, shall explain how to request an administrative hearing and aid paid pending under Sections 51014.1 and 51014.2 of Title 22 of the California Code of Regulations.

CA Health and Safety Code section 1368.01(a) and (c)
(a) The grievance system shall require the plan to resolve grievances within 30 days, except as provided in subdivision (c).
(c) A health care service plan contract in the individual, small group, or large group markets that provides coverage for outpatient prescription drugs shall comply with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts or any entity that enters into a contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

CA Health and Safety Code section 1368.02(b)
(b) Every health care service plan shall publish the department's toll-free telephone number, the department's TDD line for the hearing and speech impaired, the plan's telephone number, and the department's Internet address, on every plan contract, on every evidence of coverage, on copies of plan grievance procedures, on plan complaint forms, and on all written notices to enrollees required under the grievance process of the plan, including any written communications to an enrollee that offer the enrollee the opportunity to participate in the grievance process of the plan and on all written responses to grievances. The department's telephone number, the department's TDD line, the plan's telephone number, and the department's Internet address shall be displayed by the plan in each of these documents in 12-point boldface type in the following regular type statement:

"The California Department of Managed Health Care is responsible for regulating health care service plans. If you have a grievance against your health plan, you should first telephone your health plan at (**insert health plan's telephone number**) and use your health plan's grievance process before contacting the department. Utilizing this grievance procedure does not prohibit any potential legal rights or remedies that may be available to you. If you need help with a grievance involving an emergency, a grievance that has not been satisfactorily resolved by your health plan, or a grievance that has remained unresolved for more than 30 days, you may call the department for assistance. You may also be eligible for an Independent Medical Review (IMR). If you are eligible for IMR, the IMR process will provide an impartial review of medical decisions made by a health plan related to the medical necessity of a proposed service or treatment, coverage decisions for treatments that are experimental or investigational in nature and payment disputes for emergency or urgent medical services. The department also has a toll-free telephone number **(1-888-HMO-2219)** and a TDD line **(1-877-688-9891)** for the hearing and speech impaired. The department's Internet Web

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site **http://www.hmohelp.ca.gov** has complaint forms, IMR application forms and instructions online."

CA Health and Safety Code section 1374.30(i)
(i) No later than January 1, 2001, every health care service Plan shall prominently display in every Plan member handbook or relevant informational brochure, in every Plan contract, on enrollee evidence of coverage forms, on copies of Plan procedures for resolving grievances, on letters of denials issued by either the Plan or its contracting organization, on the grievance forms required under Section 1368, and on all written responses to grievances, information concerning the right of an enrollee to request an independent medical review in cases where the enrollee believes that health care services have been improperly denied, modified, or delayed by the Plan, or by one of its contracting providers

CA Health and Safety Code section 1374.72(a) and (b)(4)
(a) Every health care service plan contract issued, amended, or renewed on or after July 1, 2000, that provides hospital, medical, or surgical coverage shall provide coverage for the diagnosis and medically necessary treatment of severe mental illnesses of a person of any age, and of serious emotional disturbances of a child, as specified in subdivisions (d) and (e), under the same terms and conditions applied to other medical conditions as specified in subdivision (c).
(b) These benefits shall include the following:
(4) Prescription drugs, if the plan contract includes coverage for prescription drugs.

28 CCR 1300.67.24(b)(2) and (3)
(b) Standards for outpatient prescription drug benefit plans
(2) All clinical aspects of a plan's prescription drug benefit shall be developed by qualified medical and pharmacy professionals in accordance with good professional practice. The plan shall establish and document an internal process for ongoing review by qualified medical and pharmacy professionals of the clinical aspects of the prescription drug benefit, including review of limitations and exclusions, and the safety, efficacy, and utilization of outpatient prescription drugs.
(3) Plans seeking to establish limitations or exclusions on outpatient prescription drug benefits shall do so consistent with up-to-date evidence-based outcomes and current published, peer-reviewed medical and pharmaceutical literature.

28 CCR 1300.67.24(d)(2)
(d) Limitations
Plans that provide coverage for outpatient prescription drug benefits may apply the following limitations:
(2) When there is more than one drug that is appropriate for the treatment of a medical condition, a plan may require step therapy. A plan that requires step therapy shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements of the Act and regulations. In circumstances where an enrollee is changing plans, the new plan may not require the enrollee to repeat step therapy when that enrollee is already being treated for a medical condition by a prescription drug provided that the

drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. Nothing in this section shall preclude the new plan from imposing a prior authorization requirement pursuant to Section 1367.24 for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. For purposes of this section, "step therapy'' means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

28 CCR 1300.67.241(c)
(c)(1) A prescribing provider may use an electronic prior authorization system compliant with the SCRIPT standard as described in Health and Safety Code 1367.241, subdivision (e), in place of Form 61-211.
(2) A prescribing provider may submit prescription drug prior authorization or step-therapy exception request using the contracted physician group's process for those groups described in section 1367.241, subdivision (f)(1)-(3) of the Act.

28 CCR 1300.67.241(e)(4)(A)-(E)
(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:
(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 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;

28 CCR 1300.67.241(e)(4)(A)-(F) and (I)
(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:
(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 to subdivision (c) of this regulation, that either:
(A) The prescribing provider's request is approved; or

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(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.
(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.

28 CCR 1300.67.241(a)-(c), (e)-(f), (h)-(i), and (m)(1)-(2)
(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."
(c)(1) A prescribing provider may use an electronic prior authorization system compliant with the SCRIPT standard as described in Health and Safety Code 1367.241, subdivision (e), in place of Form 61-211.
(2) A prescribing provider may submit prescription drug prior authorization or step-therapy exception request using the contracted physician group's process for those groups described in section 1367.241, subdivision (f)(1)-(3) of the Act.
(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

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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 con- tracts 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.
(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 agree- able accessible method of notification.
(m) Review and Enforcement.
(1) A health plan or physician group that contracts with a pharmacy bene- fit 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.
(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.

CCR 1300.67.241(e)(4)(A) through (E), (l), and (k)
(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:
(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;
(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.

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45 CFR 156.122(c)(2)(ii)
(2) Expedited exception request.
(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

45 CFR 156.122(c)(3)(i)-(ii)
(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception).
(3) External exception request review. For plans years beginning on or after January 1, 2016:
(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.
(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.

45 CFR 156.122(c)(1)-(4)
(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.
(1) *Standard exception request.* For plans years beginning on or after January 1, 2016:
(i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan.
(ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.
(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

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(2) *Expedited exception request.*
(i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.
(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.
(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.
(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.
(3) *External exception request review.* For plans years beginning on or after January 1, 2016:
(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.
(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.
(iii) If a health plan grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.
(4) *Application of coverage appeals laws.*
(i) A State may determine that a health plan in the State satisfies the requirements of this paragraph (c) if the health plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan that is compliant with the State's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of this paragraph (c) and include:
(A) An internal review;
(B) An external review;
(C) The ability to expedite the reviews; and
(D) Timeframes that are the same or shorter than the timeframes under paragraphs (c)(1)(ii), (c)(2)(iii), and (c)(3)(ii) of this section.