

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

TECHNICAL ASSISTANCE GUIDE

PRESCRIPTION DRUG COVERAGE

ROUTINE MEDICAL SURVEY

OF

PLAN NAME

DATE OF SURVEY:

PLAN COPY

Issuance of this December 7, 2022 Technical Assistance Guide renders all other versions obsolete.

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PRESCRIPTION DRUG COVERAGE

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Requirement RX-001: Prior Authorization 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
- Pharmacy Benefit Manager (PBM) staff, if applicable

DOCUMENTS TO BE REVIEWED

- Pharmacy management policies and procedures
- Policies and procedures for reviewing requests for prior authorization for prescription drugs
- Delegate agreements and contracts, including PBMs and contracted physician groups (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
- Evidence of coverage (EOC) documents
- The Plan's website
- The Plan's contracting PBM website (if applicable)
- Prior authorization denial and modification template letters
- Utilization management policies and procedures
- Sample of prior authorization denial and modification files to be reviewed

RX-001 - Key Element 1:

- 1. The Plan has a process for providers to obtain prior authorization for requests for prescription drugs.**

CA Health and Safety code section 1367.206(d) and (h); CA Health and Safety code section 1367.241(b)(1)(A), (b)(2), (d) and (e); CA Health and Safety code section 1385.001; 28 CCR 1300.67.241(a), (c), (d), (e)(1), (e)(4), (h), (m)(1) and (m)(2).

Assessment Questions	
1.1	Do the Plan's policies and procedures require providers to use "Prescription Drug Prior Authorization or Step Therapy Exception Request Form," Form No. 61-211 to submit prior authorization requests for prescription drugs? Section 1367.241(d); Rule 1300.67.241(a), (h)

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1.2	Does the Plan allow providers to submit prior authorization requests for prescription drugs using an electronic prior authorization system? Section 1367.241(e); Rule 1300.67.241(c), (h)
1.3	Does the Plan make Form 61-211 electronically available on its website(s)? Rule 1300.67.241(a), (e)(1)
1.4	If the Plan contracts with a PBM, does the PBM make Form 61-211 electronically available on its website(s)? Section 1385.001; Rule 1300.67.241(d), (e)(1)
1.5	Do the Plan's policies and procedures require a response to exigent prior authorization requests within 24 hours? Section 1367.241(b)(1)(A); Rule 1300.67.241(e)(4) <i>Does not apply to Medi-Cal plans/lines of business—see Section 1367.01(h)(2) for applicable requirements</i>
1.6	Do the Plan's policies and procedures require a response to non-urgent prior authorization requests within 72 hours? Section 1367.241(b)(1)(A); Rule 1300.67.241(e)(4) <i>Does not apply to Medi-Cal plans/lines of business—see Section 1367.01(h)(1) for applicable requirements</i>
1.7	Do the Plan's policies and procedures specify that, if the Plan fails to respond to the request within the required timeframe, the request is deemed granted for the duration of the prescription, including refills? Section 1367.241(b)(1)(A) <i>Does not apply to Medi-Cal plans/lines of business</i>
1.8	Do the policies and procedures reflect that if a request for prior authorization is incomplete or clinically relevant material information necessary to make a decision is not included, the Plan, or delegated entity, if applicable, shall notify the prescribing provider within the applicable decision timeframe what additional information is needed to approve or deny the prior authorization request, or to appeal its denial? Section 1367.241(b)(2) <i>Does not apply to Medi-Cal plans/lines of business</i>
1.8.1	In the case of such a request for information, do the policies and procedures reflect that once the information is received, the applicable time period to approve or deny shall begin to elapse? Section 1367.241(b)(2) <i>Does not apply to Medi-Cal plans/lines of business</i>
1.9	Do the Plan's policies and procedures reflect that a provider may appeal a denial of a prior authorization request consistent with the Plan's current utilization management processes? Section 1367.206(d)
1.10	Do the policies and procedures reflect that an enrollee or the enrollee's designee or guardian may appeal a denial by filing a grievance? Section 1367.206(d)

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RX-001 - Key Element 2:

2. The Plan timely reviews and responds as required to prior authorization requests.

CA Health and Safety code section 1367.01(e), (h)(4); CA Health and Safety code section 1367.241(b)(1)(A) and (b)(2); CA Health and Safety code section 1368.02(b); CA Health and Safety code section 1374.30(i); 28 CCR 1300.67.241(e)(4)

Assessment Questions	
2.1	Do the Plan's denial files validate that only licensed physicians or licensed health care professionals (competent to evaluate the clinical issues) may deny or modify requests for authorization of prescription drugs for an enrollee for reasons of medical necessity? Section 1367.01(e)
2.2	Does the Plan notify the prescribing provider and enrollee of its coverage determination within 24 hours of exigent prior authorization requests? Section 1367.241(b)(1)(A); Rule 1300.67.241(e)(4) <i>Does not apply to Medi-Cal plans/lines of business—see Section 1367.01(h)(2) for applicable requirements</i>
2.3	Does the Plan notify the prescribing provider and enrollee of its coverage determination with 72 hours of nonurgent prior authorization requests? Section 1367.241(b)(1)(A); Rule 1300.67.241(e)(4) <i>Does not apply to Medi-Cal plans/lines of business—see Section 1367.01(h)(1) for applicable requirements</i>
2.4	Does the Plan fail to respond to the prescribing provider within the required timeframes? Section 1367.241(b)(1)(A) <i>Does not apply to Medi-Cal plans/lines of business</i>
2.4.1	If yes, does the Plan deem that the request is granted for the duration of the prescription, including refills? Section 1367.241(b)(1)(A) <i>Does not apply to Medi-Cal plans/lines of business</i>
2.5	Did the Plan request additional information for the prior authorization request? Section 1367.241(b)(2)
2.5.1	If the Plan needed additional information necessary to make a decision, did it notify the prescribing provider within the required timeframes? Section 1367.241(b)(2)
2.5.2	If the Plan needed additional information necessary to make a decision, did it indicate what additional or clinically relevant information would be needed to approve or deny the request? Section 1367.241(b)(2)
2.5.3	If the Plan received additional or clinically relevant information, did it approve or deny the request within the appropriate timeframe? Section 1367.241(b)(2)

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2.6	Do the Plan's notices include a clear and concise explanation of the reasons for the plan's decision? Section 1367.01(h)(4)
2.7	Do the Plan's notices include a description of the criteria and/or guidelines used for the Plan's decision? Section 1367.01(h)(4)
2.8	Do the Plan's notices include the clinical reasons for the denial? Section 1367.01(h)(4)
2.9	Do the Plan's notices to the prescribing provider include the name and the direct telephone number or telephone extension of the professional responsible for the decision? Section 1367.01(h)(4)
2.10	Do the Plan's notices contain information about how the enrollee may file a grievance with the plan? Section 1367.01(h)(4)
2.11	Do the Plan's notices inform of the external exception request review process? Section 1367.241(b)(2) <i>(Does not apply to Medi-Cal plans/lines of business)</i>
2.12	Do the Plan's denial letters include the paragraph required by section 1368.02(b)? Section 1367.01(h)(4); Section 1368.02(b); Section 1374.30(i)

End of Requirement RX-001: Prior Authorization Requests Review Processes

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Requirement RX-002: Step Therapy Exception Request Review Processes

The requirements in this section do not apply to Medi-Cal

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy
- PBM staff, if applicable

DOCUMENTS TO BE REVIEWED

- **If the Plan does not utilize a step therapy process for prescription drugs, Requirement RX-002 does not need to be assessed.**
- Pharmacy management policies and procedures
- Policies and procedures for reviewing requests for an exception to the Plan's step therapy process for prescription drugs
- Delegate agreements and contracts, including PBMs and contracted physician groups (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
- Evidence of Coverage documents
- The Plan's website
- The Plan's contracting PBM website (if applicable)
- Sample of step therapy exception denial files to be reviewed
- Step therapy exception denial template letters
- Utilization management policies and procedures

RX-002 - Key Element 1:

1. The Plan has a process for providers to request exceptions to the Plan's step therapy process.

CA Health and Safety code section 1367.206(b) – (d) and (h); CA Health and Safety code section 1367.241(b)(1), (b)(2), and (d); CA Health and Safety code section 1367.244(a); CA Health and Safety code section 1385.001; 28 CCR 1300.67.241(a), (b), (d) and (e)(1), (h), (m)(1) and (2).

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Assessment Questions	
1.1	Does the Plan utilize a step therapy process for prescription drugs? If no, stop. The Plan does not need to comply with this Requirement RX-002.
1.1.1	If yes, does the Plan require providers to use "Prescription Drug Prior Authorization or Step Therapy Exception Request Form," Form No. 61-211 to submit step therapy exception requests? Section 1367.241(d); Rule 1300.67.241(a) and (h)
1.1.2	Does the Plan have an expeditious process in place to authorize exceptions to step therapy when medically necessary? Section 1367.244(a); Section 1367.206(b)
1.2	Does the Plan make Form 61-211 electronically available on its website(s)? Rule 1300.67.241(a) and (e)(1)
1.3	If the Plan contracts with a PBM, does the PBM make Form 61-211 electronically available on its website(s)? Section 1385.001; Rule 1300.67.241(d) and (e)(1)
1.4	Do the Plan's policies and procedures reflect that the Plan will approve a step therapy exception request, if prescribing provider has submitted necessary justification and supporting clinical documentation demonstrating that any of the following are met? <ul style="list-style-type: none">• Required prescription drug is contraindicated or is likely, or expected, to cause adverse reaction or physical/mental harm to the enrollee in comparison to requested prescription, based on known clinical characteristics of enrollee and known characteristics and history of the enrollee's prescription drug regimen.• Required prescription drug is expected to be ineffective based on known clinical characteristics of the enrollee and known characteristics and history of the enrollee's prescription drug regimen.• The enrollee has tried the required prescription drug while covered by current or previous health care coverage or Medicaid and the prescription was discontinued due to lack of efficacy/effectiveness/diminished effect/adverse reaction. Plan may require submission of documentation demonstrating the enrollee tried the prescription before it was discontinued.• Required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to: worsen a comorbid condition; decrease capacity to maintain a reasonable functional ability in performing daily activities; or pose a significant barrier to adherence to, compliance with, the enrollee's drug regimen or plan of care.• The enrollee is/was stable on the prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.• Any other reason that is demonstrably shown through prescribing provider submissions of supporting clinical documentation that the required prescription drug is inconsistent with good professional practice. Section 1367.206(b)

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1.5	Do the Plan's policies and procedures require a response to exigent step therapy exception requests within 24 hours? Section 1367.241(b)(1)(A)
1.6	Do the Plan's policies and procedures require a response to non-urgent step therapy exception requests within 72 hours? Section 1367.241(b)(1)(A)
1.7	Do the Plan's policies and procedures specify that, if the Plan fails to respond to the request within the required timeframes, the request is deemed granted for the duration of the prescription, including refills? Section 1367.241(b)(1)(A)
1.8	Do the policies and procedures reflect that if a step therapy exception request is incomplete or clinically relevant material information necessary to make a decision is not included, the Plan, or delegated entity, if applicable, shall notify the prescribing provider within the applicable decision timeframe what additional information is needed to approve or deny the prior authorization request, or to appeal its denial? Section 1367.241(b)(2)
1.8.1	In the case of such a request for information, do the Plan's policies and procedures reflect that once the information is received, the applicable time period to approve or deny shall begin to elapse? Section 1367.241(b)(2)
1.9	Do the Plan's policies and procedures reflect that a provider may appeal a denial of a step therapy exception request consistent with the health care service plan's current utilization management processes? Section 1367.206(c)
1.10	Do the policies and procedures reflect that an enrollee or the enrollee's designee or guardian may appeal a denial by filing a grievance? Section 1367.206(d)

RX-002 - Key Element 2:

2. The Plan timely reviews and responds as required to step therapy exception requests.

CA Health and Safety code section 1367.01(e) and (h)(4); CA Health and Safety code section 1367.206(b); CA Health and Safety code section 1367.241(b)(1)(A) and (b)(2); CA Health and Safety code section 1368.02(b); CA Health and Safety code section 1374.30(i); 28 CCR 1300.67.241(e)(4).

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Assessment Questions	
2.1	Does the Plan utilize a step therapy process for prescription drugs? If no, stop. The Plan does not need to comply with this Requirement RX-002.
2.2	Do the Plan's denial files validate that only licensed physicians or licensed health care professionals (competent to evaluate the clinical issues) may deny or modify requests for step therapy exceptions for an enrollee for reasons of medical necessity? Section 1367.01(e)
2.3	Does the Plan approve a step therapy exception request, if the prescribing provider has submitted necessary justification and supporting clinical documentation demonstrating that any of the following are met? <ul style="list-style-type: none">• Required prescription drug is contraindicated or is likely, or expected, to cause adverse reaction or physical/mental harm to the enrollee in comparison to requested prescription, based on known clinical characteristics of enrollee and known characteristics and history of the enrollee's prescription drug regimen.• Required prescription drug is expected to be ineffective based on known clinical characteristics of the enrollee and known characteristics and history of the enrollee's prescription drug regimen.• The enrollee has tried the required prescription drug while covered by current or previous health care coverage or Medicaid and the prescription was discontinued due to lack of efficacy/effectiveness/diminished effect/adverse reaction. Plan may require submission of documentation demonstrating the enrollee tried the prescription before it was discontinued.• Required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to: worsen a comorbid condition; decrease capacity to maintain a reasonable functional ability in performing daily activities; or pose a significant barrier to adherence to, compliance with, the enrollee's drug regimen or plan of care.• The enrollee is/was stable on the prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.• Any other reason that is demonstrably shown through prescribing provider submissions of supporting clinical documentation that the required prescription drug is inconsistent with good professional practice. Section 1367.206(b)
2.4	Does the Plan notify the prescribing provider and enrollee of its coverage determination within 24 hours of exigent step therapy exception requests? Section 1367.241(b)(1)(A); Rule 1300.67.241(e)(4)
2.5	Does the Plan notify the prescribing provider and enrollee of its coverage determination with 72 hours of nonurgent prior authorization requests? Section 1367.241(b)(1)(A); Rule 1300.67.241(e)(4)

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2.6	Does the Plan fail to respond to the prescribing provider within the required timeframes? Section 1367.241(b)(1)(A)
2.6.1	If yes, does the Plan deem that the request is granted for the duration of the prescription, including refills? Section 1367.241(b)(1)(A)
2.7	Did the Plan request additional information after receiving a step therapy exception request? Section 1367.241(b)(2)
2.7.1	If the Plan needed additional information necessary to make a decision, did it notify the prescribing provider within the required timeframes? Section 1367.241(b)(2)
2.7.2	If the Plan needed additional information necessary to make a decision, did it indicate what additional or clinically relevant information would be needed to approve or deny the request? Section 1367.241(b)(2)
2.7.3	If the Plan received additional or clinically relevant information, did it approve or deny the request within the appropriate timeframe? Section 1367.241(b)(2)
2.8	If the Plan denies a provider's step therapy exception request as not medically necessary, do the Plan's notices include a clear and concise explanation of the reasons for the Plan's decision? Section 1367.01(h)(4)
2.9	Do the Plan's notices include a description of the criteria and/or guidelines used for the Plan's decision? Section 1367.01(h)(4)
2.10	Do the Plan's decisions regarding medical necessity include the clinical reasons for the denial? Section 1367.01(h)(4)
2.11	Do the Plan's notices to the prescribing provider include the name and the direct telephone number or telephone extension of the professional responsible for the decision? Section 1367.01(h)(4)
2.12	Do the Plan's notices contain information about how the enrollee may file a grievance with the plan? Section 1367.01(h)(4)
2.13	Do the Plan's notices inform of the external exception request review process? Section 1367.241(b)(2)
2.14	Do the Plan's denial letters include the paragraph required by section 1368.02(b)? Section 1367.01(h)(4); Section 1368.02(b); Section 1374.30(i)

End of Requirement RX-002: Step Therapy Exception Requests Review Processes

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Requirement RX 003: 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
- PBM staff, if applicable

DOCUMENTS TO BE REVIEWED

- Policies and procedures for reviewing formulary exception requests, including pharmacy management procedures
- Formulary disclosures
- Evidence of coverage (EOC) documents
- Provider Manual
- The Plan's website
- The PBM's website (if applicable)
- Formulary exception denial template letters
- Utilization management policies and procedures
- pdf copy of each formulary by product line (if different)
- Provide location/hyperlink to formulary posted on the Plan's contracting PBM's website (if applicable), by product line. (if different)
- Sample of formulary exception denial files to be reviewed

RX-003 - 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 1367.206(c) and (d); CA Health and Safety code section 1367.22(a); CA Health and Safety code section 1367.24(a) - (d) and (k); CA Health and Safety code section 1368.01(c); 45 CFR 156.122(c)(1)(ii), (c)(2)(iii), (c)(2)(iv); (c)(3)(i), (c)(3)(ii) (c)(3)(iii).

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? Section 1342.71(c); Section 1367.24(a)
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

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	<p>requests within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist?</p> <p>Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(1)(ii) and (2)(iii)</p> <p><i>Does not apply to Medi-Cal plans/lines of business—see Section 1367.01(h)(1) and (2) for applicable requirements</i></p>
1.3	<p>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?</p> <p>Section 1367.22(a); Section 1367.24(c)</p>
1.3.1	<p>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?</p> <p>Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(1)(ii)</p> <p><i>Does not apply to Medi-Cal plans/lines of business.</i></p>
1.3.2	<p>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?</p> <p>Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(2)(iv)</p> <p><i>Does not apply to Medi-Cal plans/lines of business.</i></p>
1.4	<p>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</p> <p>Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(3)(i)</p> <p><i>Does not apply to Medi-Cal plans/lines of business.</i></p>
1.4.1	<p>Do the Plan's policies and procedures require the Plan to make its determination on the external exception request review 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?</p> <p>Section 1367.24(k); 45 CFR 156.122(c)(3)(ii)</p> <p><i>Does not apply to Medi-Cal plans/lines of business.</i></p>

¹ Also known as an external exception request review.
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1.4.2	Do the Plan's policies and procedures require the Plan to make its determination on the external exception request review 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? Section 1367.24(k); 45 CFR 156.122(c)(3)(ii) <i>Does not apply to Medi-Cal plans/lines of business.</i>
1.4.3	Do the Plan's policies and procedures require that, if the Plan grants an external exception request review for a standard nonformulary request, the Plan provide coverage of the non-formulary drug for the duration of the prescription? Section 1367.24(k); 45 CFR 156.122(c)(3)(iii) <i>Does not apply to Medi-Cal plans/lines of business.</i>
1.4.4	Do the Plan's policies and procedures require that, if the Plan grants an external exception request review for an expedited nonformulary request, the Plan provide coverage of the non-formulary drug for the duration of the exigency? Section 1367.24(k); 45 CFR 156.122(c)(3)(iii) <i>Does not apply to Medi-Cal plans/lines of business.</i>
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? Section 1367.24(d)
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? Section 1367.24(d)
1.6	Does the Plan provide a written description of its formulary exception request process, including timelines, to its prescribing providers? Section 1367.24(d)
1.7	Do the Plan's policies and procedures reflect that a provider may appeal a denial of formulary exception request consistent with the Plan's current utilization management processes? Section 1367.206(c)
1.8	Do the policies and procedures reflect that an enrollee or the enrollee's designee or guardian may appeal a denial by filing a grievance? Section 1367.24(b); Section 1367.206(d)

RX-003 - Key Element 2:

2. The Plan timely reviews and responds as required to formulary exception requests.

CA Health and Safety code section 1367.01(e) and (h)(4); CA Health and Safety code section 1367.24(b) and (k); CA Health and Safety code section 1368.01(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)(ii), (2)(iii) and (c)(3).

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Assessment Questions	
2.1	Do the Plan's denial files validate that only licensed physicians or licensed health care professionals (competent to evaluate the clinical issues) may deny or modify requests for formulary exception prescription drugs for an enrollee for reasons of medical necessity? Section 1367.01(e)
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? Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(1)(ii) and (2)(iii) <i>(Does not apply to Medi-Cal plans/lines of business – see Section 1367.01(h) for applicable requirements.)</i>
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? Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(1)(ii) and (2)(iii) <i>(Does not apply to Medi-Cal plans/lines of business – see Section 1367.01(h) for applicable requirements.)</i>
2.4	If the Plan denies or modifies a provider's formulary exception request as not medically necessary, do the Plan's notices include a clear and concise explanation of the reasons for the Plan's decision? Section 1367.01(h)(4)
2.5	Do the Plan's notices include a description of the criteria and/or guidelines used for the Plan's decision? Section 1367.01(h)(4)
2.6	Do the Plan's notices include the clinical reasons for the Plan's decision regarding medical necessity? Section 1367.01(h)(4)
2.7	Do the Plan's notices to the prescribing provider include the name and the direct telephone number or telephone extension of the professional responsible for the decision? Section 1367.01(h)(4)
2.8	Do the Plan's 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? Section 1367.01(h)(4); Section 1367.24(b)
2.9	Do the Plan's notices indicate that the enrollee may file a grievance seeking an external exception request review? Section 1367.24(b) <i>(Does not apply to Medi-Cal plans/lines of business)</i>

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2.10	Do the Plan's 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? Section 1367.24(b) and (k); Section 1368.01(c); 45 CFR 156.122(c)(3) <i>(Does not apply to Medi-Cal plans/lines of business)</i>
2.11	Do the Plan's denial letters include the paragraph required by section 1368.02(b)? Section 1367.01(h)(4); Section 1368.02(b); Section 1374.30(i)

End of Requirement RX-003: Formulary Exception Request Authorization

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Requirement RX-004: External Exception Request Reviews

This Requirement applies only to individual, small group, and large group product lines. It does not apply to Medi-Cal managed care plans or lines of business.

INDIVIDUAL(S)/ POSITIONS TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- Medical Director
- UM Director
- Director or Manager of Pharmacy
- PBM staff, if applicable

DOCUMENTS TO BE REVIEWED

- Policies and procedures for reviewing external exception requests, including pharmacy management procedures
- Evidence of coverage (EOC) documents
- Provider Manual
- The Plan's website
- The PBM's website (if applicable)
- Sample of external exception request review files to be reviewed, if applicable

RX-004 - Key Element 1:

- 1. The Plan provides for timely reviews of prior authorization request, step therapy exception request, and formulary exception request denials by an independent review organization.**

CA Health and Safety code section 1367.24(k); CA Health and Safety code section 1367.241(b)(1)(B) and (b)(3); CA Health and Safety code section 1368.01(c); 45 CFR 156.122(c)(3)(i)-(ii).

Assessment Questions	
1.1	Are all external exception request reviews completed by an independent review organization? Section 1367.24(k); Section 1367.241(b)(1)(B); Section 1368.01(c); 45 CFR 156.122(c)(3)(i)-(ii)
1.2	If the enrollee, the enrollee's designee, or the prescribing provider requests an external exception request review for a standard 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? Section 1367.24(k); Section 1367.241(b)(1)(B); Section 1368.01(c); 45 CFR 156.122(c)(3)(i)-(ii)

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1.3	If the enrollee, the enrollee's designee, or the prescribing provider requests an external exception request review for an expedited prior authorization, step therapy exception, or 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? Section 1367.24(k); Section 1367.241(b)(1)(B); Section 1368.01(c); 45 CFR 156.122(c)(3)(i)-(ii)
1.4	If a Plan utilizes step therapy, does the external independent review organization approve a step therapy exception request if any of the criteria in Section 1367.206(b) are satisfied? Section 1367.241(b)(3)
1.5	If the independent review organization reverses the denial of a prior authorization, formulary exception, or step therapy request, is the decision binding on the Plan? Section 1367.241(b)(1)(B); Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(3)(i)-(ii)
1.5.1	If so, does it apply to the duration of the prescription, including refills? Section 1367.241(b)(1)(B); Section 1367.24(k); Section 1368.01(c); 45 CFR 156.122(c)(3)(i)-(ii)

End of Requirement RX-004: External Exception Request Reviews

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Requirement RX 005: 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:

- Medical Director
- UM Director
- Director or Manager of Pharmacy
- PBM staff, if applicable

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving prescriptions previously approved for coverage by the plan for the medical condition
- Evidence of coverage (EOC) sections referencing prescription coverage

RX-005 - 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? Section 1367.22(a)

End of Requirement RX-005: Plan's Obligations Relating to Drug Previously Approved for Enrollee Medical Condition

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Requirement RX-006: 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
- PBM staff, if applicable

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving non-formulary drugs and pain management medication for the terminally ill
- Pharmacy management procedures
- Evidence of coverage (EOC) sections referencing prescription coverage
- Summary of Plan Design
- Online formulary

RX-006 - 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 1367.215(a); CA Health and Safety code section 1367.01(e) and (h)(3).

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? Section 1367.215(a)
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? Section 1367.01(e)

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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? Section 1367.215(a)
1.3.1	Do Plan policies and procedures require the Plan notify the prescribing provider within 24 hours of the decision and notify the enrollee or the enrollee's designee of its decision within two business days except in the case of concurrent review? Section 1367.01(h)(3)
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? Section 1367.215(a)

End of Requirement RX-006: Coverage for Pain Management Medications for Terminally Ill Patients

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Requirement RX-007: 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 website
- The PBM's website, if applicable
- Policies and/or procedures for updating the Plan's formulary or formularies
- Evidence of coverage (EOC) sections referencing the Plan's formulary and prescription coverage
- Plan's formulary or formularies for nongrandfathered individual and small group products

RX-007 - 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 1367.24(e)(2); CA Health and Safety code Section 1363.5(b); Section 1367.41(a), (b), (c), (d), (e), (f)(1), (f)(4)-(6); 28 CCR 1300.67.24(b)(2) and (b)(3).

Assessment Questions	
1.1	Does the Plan maintain a pharmacy and therapeutics committee? Section 1367.41(a)

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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? Section 1367.41(b)(1)
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? Section 1363.5(b)(1); Section 1367.41(b)(2); Rule 1300.67.24(b)(2)
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? Section 1367.41(c)
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? Section 1367.41(d)
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? Section 1367.41(c)
1.7	Does the Plan's pharmacy and therapeutics committee meet at least quarterly? Section 1367.41(e)
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? Section 1367.41(e); Section 1367.24(e)(2)
1.9	Does the pharmacy and therapeutics committee develop and document procedures to ensure appropriate drug review and inclusion? Section 1363.5(b); Section 1367.41(f)(1); Section 1367.24(e)(2); Rule 1300.67.24(b)(3)
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? Section 1363.5(b); Section 1367.41(f)(4); Section 1367.24(e)(2); Rule 1300.67.24(b)(3)
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? Section 1363.5(b); Section 1367.41(f)(5); Section 1367.24(e)(2); Rule 1300.67.24(b)(3)
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? Section 1363.5(b); Section 1367.41(f)(6); Section 1367.24(e)(2); Rule 1300.67.24(b)(3)

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RX-007 - 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 1367.205(a)(1)-(2); 28 CCR 1300.67.205(b), (c)(1)-(c)(7), (d)(1)-(2),(4), (5)-(13), (15), (16), (18)-(19).

Assessment Questions	
2.1	Does the Plan post its formulary or formularies for each product on its website? Section 1367.205(a)(1)
2.2	Are each of the Plan's formularies accessible and searchable? Section 1367.205(a)(1); Rule 1300.67.205(b) and (c)(6)
2.3	Does the Plan update its formulary or formularies with any changes on a monthly basis? Section 1367.205(a)(2)
2.4	Do each of the Plan's formularies include the following sections in the order listed: (1) Cover page; (2) Table of contents; (3) Informational section; (4) Categorical list of prescription drugs; and (5) Index of prescription drugs. Rule 1300.67.205(b)(1)-(5)
2.5	Does each formulary include a cover page? Rule 1300.67.205(c)
2.5.1	Does the cover page include the title of the document? Rule 1300.67.205(c)(1)
2.5.2	Does the coverage page include the name of the health plan offering the formulary? Rule 1300.67.205(c)(2)
2.5.3	Does the cover page include the name of each health plan product to which the formulary applies? Rule 1300.67.205(c)(3)
2.5.4	Does the cover page include the date the formulary was last updated? Rule 1300.67.205(c)(4)
2.5.5	Does the cover page include a notice that the formulary is subject to change and all previous versions of the formulary are no longer in effect? Rule 1300.67.205(c)(5)
2.5.6	Does the cover page include a direct website link/URL for the location of the electronic version of the formulary posted on the Plan's public website? Rule 1300.67.205(c)(6)

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2.5.7	Does the cover page include either: (a) a direct website link/URL for the location of plan-specific coverage documents that include cost sharing applicable to prescription drugs for each health plan product to which the formulary applies; OR (b) specific instructions for locating plan-specific coverage documents that include cost sharing applicable to prescription drugs for each health plan product to which the formulary applies? Rule 1300.67.205(c)(7)
2.6	Does the informational section for each formulary include instructions for contacting the Plan's customer service department? Rule 1300.67.205(d)(1)
2.7	Does the informational section for each formulary include a definition section? Rule 1300.67.205(d)(2)
2.8	Does the informational section for each formulary include instructions for locating a prescription drug in the categorical list of prescription drugs? Rule 1300.67.205(d)(4)
2.8.1	Does the description explain a drug is listed alphabetically by its brand and generic names in the therapeutic category and class to which it belongs? Rule 1300.67.205(d)(5)(A)
2.8.2	Does the description include an example of a drug available both as a brand name drug and a generic equivalent to illustrate how such a drug is listed? Rule 1300.67.205(d)(5)(B)
2.9	Does the informational section for each formulary include a description of how drugs are listed in the categorical list of prescription drugs? Rule 1300.67.205(d)(5)
2.9.1	Does the description explain the generic name of a brand name drug is included after the brand name in parenthesis in all bold and italicized lowercase letters? Rule 1300.67.205(d)(5)(B)
2.9.2	Does the description explain if a generic equivalent for a brand name is available, and both the brand name and generic equivalents are covered, the generic drug will be listed separately from the brand name drug in all bold and italicized lowercase letters? Rule 1300.67.205(d)(5)(C)
2.9.3	Does the description explain that, in the event a generic drug is marketed under a proprietary, trademark protected brand name, the brand name will be listed in all CAPITAL letters after the generic name in parentheses and regular typeface with first letter of each word capitalized? Rule 1300.67.205(d)(5)(D)

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2.10	Does the informational section for each formulary include a description of the drug tiers (if the drugs are grouped into tiers) that (i) accurately describes the types of prescription drugs placed in each tier and (ii) explains how to determine which (A) prescription drugs are preferred drugs and (B) the cost sharing for each drug tier? Rule 1300.67.205(d)(6)
2.11	Does the informational section of each formulary include a description of all utilization management restrictions the Plan imposes on prescription drug coverage, including, but not limited to, prior authorization requirements, step therapy requirements, quantity limits, and network limitations on access including specialty pharmacy restrictions? Rule 1300.67.205(d)(7)
2.12	Does the informational section of each formulary include information about the differences between drugs covered under the medical benefit and drugs covered under the outpatient benefit and instructions on how to obtain coverage information concerning drugs covered under the medical benefit? Rule 1300.67.205(d)(8)
2.13	Does the informational section of each formulary include notice that the health plan will update the formulary with any changes on a monthly basis? Rule 1300.67.205(d)(9)
2.13.1	Does the informational section include a description of the types of changes a health plan may make to the formulary during the policy year and the dates on which such changes shall be effective, including (at a minimum) (A) change in drug or dosage form; (B) changes in tier placement of a drug that results in an increase in cost sharing; and (C) any changes of utilization management restrictions, including any additions of these restrictions? Rule 1300.67.205(d)(9)
2.14	Does the informational section include an explanation that the presence of a prescription drug on the formulary does not guarantee an enrollee will be prescribed the prescription drug by their prescribing provider for a particular medical condition? Rule 1300.67.205(d)(10)
2.15	Does the informational section of each formulary include notice that the Plan shall cover nonformulary drugs when medically necessary and a detailed description of the process for requesting coverage of a nonformulary drug? Rule 1300.67.205(d)(11)
2.15.1	Does the description state that the Plan shall notify the enrollee or the enrollee's designee and the enrollee's prescribing provider of its coverage determination within 24 hours of receipt of exigent request and within 72 hours of receipt of all other requests? Rule 1300.67.205(d)(11) <i>Does not apply to Medi-Cal plans/lines of business.</i>

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2.15.2	Does the description state that the plan shall provide coverage pursuant to a non-urgent request for the duration of the prescription, including refills? Rule 1300.67.205(d)(11)
2.15.3	Does the description state that the plan shall provide coverage, including refills, pursuant to a request based on exigent circumstances for the duration of the exigency? Rule 1300.67.205(d)(11)
2.15.4	Does the description state an enrollee may file a grievance or complaint relating to denial of a coverage request for a nonformulary drug and that the coverage documents provide information on appeal rights and procedures? Rule 1300.67.205(d)(11)
2.16	Does the informational section of each formulary include instructions on how to locate and fill a prescription through a network retail pharmacy, mail order pharmacy, and specialty pharmacy, as applicable? Rule 1300.67.205(d)(12)
2.17	Does the informational section of each formulary include a detailed description of the process for requesting prior authorization or a step therapy exception? Rule 1300.67.205(d)(13)
2.17.1	Does the description state that if the Plan fails to respond to a completed prior authorization or step therapy exception request within 72 hours of receiving a non-urgent request and 24 hours of receiving a request based on exigent circumstances, the request is deemed granted? Rule 1300.67.205(d)(13) <i>Does not apply to Medi-Cal plans/lines of business.</i>
2.18	Does the informational section of each formulary include notice that a health plan may not limit or exclude coverage for a drug if the health plan previously approved coverage of the drug for the enrollee's medical condition and the prescribing provider continues to prescribe the drug for the medical condition, provided the drug is appropriately prescribed and safe and effective for treating the enrollee's medical condition? Rule 1300.67.205(d)(15)
2.19	Does the informational section of each formulary include a description of the coverage provided under the outpatient prescription drug benefit for drugs, devices, and products for preventative, contraceptive, and diabetes care? Rule 1300.67.205(d)(16)
2.19.1	Does this description include a detailed explanation of the requirements and process to acquire these drugs, devices, and products through the outpatient prescription drug benefit? Rule 1300.67.205(d)(16)

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2.20	Does the informational section of each formulary include a detailed description of the process for requesting coverage and obtaining drugs that are subject to specialty pharmacy restrictions or other network limitations on coverage, if applicable to any drugs listed on the formulary? Rule 1300.67.205(d)(18)
2.21	Does the informational section of each formulary include an annotated legend or key to all abbreviations, symbols, and notations used in the formulary? Rule 1300.67.205(d)(19)

End of Requirement RX-007: Formulary Development

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Requirement RX-008: 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
- Evidence of Coverage (EOC) Documents
- Summary of Plan Design
- Online formulary

RX-008 - 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). **[Effective until 12/31/2020]**

CA Health and Safety Code sections 1374.72(a)(1), (b)(3), and (c). **[Effective as of 01/01/2021]**

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? Section 1374.72(a)(1), (b)(3), (4), and (c)

End of Requirement RX-008: 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 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.

(c) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.

(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 regimens 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 1367.205(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.

CA Health and Safety Code section 1367.206

(a) If there is more than one drug that is clinically appropriate for the treatment of a medical condition, a health care service plan that provides coverage for prescription drugs may require step therapy.

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(b) A health care service plan shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 1367.241 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee, taking into consideration the enrollee's needs and medical history, along with the professional judgment of the enrollee's provider. The basis of the provider's determination may include, but is not limited to, any of the following criteria:

(1) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the enrollee in comparison to the requested prescription drug, based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.

(3) The enrollee has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health care service plan may require the submission of documentation demonstrating that the enrollee tried the required prescription drug before it was discontinued.

(4) The required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to do any of the following, as determined by the enrollee's prescribing provider:

(A) Worsen a comorbid condition.

(B) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.

(C) Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care.

(5) The enrollee is stable on a prescription drug selected by the enrollee's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.

(c) A health care provider or prescribing provider may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the health care service plan's current utilization management processes.

(d) An enrollee or the enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.

(e) This section does not prohibit either of the following:

(1) A health care service plan or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent or interchangeable biological product before providing coverage for the equivalent branded prescription drug.

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(2) A health care provider from prescribing a prescription drug that is clinically appropriate.

(f) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(g) For purposes of this section, "step therapy exception" means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual enrollee.

(h) Commencing January 1, 2022, a health care service plan contract with a utilization review organization, medical group, or other contracted entity that performs utilization review or utilization management functions on a health care service plan's behalf shall include terms that require the contracted entity to comply with this section and Section 1367.241.

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.

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CA Health and Safety Code section 1367.24(a)-(d), (e)(2) 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.

(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.

...

(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 described in subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply

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to Medi-Cal managed care health care service plan contracts as described in subdivision (l).

CA Health and Safety Code section 1367.241²

(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)(1)(A) If a health care service plan, contracted physician group, or utilization review organization fails to notify a prescribing provider of its coverage determination within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization or step therapy exception request, the prior authorization or step therapy exception request shall be deemed approved for the duration of the prescription, including refills. 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.

(B) The external exception request review process shall apply to a denial of a prior authorization or step therapy exception request. An independent review organization's reversal of a health care service plan's denial of a request for an exception, prior authorization, or a step therapy exception shall be binding on the health care service plan and shall apply for the duration of the prescription, including refills. A health care service plan shall notify the enrollee and prescribing provider of the independent review organization's coverage determination, or request for additional or clinically relevant material information necessary to make a coverage determination, within the time limits required by paragraph (2). This subparagraph shall not affect or limit an enrollee's eligibility for independent medical review under Section 1374.30 or to file an internal appeal with the health care service plan.

(2) If a request for prior authorization or a step therapy exception is incomplete or clinically relevant material information necessary to make a coverage determination is not included, the health care service plan, contracted physician group, or utilization

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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review organization shall notify the prescribing provider within 72 hours of receipt, or within 24 hours of receipt if exigent circumstances exist, what additional or clinically relevant material information is needed to approve or deny the prior authorization or step therapy exception request, or to appeal the denial thereof. Once the requested information is received, the applicable time period to approve or deny a prior authorization or step therapy exception request, or to appeal, shall begin to elapse. If a coverage determination or request for additional or clinically relevant material information by a health care service plan, contracted physician group, or utilization review organization is not received by the prescribing provider within the time allotted, the prior authorization or step therapy exception request, or appeal of a denial thereof, shall be deemed approved for the duration of the prescription, including refills. In the event of a denial, the health care service plan, contracted physician group, or utilization review organization shall inform the prescribing provider and enrollee of the external appeal process under subparagraph (B) of paragraph (1), which shall also apply to a denial of a prior authorization or step therapy exception request.

(3) A health care service plan, contracted physician group, utilization review organization, or external independent review organization shall approve a step therapy exception request, or internal or external appeal of a denial thereof, if any of the criteria in subdivision (b) of Section 1367.206 are satisfied.

(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

(d) The prior authorization form developed pursuant to subdivision (c) shall meet the following criteria:

(1) The form shall not exceed two pages.

(2) The form shall be made electronically available by the department and the health care service plan.

(3) The completed form may also be electronically submitted from the prescribing provider to the health care service plan.

(4) The department and the Department of Insurance shall develop the form with input from interested parties from at least one public meeting.

(5) The department and the Department of Insurance, in development of the standardized form, shall take into consideration the following:

(A) Existing prior authorization forms established by the federal Centers for Medicare and Medicaid Services and the State Department of Health Care Services.

(B) National standards pertaining to electronic prior authorization.

(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.

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(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.

(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.

(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.

(g) For prescription drugs, prior authorization requirements described in subdivisions (c) and (e) apply regardless of how that benefit is classified under the terms of the health plan's group or individual contract.

(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.

(4) "Step therapy exception" means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual enrollee.

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.

(b) The department and the Department of Insurance shall include a provision for step therapy exception requests in the uniform prior authorization form developed pursuant to subdivision (c) of Section 1367.241.

(c) "Step therapy exception" means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual enrollee.

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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.

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CA Health and Safety Code section 1368.01(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 Section 14591) 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 site <http://www.hmohelp.ca.gov> has complaint forms, IMR application forms and instructions online."

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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)(1), and (b)(4)

[Effective **until** 12/31/2020]

(a)(1) 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.

CA Health and Safety Code section 1374.72(a), (b)(3) and (c)

[Effective **as of** 01/01/2021]

(a)(1) Every health care service plan contract issued, amended, or renewed on or after January 1, 2021, that provides hospital, medical, or surgical coverage shall provide coverage for medically necessary treatment of mental health and substance use disorders, under the same terms and conditions applied to other medical conditions as specified in subdivision (c).

...

(b) The benefits that shall be covered pursuant to this section shall include, but not be limited to, the following:

...

(3) Prescription drugs, if the plan contract includes coverage for prescription drugs.

...

(c) The terms and conditions applied to the benefits required by this section, that shall be applied equally to all benefits under the plan contract, shall include, but not be limited to, all of the following patient financial responsibilities:

- (1) Maximum annual and lifetime benefits, if not prohibited by applicable law.
- (2) Copayments and coinsurance.
- (3) Individual and family deductibles.
- (4) Out-of-pocket maximums.

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CA Health and Safety Code section 1385.001

For the purposes of this article, “pharmacy benefit manager” means a person, business, or other entity that, pursuant to a contract with a health care service plan, manages the prescription drug coverage provided by the health care service plan, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs. This definition shall not include a health care service plan licensed under this chapter or any individual employee of a health care service plan or its contracted provider, as defined in subdivision (i) of Section 1345, performing the services described in this section.

28 CCR 1300.67.205(b)(1)-(5), (c)(1)-(7), (d)(1)-(19)

(b) Format of the formulary. The formulary shall be in a searchable format and shall include the following sections in the order listed:

- (1) Cover page;
- (2) Table of contents;
- (3) Informational section;
- (4) Categorical list of prescription drugs; and
- (5) Index of prescription drugs.

(c) Cover page. The cover page of the formulary shall include all of the following:

- (1) The title of the document.
- (2) The name of the health plan offering the formulary.
- (3) The name of each health plan product to which the formulary applies.
- (4) The date the formulary was last updated.
- (5) A notice that the formulary is subject to change and all previous versions of the formulary are no longer in effect.
- (6) A direct website link/URL for the location of the electronic version of the formulary posted on the health plan's public website. The formulary shall be accessible to potential enrollees, enrollees, providers, and the general public. The formulary is accessible if it can be viewed on the website through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number, and if the health plan offers more than one health plan product, when an individual can easily discern which formulary applies to which health plan product.
- (7) A direct website link/URL for the location of, or specific instructions for locating, plan-specific coverage documents that include cost sharing applicable to prescription drugs for each health plan product to which the formulary applies.

(d) Informational section. The informational section of the formulary shall include all of the following:

- (1) Instructions for contacting the health plan's customer service department. A health plan shall have customer service representatives readily available during normal business hours to provide accurate, specific information concerning prescription drug benefits, including but not limited to:

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- (A) information concerning drugs covered under the medical benefit of the enrollee's contract;
 - (B) the actual dollar amount of cost sharing under the enrollee's contract for drugs subject to a copayment or coinsurance; and
 - (C) the process for submitting an exception request and requesting prior authorization and step therapy exceptions.
- (2) Definitions. The informational section of the formulary shall have a definition section as prescribed below. A health plan may request an omission, deviation, or substitutions of the stated definitions to the Director for review and approval.
- (A) "Brand name drug" is a drug that is marketed under a proprietary, trademark protected name. The brand name drug shall be listed in all CAPITAL letters.
 - (B) "Coinsurance" is a percentage of the cost of a covered health care benefit that an enrollee pays after the enrollee has paid the deductible, if a deductible applies to the health care benefit, such as the prescription drug benefit.
 - (C) "Copayment" is a fixed dollar amount that an enrollee pays for a covered health care benefit after the enrollee has paid the deductible, if a deductible applies to the health care benefit, such as the prescription drug benefit.
 - (D) "Deductible" is the amount an enrollee pays for covered health care benefits before the enrollee's health plan begins payment for all or part of the cost of the health care benefit under the terms of the policy.
 - (E) "Drug Tier" is a group of prescription drugs that corresponds to a specified cost sharing tier in the health plan's prescription drug coverage. The tier in which a prescription drug is placed determines the enrollee's portion of the cost for the drug.
 - (F) "Enrollee" is a person enrolled in a health plan who is entitled to receive services from the plan. All references to enrollees in this formulary template shall also include subscribers as defined in this section below.
 - (G) "Exception request" is a request for coverage of a prescription drug. If an enrollee, his or her designee, or prescribing health care provider submits an exception request for coverage of a prescription drug, the health plan must cover the prescription drug when the drug is determined to be medically necessary to treat the enrollee's condition.
 - (H) "Exigent circumstances" are 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.
 - (I) "Formulary" is the complete list of drugs preferred for use and eligible for coverage under a health plan product, and includes all drugs covered under the outpatient prescription drug benefit of the health plan product. Formulary is also known as a prescription drug list,
 - (J) "Generic drug" is the same drug as its brand name equivalent in dosage, safety, strength, how it is taken, quality, performance, and intended use. A generic drug is listed in bold and italicized lowercase letters.
 - (K) "Nonformulary drug" is a prescription drug that is not listed on the health plan's formulary.

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(L) “Out-of-pocket cost” are copayments, coinsurance, and the applicable deductible, plus all costs for health care services that are not covered by the health plan.

(M) “Prescribing provider” is a health care provider authorized to write a prescription to treat a medical condition for a health plan enrollee.

(N) “Prescription” is an oral, written, or electronic order by a prescribing provider for a specific enrollee that contains the name of the prescription drug, the quantity of the prescribed drug, the date of issue, the name and contact information of the prescribing provider, the signature of the prescribing provider if the prescription is in writing, and if requested by the enrollee, the medical condition or purpose for which the drug is being prescribed.

(O) “Prescription drug” is a drug that is prescribed by the enrollee's prescribing provider and requires a prescription under applicable law.

(P) “Prior Authorization” is a health plan's requirement that the enrollee or the enrollee's prescribing provider obtain the health plan's authorization for a prescription drug before the health plan will cover the drug. The health plan shall grant a prior authorization when it is medically necessary for the enrollee to obtain the drug.

(Q) “Step therapy” is a process specifying the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are prescribed. The health plan may require the enrollee to try one or more drugs to treat the enrollee's medical condition before the health plan will cover a particular drug for the condition pursuant to a step therapy request. If the enrollee's prescribing provider submits a request for step therapy exception, the health plans shall make exceptions to step therapy when the criteria is met.

(R) “Subscriber” means the person who is responsible for payment to a plan or whose employment or other status, except for family dependency, is the basis for eligibility for membership in the plan.

(4) Instructions for locating a prescription drug in the categorical list of prescription drugs. The instructions shall explain: (A) if a prescription drug may be located by looking up the therapeutic category and class of the drug or the brand or generic name of the drug in the alphabetical index; and (B) if a generic equivalent for a brand name drug is not available or is not covered, the drug will not be separately listed by its generic name.

(5) A description of how drugs are listed in the categorical list of prescription drugs. At minimum, the description shall explain: (A) a drug is listed alphabetically by its brand and generic names in the therapeutic category and class to which it belongs; (B) the generic name of a brand name drug is included after the brand name in parenthesis and all bold and italicized lowercase letters; (C) if a generic equivalent for a brand name drug is available, and both the brand name and generic equivalents are covered, the generic drug will be listed separately from the brand name drug in all bold and italicized lowercase letters; and (D) in the event a generic drug is marketed under a proprietary, trademark protected brand name, the brand name will be listed in all CAPITAL letters after the generic name in parentheses and regular typeface with first letter of each word capitalized. The description shall include an example of a drug available both as a brand name drug and a generic equivalent to illustrate how such a drug is listed.

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(6) A description of the drug tiers in the formulary, if the drugs are grouped into tiers. The description shall include tier numbers designating the tiers and shall accurately describe the types of prescription drugs placed in each tier. The same description shall be used in the corresponding coverage documents. The description shall explain how to determine the following: (A) which prescription drugs on the formulary are preferred drugs; and (B) the cost sharing for each drug tier, including any applicable dollar maximum amounts for products subject to sections 1342.71 and 1342.73 of the Health and Safety Code. If the formulary has four tiers and is subject to sections 1342.71 and 1342.73 of the Health and Safety Code, drugs shall be placed in tiers consistent with the drug tier definitions in those sections of the Knox-Keene Act.

(7) A description of all utilization management restrictions the health plan imposes on prescription drug coverage, including but not limited to, prior authorization requirements, step therapy requirements, quantity limits, and network limitations on access including specialty pharmacy restrictions.

(8) Information about the differences between drugs covered under the medical benefit and drugs covered under the outpatient prescription drug benefit of the health plan product and instructions on how to obtain coverage information concerning drugs covered under the medical benefit.

(9) Notice that the health plan will update the formulary with any changes on a monthly basis. The notice shall include a description of the types of changes a health plan may make to the formulary during the policy year, the dates on which such changes shall be effective, and may include a description of any prior notification a health plan will provide an affected enrollee of a formulary change. At minimum, the notice shall include, but not be limited to, the following information: (A) change in drug or dosage form; (B) changes in tier placement of a drug that results in an increase in cost sharing; and (C) any changes of utilization management restrictions, including any additions of these restrictions.

(10) An explanation that the presence of a prescription drug on the formulary does not guarantee an enrollee will be prescribed that prescription drug by his or her prescribing provider for a particular medical condition.

(11) Notice that the health plan shall cover nonformulary drugs when medically necessary and a detailed description of the process for requesting coverage of a nonformulary drug. Subject to the exception in subdivision (k) of section 1367.24 of the Health and Safety Code, the description shall state that: (A) the health plan shall notify the enrollee or his or her designee and the enrollee's prescribing provider of its coverage determination within 24 hours of receipt of a request based on exigent circumstances and within 72 hours of receipt of all other requests; (B) the health plan shall provide coverage pursuant to a non-urgent request for the duration of the prescription, including refills; and (C) the health plan shall provide coverage, including refills, pursuant to a request based on exigent circumstances for the duration of the exigency. The description shall also state an enrollee may file a grievance or complaint, pursuant to section 1368 of the Health and Safety Code, relating to denial of a coverage request and that the coverage documents provide information on appeal rights and procedures.

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(12) Instructions on how to locate and fill a prescription through a network retail pharmacy, mail order pharmacy, and specialty pharmacy, as applicable.

(13) A detailed description of the process for requesting prior authorization or a step therapy exception. Subject to the exceptions in subdivision (b) of section 1367.241 of the Health and Safety Code, the description shall state that if a health plan fails to respond to a completed prior authorization or step therapy request within 72 hours of receiving a non-urgent request and 24 hours of receiving a request based on exigent circumstances, the request is deemed granted.

(15) Notice pursuant to section 1367.22 of the Health and Safety Code that a health plan may not limit or exclude coverage for a drug if the health plan previously approved coverage of the drug for the enrollee's medical condition and the prescribing provider continues to prescribe the drug for the medical condition, provided the drug is appropriately prescribed and safe and effective for treating the enrollee's medical condition.

(16) A description of the coverage provided under the outpatient prescription drug benefit for drugs, devices, and FDA-approved products pursuant to sections 1367.002, 1367.25, and 1367.51 of the Health and Safety Code. The description shall include a detailed explanation of the requirements and process to acquire those drugs, devices, and FDA-approved products through the outpatient prescription drug benefit.

(18) If applicable to any drugs listed on the formulary, a detailed description of the process for requesting coverage and obtaining drugs that are subject to specialty pharmacy restrictions or other network limitations on coverage.

(19) An annotated legend or key to all abbreviations, symbols, and notations used in the formulary.

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 1300.67.241(a), (c), (d), (e)(1)-(4), (h)

(a) Health plans that utilize a prescription drug prior authorization or steptherapy 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:

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(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.

...

(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.

(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-

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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.

...

(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.

45 CFR 156.122(c)(1)-(3)

(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.

(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.

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(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.