

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

TECHNICAL ASSISTANCE GUIDE

**PRESCRIPTION (RX) DRUG
BEHAVIORAL HEALTH SURVEY
OF
PLAN NAME**

DATE OF SURVEY:

PLAN COPY

Issuance of this March 27, 2015 Technical Assistance Guide renders all other versions obsolete.

PRESCRIPTION (RX) DRUG REQUIREMENTS*

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***The following RX Drug Requirement from the Full Service TAGs is not applicable to Behavioral Health Plan Surveys:**

- **Requirement RX-003: Coverage for Pain Management Medications for Terminally Ill Patients (formerly UM-007)**

***The following RX Drug Requirement from the Behavioral Health TAG is not applicable to EAP plans:**

- **Requirement RX-001: Non-Formulary Prescription Drug Authorization
EAP plan providers do not typically cover prescription drugs.**

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Requirement RX-001: Non-Formulary Prescription Drug Authorization

STATUTORY/REGULATORY CITATIONS

CA Health and Safety Code section 1367.01(e)

(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).

CA Health and Safety Code sections 1367.01(h)(1) through (4)

(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:

(1) Decisions to approve, modify, or deny, based on medical necessity, requests by providers prior to, or concurrent with the provision of health care services to enrollees that do not meet the requirements for the 72-hour review

required by paragraph (2), shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed five business days from the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. In cases where the review is retrospective, the decision shall be communicated to the individual who received services, or to the individual's designee, within 30 days of the receipt of information that is reasonably necessary to make this determination, and shall be communicated to the provider in a manner that is consistent with current law. For purposes of this section, retrospective reviews shall be for care rendered on or after January 1, 2000.

(2) When the enrollee's condition is such that the enrollee faces an imminent and serious threat to his or her health, including, but not limited to, the potential loss of life, limb, or other major bodily function, or the normal timeframe for the decision making process, as described in paragraph (1), would be detrimental to the enrollee's life or health or could jeopardize the enrollee's ability to regain maximum function, decisions to approve, modify, or deny requests by providers prior to, or concurrent with, the provision of health care services to enrollees, shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed 72 hours after the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. Nothing in this section shall be construed to alter the requirements of subdivision (b) of Section 1371.4. Notwithstanding Section 1371.4, the requirements of this division shall be applicable to all health plans and other entities conducting utilization review or utilization management.

(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

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communicated to the enrollee's treating provider within 24 hours, decisions resulting in denial, delay, or modification of all or part of the requested health care service shall be communicated to the enrollee in writing within two business days of the decision. In the case of concurrent review, care shall not be discontinued until the enrollee's treating provider has been notified of the plan's decision and a care plan has been agreed upon by the treating provider that is appropriate for the medical needs of that patient.

(4) Communications regarding decisions to approve requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall specify the specific health care service approved. Responses regarding decisions to deny, delay, or modify health care services requested by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall be communicated to the enrollee in writing, and to providers initially by telephone or facsimile, except with regard to decisions rendered retrospectively, and then in writing, and shall include a clear and concise explanation of the reasons for the plan's decision, a description of the criteria or guidelines used, and the clinical reasons for the decisions regarding medical necessity. Any written communication to a physician or other health care provider of a denial, delay, or modification of a request shall include the name and telephone number of the health care professional responsible for the denial, delay, or modification. The telephone number provided shall be a direct number or an extension, to allow the physician or health care provider easily to contact the professional responsible for the denial, delay, or modification. Responses shall also include information as to how the enrollee may file a grievance with the plan pursuant to Section 1368, and in the case of Medi-Cal enrollees, shall explain how to request an administrative hearing and aid paid pending under Sections 51014.1 and 51014.2 of Title 22 of the California Code of Regulations.

CA Health and Safety Code section 1367.20

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

CA Health and Safety Code sections 1367.24(a) and (b)

(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 non-formulary 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 non-formulary 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.

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(b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a non-formulary 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.

CA Health and Safety Code section 1367.24(d)

(d) The process described in subdivision (a) by which enrollees may obtain medically necessary non-formulary 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.

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 website <http://www.hmohelp.ca.gov> has complaint forms, IMR application forms and instructions online."

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CA Health and Safety Code section 1374.72(h)

Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

***The following RX Drug Requirement from the Behavioral Health TAG is not applicable to EAP plans:**

- **Requirement RX-001: Non-Formulary Prescription Drug Authorization**
EAP plan providers do not typically cover prescription drugs.

INDIVIDUAL(S)/POSITION(S) TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

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

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving non-formulary drugs, including pharmacy management procedures.
- Pharmacy management procedures.
- Formulary disclosures.
- Plan's formulary for psychotropic medications, and formulary disclosures.
- EOC.
- Pharmacy and Therapeutics Committee minutes.
- Provider Manual.
- The Plan's Web site, if the formulary information is posted on the Web site.
- Sample of files to be reviewed onsite.

RX-001 - Key Element 1:

1. The Plan has an expeditious process for providers to obtain authorization for medically necessary non-formulary prescription drugs.

CA Health and Safety Code section 1367.01(e); CA Health and Safety Code sections 1367.01(h)(1) through (4); CA Health and Safety Code sections 1367.24(a) and (b); CA Health and Safety Code section 1368.02(b)

| Assessment Questions | Yes | No | N/A |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|-----|
| 1.1 Do the Plan's policies and procedures provide an expeditious process for providers to obtain authorization for medically necessary non-formulary prescription drugs? | | | |
| 1.2 Do the Plan's denial files validate that only licensed | | | |

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| Assessment Questions | Yes | No | N/A |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|-----|
| Physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny medically necessary non-formulary drugs? | | | |
| 1.3 Does the Plan make decisions to approve, modify, or deny requests by providers in a timely fashion, <u>not to exceed five business days</u> after the Plan's receipt of the information reasonably necessary to make the determination? (This applies to requests prior to, or concurrent with the provision of health care services to enrollees.) | | | |
| 1.4 For urgent referrals and requests for other health care services, does the Plan make the decision to approve, modify, or deny requests by providers in a timely fashion, <u>not to exceed 72 hours</u> after the Plan's receipt of the information reasonably necessary and requested by the Plan to make the determination? (This applies to requests prior to, or concurrent with the provision of health care services to enrollees.) | | | |
| 1.5 Does the Plan communicate utilization review decisions to approve, deny, delay, or modify health care services to requesting providers initially by telephone, facsimile or electronic mail and then in writing <u>within 24 hours of making the decision?</u> | | | |
| 1.6 Does the Plan communicate UM decisions to deny, delay, or modify health care services to enrollees in writing within 2 business days once it has the information reasonably necessary to make a decision? | | | |
| 1.7 Do the Plan's denial notices of non-formulary prescription drugs include a clear and concise explanation of the reasons for the Plan's decision? | | | |
| 1.8 Do the Plan's denial notices of non-formulary prescription drugs include the clinical reasons for the denial? | | | |
| 1.9 Do the Plan's denial notices of non-formulary prescription drugs include the name of the professional that made the determination? | | | |
| 1.10 Do the Plan's denial notices of non-formulary prescription drugs include the telephone number of the professional that made the determination? | | | |
| 1.11 Do the Plan's denial notices indicate that the enrollee may file a grievance to the Plan? | | | |
| 1.12 Do the Plan's denial notices of non-formulary drugs include information as to how he/she may request an independent medical review? | | | |
| 1.13 Do the Plan's denial notices of non-formulary prescription drugs include alternative drugs or treatments offered by the Plan? | | | |

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RX-001 - Key Element 2:

- 2. The Plan's process for providers to obtain authorization for medically necessary non-formulary prescription drugs is communicated in the Evidence of Coverage (EOC) and disclosure forms. The information includes how to obtain medically necessary non-formulary drugs.
CA Health and Safety Code section 1367.20; CA Health and Safety Code section 1367.24(d)**

| Assessment Questions | Yes | No | N/A |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|------------|
| 2.1 Does the Plan communicate the process by which enrollees may obtain medically necessary non-formulary drugs through its EOC and disclosure forms? | | | |
| 2.2 Is the information provided in the EOC and disclosure forms consistent with the Plan's policy and procedure? | | | |

End of Requirement RX-001: Non-Formulary Prescription Drug Coverage

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Requirement RX-002: Plan's Obligations Relating to Drug Previously Approved for Enrollee Medical Condition

STATUTORY/REGULATORY CITATIONS

CA Health and Safety Code section 1367.22(a)

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

CA Health and Safety Code section 1386(b)(1)

(b) The following acts or omissions constitute grounds for disciplinary action by the director:

(1) The plan is operating at variance with the basic organizational documents as filed pursuant to Section 1351 or 1352, or with its published plan, or in any manner contrary to that described in, and reasonably inferred from, the plan as contained in its application for licensure and annual report, or any modification thereof, unless amendments allowing the variation have been submitted to, and approved by, the director.

INDIVIDUAL(S)/POSITION(S) TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

- None

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving prescriptions previously approved for coverage by the Plan for the medical condition.
- EOC.

RX-002 - 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.

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CA Health and Safety Code section 1367.22(a); CA Health and Safety Code section 1386(b)(1)

| Assessment Questions | Yes | No | N/A |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|------------|
| 1.1 Does the Plan have policies and procedures that require coverage of a prescription previously approved for coverage by the Plan for the medical condition? | | | |

End of Requirement RX-002: Plan's Obligations Relating to Drug Previously Approved for Enrollee Medical Condition

Requirement RX-003: Coverage for Pain Management Medications for Terminally Ill Patients

***This requirement does not apply to Behavioral Health plans.**

End of Requirement RX-003: Coverage for Pain Management Medications for Terminally Ill Patients

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Requirement RX-004: Formulary Development for Psycho-pharmacologic Drugs

STATUTORY/REGULATORY CITATIONS

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 1367.24(e)(2)

(e) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:

- (2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

CA Health and Safety Code section 1374.72(h)

(h) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

28 CCR 1300.67.24(b)(2) and (3)

(b) Standards for outpatient prescription drug benefit plans

(2) All clinical aspects of a plan's prescription drug benefit shall be developed by qualified medical and pharmacy professionals in accordance with good professional practice. The plan shall establish and document an internal process for ongoing review by qualified medical and pharmacy professionals of the clinical aspects of the prescription drug benefit, including review of limitations and exclusions, and the safety, efficacy, and utilization of outpatient prescription drugs.

(3) Plans seeking to establish limitations or exclusions on outpatient prescription drug benefits shall do so consistent with up-to-date evidence-based outcomes and current published, peer-reviewed medical and pharmaceutical literature.

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INDIVIDUAL(S)/POSITION(S) TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

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

DOCUMENTS TO BE REVIEWED

- Policies and procedures for approving non-formulary drugs and pain management medication for the terminally ill.
- Pharmacy management procedures.
- EOC sections referencing prescription coverage.
- Minutes of the Pharmacy and Therapeutics Committee or other formulary decision-making body.
- Sample of files to be reviewed onsite.

RX-004 - Key Element 1:

1. The Plan involves psychiatrists, pediatricians and other mental health prescribing practitioners in the development of the formulary for psycho-pharmacologic drugs and pertinent pharmacy management processes, including, but not limited to, cost-control measures, therapeutic substitution and step-therapy.

CA Health and Safety Code section 1363.5(b); CA Health and Safety Code section 1367.24(e)(2); 28 CCR 1300.67.24(b)(2) and (b)(3)

| Assessment Questions | Yes | No | N/A |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|-----|
| 1.1 Does the Plan involve psychiatrists, pediatricians, and other mental health prescribing practitioners in the development of the formulary for psycho-pharmacological drugs? | | | |
| 1.2 Does the Plan involve psychiatrists, pediatricians, and other mental health prescribing practitioners in the development of pertinent pharmacy management processes, including but not limited to costs-control measures, therapeutic substitution, and step-therapy? | | | |

End of Requirement RX-004: Formulary Development for Psycho-pharmacologic Drugs

BEHAVIORAL HEALTH TAG

Requirement RX-005: Coverage for Mental Health Parity Prescriptions

STATUTORY/REGULATORY CITATIONS

CA Health and Safety Code sections 1374.72(a) and (b)(4)

(a) Every health care service plan contract issued, amended, or renewed on or after July 1, 2000, that provides hospital, medical, or surgical coverage shall provide coverage for the diagnosis and medically necessary treatment of severe mental illnesses of a person of any age, and of serious emotional disturbances of a child, as specified in subdivisions (d) and (e), under the same terms and conditions applied to other medical conditions as specified in subdivision (c).

(b) These benefits shall include the following:

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

CA Health and Safety Code section 1386(b)(1)

(b) The following acts or omissions constitute grounds for disciplinary action by the director:

(1) The plan is operating at variance with the basic organizational documents as filed pursuant to Section 1351 or 1352, or with its published plan, or in any manner contrary to that described in, and reasonably inferred from, the plan as contained in its application for licensure and annual report, or any modification thereof, unless amendments allowing the variation have been submitted to, and approved by, the director.

INDIVIDUAL(S)/POSITION(S) TO BE INTERVIEWED

Staff responsible for the activities described above, for example:

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

DOCUMENTS TO BE REVIEWED

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

RX-005 - 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); CA Health and Safety Code section 1386(b)(1)

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| Assessment Question | Yes | No | N/A |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|------------|
| 1.1 Are the Plans coverage limits and co-payments for psychopharmacologic drugs consistent with or not more stringent than limits for medical prescriptions? | | | |

End of Requirement RX-005: Coverage for Mental Health Parity Prescriptions