§ 1300.67.2.3. Timely Access Quality Assurance for Measurement Year 2022.

(a) Quality Assurance Processes for Measurement Year 2022. Each plan shall have written quality assurance systems, policies and procedures designed to ensure that the plan's network is sufficient to provide accessibility, availability and continuity of covered health care services as required by the Knox–Keene Act and this section. In addition to the requirements established by Rule 1300.70, a plan's quality assurance program shall address:

(1) Standards for the provision of covered services in a timely manner consistent with the requirements of this section.

(2) Compliance monitoring policies and procedures, filed for the Department's review and approval, designed to accurately measure the accessibility and availability of contracted providers, which shall include:

(A) Tracking and documenting network capacity and availability with respect to the standards set forth in Rule 1300.67.2.2(c);

(B) Conducting an annual enrollee experience survey, which shall be conducted in accordance with a valid and reliable survey methodology and designed to ascertain compliance with the standards set forth at Rule 1300.67.2.2(c);

(C) Conducting an annual provider survey, which shall be conducted in accordance with a valid and reliable survey methodology and designed to solicit, from physicians and non–physician mental health providers, perspective and concerns regarding compliance with the standards set forth at Rule 1300.67.2.2(c);

(D) Reviewing and evaluating, on not less than a quarterly basis, the information available to the plan regarding accessibility, availability and continuity of care, including but not limited to information obtained through enrollee and provider surveys, enrollee grievances and appeals, and triage or screening services; and

(E) Verifying the advanced access programs reported by network providers, medical groups and independent practice associations to confirm that appointments are scheduled consistent with the definition of advanced access in Rule 1300.67.2.2(b)(1).

(F) A plan that provides services through a preferred provider organization network may, for that portion of its network, demonstrate compliance with

subsections (a)(2)(A) and (D) of this Rule by monitoring, on not less than an annual basis the following: the number of PPO primary care and specialty physicians under contract with the plan in each county of the plan's network service area; enrollee grievances and appeals regarding timely access; and the rates of compliance with the time–elapsed standards established in Rule 1300.67.2.2, subsection (c)(5).

(3) A plan shall implement prompt investigation and corrective action when compliance monitoring discloses that the plan's network is not sufficient to ensure timely access as required by this section, including taking all necessary and appropriate action to identify the cause(s) underlying identified timely access deficiencies and to bring its network into compliance. Plans shall give advance written notice to all network providers affected by a corrective action, and shall include a description of the identified deficiencies, the rationale for the corrective action, and the name and telephone number of the person authorized to respond to provider concerns regarding the plan's corrective action.

(b)(1) The definitions in Rule 1300.67.2.2 shall apply for the purpose of this section, except as specified in Rule 1300.67.2.3, subsection (b)(2).

(2) The definition set forth in Rule 1300.67.2.2(b)(12)(A) shall not apply to reports or reviews for compliance pursuant to this section.

(c) This section shall become inoperative on January 1, 2023.

NOTE: Authority cited: Sections 1344, 1346 and 1367.03, Health and Safety Code. Reference: Sections 1342, 1367, 1367.01, 1367.03, 1370, 1375.7 and 1380, Health and Safety Code.

HISTORY:

1. New section filed 12-18-2009; operative 1-17-2010 (Register 2009, No. 51).

§ 1300.67.3. Standards for Plan Organization.

(a) The organization of each plan shall provide the capability to furnish in a reasonable and efficient manner the health care services for which subscribers and enrollees have contracted. Such organization shall include:

(1) separation of medical services from fiscal and administrative management sufficient to assure the Director that medical decisions will not be unduly influenced by fiscal and administrative management,

(2) staffing in medical and other health services, and in fiscal and administrative services sufficient to result in the effective conduct of the plan's business, and

(3) written procedures for the conduct of the business of the plan, including the provision of health care services, so as to provide effective controls.

NOTE: Authority cited: Sections 1344, 1346 and 1367.03, Health and Safety Code. Reference: Sections 1342, 1367, 1367.01, 1367.03, 1367.035, 1367.04, 1370, 1371.31, 1375.7 and 1380, Health and Safety Code.

HISTORY:

1. New section filed 3–16–2022; operative 4–1–2022 pursuant to Government Code section 11343.4(b)(3). Submitted to OAL for filing and printing only pursuant to Government Code section 11343.8. Exempt from the APA pursuant to Health and Safety Code section 1367.03(f)(3) (Register 2022, No. 11).

§ 1300.67.4. Subscriber and Group Contracts.

(a) All subscriber and group contracts and endorsements and amendments shall be printed legibly in not less than 8-point type and shall include at least the following:

(1) The information required to be included on disclosure forms by Section 1363(a) of the Code and

(A) the information required to be included on disclosure forms by Section 1300.63 (except subsections (2), (3), (4) and (11) of subsection (b) thereof), and required to be included on evidences of coverage by subsections (b)(2) and (c) (except subsection (16) thereof) of Section 1300.63.1, or

(B) if the plan complies with the provisions of Section 1300.63.2, the information required to be included on combined evidences of coverage and disclosure forms by Section 1300.63.2 (except subsections (1) and (4) of subsection (b) and subsections (2), (25), and (27) of subsection (c) thereof).

(2) Definitions of all terms contained in the contract.

(A) Which are defined by the Act or Chapter 1 of Title 28 of the California Code of Regulations,

(B) Which are any of the following: "pre-existing condition," "guaranteed renewable," or "non-cancellable," or,

(C) Which require definition in order to be understood by a reasonable person not possessing special knowledge of law, medicine, or plans;

(D) Which specifically describes the eligibility of persons as subscribers or enrollees.

(3) Appropriate captions, in boldface type, for the following provisions: limitations, exclusions, exceptions, reductions, deductibles, copayments and other provisions which may decrease or limit benefits to, or increase costs of, any subscriber or enrollee;

(A) A benefit afforded by the contract shall not be subject to any limitation, exclusion, exception, reduction, deductible, or copayment which renders the benefit illusory.

(4) In the same section describing any particular benefit(s), any provisions described in (3) above which are applicable only to any such particular benefit(s);

(5) Provisions relating to cancellation under an appropriate caption, in boldface type, which provisions shall include:

(A) A statement of the bases for cancellation, which shall conform to Section 1365(a) of the Act and these rules;

(B) A statement of the opportunity for review of certain cancellations by the Director as provided in Section 1365(b) of the Code;

(C) A statement that, in the event of cancellation by either the plan (except in the case of fraud or deception in the use of services or facilities of the plan or knowingly permitting such fraud or deception by another) or the other party, the plan shall within 30 days return to the other part the pro rata portion of the money paid to plan which corresponds to any unexpired period for which payment had been received together with amounts due on claims, if any, less any amounts due the plan;

(D) A statement of the time when a notice of cancellation becomes effective;

(E) A statement that receipt by the plan of the proper prepaid or periodic payment after cancellation of the contract for nonpayment shall reinstate the contract as though it had never been cancelled if such payment is received on or before the due date of the succeeding prepaid or periodic payment, provided, however, that the contract may specify one or more of the following methods by which the plan may avoid such reinstatement:

1. In the notice of cancellation, the plan notifies the other party that if payment is not received within 15 days of issuance of the notice of cancellation, a new application is required and the conditions under which a new contract will be issued or the original contract reinstated; or

2. If such payment is received more than 15 days after issuance of the notice of cancellation, the plan refunds such payment within 20 business days; or

3. If such payment is received more than 15 days after issuance of the notice of cancellation, the plan issues to the other party, within 20 business days of

receipt of such payment, a new contract accompanied by written notice stating clearly those respects in which the new contract differs from the cancelled contract in benefits, coverage or otherwise;

(6) A provision prohibiting the plan from increasing the amount paid by the other party, except after a period of at least 30 days from and after the postage paid mailing to the other party at the other party's most current address of record with the plan;

(7) A provision prohibiting the plan from decreasing in any manner the benefits stated in the contract, except after a period of at least 30 days from and after the postage paid mailing to the other party at the other party's most current address of record with the plan;

(8) A provision requiring the plan to provide written notice within a reasonable time to the other party of any termination or breach of contract by, or inability to perform of, any contracting provider if the other party may be materially and adversely affected thereby;

(9) A provision that (i) the plan is subject to the requirements of Chapter 2.2 of Division 2 of the Code and of Chapter 1 of Title 28 of the California Code of Regulations, and (ii) any provision required to be in the contract by either of the above shall bind the plan whether or not provided in the contract.

(10) A provision that, upon termination of a provider contract, the plan shall be liable for covered services rendered by such provider (other than for copayments as defined in subdivision (g) of Section 1345) to a subscriber or enrollee who retains eligibility under the applicable plan contract or by operation of law under the care of such provider at the time of such termination until the services being rendered to the subscriber or enrollee by such provider are completed, unless the plan makes reasonable and medically appropriate provision for the assumption of such services by a contracting provider.

(11) In the case of a group contract, a reasonable provision requiring the group contract holder to mail promptly to each subscriber a legible, true copy of any notice of cancellation of the plan contract which may be received from the plan and to provide promptly to the plan proof of such mailing and the date thereof, if the plan wishes to obligate the group contract holder in connection with the obligations imposed on the plan by Section 1300.65.

(b) For the purposes of this section:

(1) "Other party" means (i) in the case of a group contract, the group representative designated in the contract, and (ii) in the case of an individual contract, the subscriber.

(2) Any express or implied requirement of notice to the other party, in the context of a group contact, requires notice to the group representative designated in the contract and, with respect to material matters, to subscribers and enrollees under the group contract; however, a plan may fulfill any obligation imposed by this section to notify subscribers and enrollees under a group contract if it provides notice to the group representative designated in the contract, and the group contract requires the group representative to disseminate such notice to subscribers and enrollees in the group by the next regular communication to the group but in no event later than 30 days after the receipt thereof.

NOTE: Authority cited: Section 1344, Health and Safety Code. Reference: Sections 1367 and 1379, Health and Safety Code.

HISTORY:

1. New subsection (a)(10) filed 6-2-78; effective thirtieth day thereafter (Register 78, No. 22).
2. Amendment of subsection (a)(5) filed 9-27-79; effective thirtieth day thereafter (Register 79, No. 39).
3. Amendment of subsection (a) filed 1-12-83; effective thirtieth day thereafter (Register 83, No. 3).

4. Amendment of subsections (a)(2)(A), (a)(6), (a)(7) and (a)(9) filed 12-26-91; operative 1-27-92 (Register 92, No. 12).
5. Change without regulatory effect amending subsection (a)(5)(B) filed 7-18-2000 pursuant to section 100, title 1, California Code of Regulations (Register 2000, No. 29).
6. Change without regulatory effect amending subsections (a)(2)(A) and (a)(9) filed 12-22-2000 pursuant to section 100, title 1, California Code of Regulations (Register 2000, No. 51).

§ 1300.67.8. Contracts with Providers.

Written contracts must be executed between the plan and each provider of health care services which regularly furnishes services under the plan. All contracts with providers shall be subject to the following requirements:

(a) A written contract shall be prepared or arranged in a manner which permits confidential treatment by the Director of payment rendered or to be rendered to the provider without concealment or misunderstanding of other terms and provisions of the contract.

(b) The contract shall require that the provider maintain such records and provide such information to the plan or to the Director as may be necessary for compliance by the plan with the provisions of the Act and the rules thereunder, that such records will be retained by the provider for at least two years, and that such obligation is not terminated upon a termination of the agreement, whether by rescission or otherwise. (See Section 1300.75.1)

(c) That the plan shall have access at reasonable times upon demand to the books, records and papers of the provider relating to the health care services provided to subscribers and enrollees, to the cost thereof, to payments received by the provider from subscribers and enrollees of the plan (or from others on their behalf), and, unless the provider is compensated on a fee-for-service basis, to the financial condition of the provider.

(d) The contract shall prohibit surcharges for covered services and shall provide that whenever the plan receives notice of any such surcharge it shall take appropriate action.

(e) The contract shall contain provisions complying with Section 1379 of the Act and requiring that, upon termination of the contract of the provider for any cause, such provider shall comply with the provisions of subdivision (a)(10) of Section 1300.67.4.

NOTE: Authority cited: Section 1344, Health and Safety Code. Reference: Sections 1367, 1381 and 1385, Health and Safety Code.

HISTORY:
1. Amendment filed 6-2-78; effective thirtieth day thereafter (Register 78, No. 22).
2. Amendment of subsection (b) filed 1-12-83; effective thirtieth day thereafter (Register 83, No. 3).
3. Change without regulatory effect amending subsections (a)-(b) filed 7-18-2000 pursuant to section 100, title 1, California Code of Regulations (Register 2000, No. 29).
4. New subsections (f)-(f)(5) filed 10-20-2003; operative 11-19-2003 (Register 2003, No. 43).
5. Repealer of subsections (f)-(f)(5) filed 1-24-2007; operative 2-23-2007 (Register 2007, No. 4).

§ 1300.67.10. Discrimination Prohibited. [Repealed]

HISTORY:
1. Repealer filed 12-26-91; operative 1-27-92 (Register 92, No. 12).

§ 1300.67.11. Disclosure of Conflicts of Interest.

(a) A plan shall not enter into any transaction with a person currently named in Item F of its application under Section 1300.51 (or currently named pursuant to Items 7, 8, or 9 of that application as in effect prior to the effective

date of Section 1300.51.3) unless, prior thereto, each of the following conditions is met:

(1) The material facts concerning the transaction and the person's interest therein are disclosed to the governing body of the plan.

(2) The transaction is approved by a disinterested majority of the governing body.

(3) Such facts and such approval are made a part of the minutes of such governing body or, if no minutes are required of such governing body, otherwise retained as a record of the plan.

(b) A plan shall promptly give written notice to the Director if a transaction is entered into otherwise than in conformity with the terms of this section.

(c) For the purposes of this section, "governing body" means the board of directors, all general partners, the sole proprietor, the board of trustees, and any other persons occupying a similar position or performing similar functions.

NOTE: Authority cited: Section 1344, Health and Safety Code. Reference: Sections 1351 and 1367(h), Health and Safety Code.

HISTORY:

1. Amendment of subsection (a) filed 12-17-85; effective thirtieth day thereafter (Register 85, No. 51.
2. Change without regulatory effect amending subsection (b) filed 7-18-2000 pursuant to section 100, title 1, California Code of Regulations (Register 2000, No. 29).

§ 1300.67.12. Contracts with Solicitor Firms.

A plan shall not permit a solicitor firm to solicit enrollments or subscriptions on its behalf except pursuant to a written contract which meets all of the following minimum requirements:

(a) All funds received by the solicitor firm for the account of the plan shall at all times be segregated from the assets of the solicitor firm and shall be promptly deposited to a trust account in a state or federal bank authorized to do business in this state and insured by an appropriate federal insuring agency. "Promptly deposited" means deposited no later than the business day following receipt by the solicitor firm.

(b) All funds received by the solicitor firm for the account of the plan shall be transmitted to the plan, or to a person designated in the contract, net of actual commissions earned under the particular contract within (5) five business days after such funds are received by the solicitor firm.

(c) The solicitor firm shall comply and shall cause its principal persons and employees to comply with all applicable provisions of the Act and the rules thereunder.

(d) The solicitor firm shall promptly notify the plan of the institution of any disciplinary proceedings against it or against any of its principal persons or employees relating to any license issued to any such person by the California Insurance Commissioner.

NOTE: Authority cited: Section 1344, Health and Safety Code. Reference: Section 1367, Health and Safety Code.

HISTORY:

1. Amendment filed 12-20-77 as an emergency; effective upon filing (Register 77, No. 52).
2. Amendment filed 1-12-83; effective thirtieth day thereafter (Register 83, No. 3).

§ 1300.67.13. Coordination of Benefits ("COB").

(a)(1) This rule does not require the use of COB provisions in plan contracts. If a contract contains a COB provision, the provision must be consistent with the standard provision set forth in subdivision (b), as interpreted by the

"Instructions" set forth in that subdivision. COB provisions, or provisions for the reduction of benefits otherwise payable because of other coverage by whatever name designated, which are not consistent with the standard provision set forth in subdivision (b), may not be used, except that plans of coverage designed to be supplementary over the subscriber's or enrollee's underlying basic plan of coverage may provide that coverage shall be excess to that specific subscriber's or enrollee's plan of basic coverage from whatever source provided.

(2) A COB provision may not relieve a plan of a duty otherwise arising from a plan contract to deliver any health care service to any subscriber or enrollee because the subscriber or enrollee may be or is entitled to coverage for the service by any other plan or insurer.

(3) A COB provision may not result in a delay in furnishing any reasonably necessary health care service to any subscriber or enrollee pursuant to a plan contract.

(b) Standard COB Provision:

(1) Benefits Subject to This Provision

All of the benefits provided under this Plan contract are subject to this provision.

Instructions

When the contract provides both integrated Major Medical Expense Benefits and the Basic Benefits, but the COB provision applies to all or some of the benefits, use appropriate alternate wording such as: "Only the Major Medical Expense Benefits provided under this contract are subject to this provision."

(2) Definitions

(A) "Plan" means any plan providing benefits or services for or by reason of medical or dental care or treatment, which benefits or services are provided by (i) group, blanket or franchise insurance coverage, (ii) service plan contracts, group practice, individual practice and other prepayment coverage, (iii) any coverage under labor-management trusteed plans, union welfare plans, employer organization plans, or employee benefit organization plans, and (iv) any coverage under governmental programs, and any coverage required or provided by any statute.

The term "Plan" shall be construed separately with respect to each policy, contract, or other arrangement for benefits or services and separately with respect to that portion of any such policy, contract, or other arrangement which reserves the right to take the benefits or services of other Plans into consideration in determining its benefits and that portion which does not.

(B) "This Plan" means that portion of this contract which provides the benefits that are subject to this provision.

(C) "Allowable Expense" means any necessary, reasonable, and customary item of expense at least a portion of which is covered under at least one of the Plans covering the person for whom claim is made. When a Plan provides benefits in the form of services rather than cash payments, the reasonable cash value of each service rendered shall be deemed to be both an Allowable Expense and a benefit paid.

(D) "Claim Determination Period" means a calendar year.

Instructions

The definition of a "Plan" within the COB provision of group contracts enumerates the types of coverage which the Plan may consider in determining whether other coverage exists with respect to a specific claim. The definition:

1. May not include individual or family policies, or individual or family subscriber contracts, except as otherwise provided in this special instruction.

2. May include all group policies, group subscriber contracts, selected group disability insurance contracts issued pursuant to section 10270.97 of the Insurance Code and blanket insurance contracts, except blanket insurance contracts issued pursuant to section 10270.2(b) or (e) which contain nonduplication of benefits or excess policy provisions.

3. May not include any entitlements to Medi-Cal benefits under chapter 7 (commencing with section 14000) or chapter 8 (commencing with section 14500) of part 3 of division 9 of the Welfare and Institutions Code, or benefits under the California Crippled Children Services program under section 10020 of the Welfare and Institutions Code or any other coverage provided for or required by law when, by law, its benefits are excess to any private insurance or other non-governmental program.

4. May not include the medical payment benefits customarily included in the traditional automobile contracts.

5. May include "Medicare" or any other similar governmental benefits so long as it does not expand the definition of "Allowable Expenses" beyond the hospital, medical and surgical benefits as may be provided by the government program and so long as such benefits are not by law excess to this Plan.

(3) Effect on Benefits

(A) This provision shall apply in determining the benefits as to a person covered under this Plan for any Claim Determination Period if, for the Allowable Expenses incurred as to such person during such period, the sum of:

(i) the value of the benefits that would be provided by this Plan in the absence of this provision, and

(ii) the benefits that would be payable under all other plans in the absence therein of provisions of similar purpose to this provision would exceed such Allowable Expenses.

(B) As to any Claim Determination Period to which this provision is applicable, the benefits that would be provided under this Plan in the absence of this provision for the Allowable Expenses incurred as to such person during such Claim Determination Period shall be reduced to the extent necessary so that the sum of such reduced benefits and all the benefits payable for such Allowable Expenses under all other Plans, except as provided in paragraph (3)C., shall not exceed the total of such Allowable Expenses. Benefits payable under another Plan include the benefits that would have been payable had claim been made therefor.

(C) If

(i) another Plan which is involved in paragraph (3)B. and which contains a provision coordinating its benefits with those of this Plan would, according to its rules, determine its benefits after the benefits of this Plan have been determined, and

(ii) the rules set forth in paragraph (4) would require this Plan to determine its benefits before such other Plan, then the benefits of such other Plan will be ignored for the purposes of determining the benefits under this Plan.

(4) For the purposes of paragraph (3), use the first of the following rules establishing the order of determination which applies:

(A) The benefits of a Plan which covers the person on whose expenses claim is based other than as a dependent shall be determined before the benefits of a Plan which covers such person as a dependent, except that, if the person is also a Medicare beneficiary and as a result of the rules established by Title XVIII of the Social Security Act (42 USC 1395 et seq.) and implementing regulations, Medicare is (i) secondary to the Plan covering the person as a dependent and

(ii) primary to the Plan covering the person as other than a dependent (e.g., a retired employee), then the benefits of the Plan covering the person as a dependent are determined before those of the Plan covering that person as other than a dependent.

(B) Except for cases of a person for whom claim is made as a dependent child whose parents are separated or divorced, the benefits of a Plan which covers the person on whose expenses claim is based as a dependent of a person whose date of birth, excluding year of birth, occurs earlier in a calendar year, shall be determined before the benefits of a Plan which covers such person as a dependent of a person whose date of birth, excluding year of birth, occurs later in a calendar year. If either Plan does not have the provisions of this subparagraph regarding dependents, which results either in each Plan determining its benefits before the other or in each Plan determining its benefits after the other, the provisions of this subparagraph shall not apply, and the rule set forth in the Plan which does not have the provisions of this subparagraph shall determine the order of the benefits.

(C) Except as provided in subparagraph (E), in the case of a person for whom claim is made as a dependent child whose parents are separated or divorced and the parent with custody of the child has not remarried, the benefits of a Plan which covers the child as a dependent of the parent with custody of the child will be determined before the benefits of a Plan which covers the child as a dependent of the parent without custody.

(D) Except as provided in subparagraph (E), in the case of a person for whom claim is made as a dependent child whose parents are divorced and the parent with custody of the child has remarried, the benefits of a Plan which covers the child as a dependent of the parent with custody shall be determined before the benefits of a Plan which covers that child as a dependent of the stepparent, and the benefits of a Plan which covers that child as a dependent of the stepparent will be determined before the benefits of a Plan which covers that child as a dependent of the parent without custody.

(E) In the case of a person for whom claim is made as a dependent child whose parents are separated or divorced, where there is a court decree which would otherwise establish financial responsibility for the medical, dental or other health care expenses with respect to the child, then, notwithstanding subparagraphs (C) and (D), the benefits of a Plan which covers the child as a dependent of the parent with such financial responsibility shall be determined before the benefits of any other Plan which covers the child as a dependent child.

(F) Except as provided in subparagraph (G), the benefits of a Plan covering the person for whose expenses claim is based as a laid-off or retired employee, or dependent of such person, shall be determined after the benefits of any other Plan covering such person as an employee, other than a laid-off or retired employee, or dependent of such person;

(G) If either Plan does not have a provision regarding laid-off or retired employees, which results in each Plan determining its benefits after the other, then the rule under subparagraph (F) shall not apply;

(H) If a person whose coverage is provided under a right of continuation pursuant to federal or state law also is covered under another Plan, the following shall be the order of benefit determination:

(1) First, the benefits of a Plan covering the person as an employee, member, or subscriber, or as that person's dependent;

(2) Second, the benefits under continuation coverage. If the other Plan does not have the rules described above, and if, as a result, the Plans do not agree on the order of benefits, the rule under this subparagraph is ignored.

(I) When subparagraphs (A) through (H) do not establish an order of benefit determination, the benefits of a Plan which has covered the person on whose expenses claim is based for the longer period of time shall be determined before the benefits of a Plan which has covered such person the shorter period of time.

(5) When this provision operates to reduce the total amount of benefits otherwise payable as to a person covered under this Plan during any Claim Determination Period, each benefit that would be payable in the absence of this provision shall be reduced proportionately, and such reduced amount shall be charged against any applicable benefit limit of this Plan.

Instructions

1. When a claim under a Plan with a COB provision involves another Plan which also has a COB provision, the carriers involved shall use the above rules to decide the order in which the benefits payable under the respective Plans will be determined.

2. In determining the length of time an individual has been covered under a given Plan, two successive Plans of a given group shall be deemed to be one continuous Plan so long as the claimant concerned was eligible for coverage within 24 hours after the prior Plan terminated. Thus, neither a change in the amount or scope of benefits provided by a Plan, a change in the carrier insuring the Plan, nor a change from one type of Plan to another (e.g., single employer to multiple employer Plan, or vice versa, or single employer to a Taft-Hartley Welfare Plan) would constitute the start of a new Plan for purposes of this instruction.

3. If a claimant's effective date of coverage under a given Plan is subsequent to the date the carrier first contracted to provide the Plan for the group concerned (employer, union, association, etc.), then, in the absence of specific information to the contrary, the carrier shall assume, for purposes of this instruction, that the claimant's length of time covered under that Plan shall be measured from claimant's effective date coverage. If a claimant's effective date of coverage under a given Plan is the same as the date the carrier first contracted to provide the Plan for the group concerned, then the carrier shall require the group concerned to furnish the date the claimant first became covered under the earliest of any prior Plans the group may have had. If such date is not readily available, the date the claimant first became a member of the group shall be used as the date from which to determine the length of time his coverage under that Plan has been in force.

4. It is recognized that there may be existing group plans containing provisions under which the coverage is declared to be "excess" to all other coverages, or other COB provisions not consistent with this rule. In such cases, plans are urged to use the following claims administration procedures: A group plan should pay first if it would be primary under the COB order of benefits determination. In those cases where a group plan would normally be considered secondary, the plan should make every effort to coordinate in a secondary position with benefits available through any such "excess" plans. The plan should try to secure the necessary information from the "excess" plan.

(6) Right to Receive and Release Necessary Information. For the purpose of determining the applicability of and implementing the terms of this provision of this Plan or any provision of similar purpose of any other Plan, the Plan may release to or obtain from any insurance company or other organization or person any information, with respect to any person, which the Plan deems to be necessary for such purposes. Any person claiming benefits under this Plan shall furnish such information as may be necessary to implement this provision.

(7) Facility of Payment. Whenever payments which should have been made under this Plan in accordance with this provision have been made under any other Plans, the Plan shall have the right, exercisable alone and in its sole discretion, to pay over to any organizations making such other payments any amounts it shall determine to be warranted in order to satisfy the intent of this provision, and amounts so paid shall be deemed to be benefits paid under this Plan and, to the extent of such payments, the Plan shall be fully discharged from liability under this Plan.

(8) Right of Recovery. Whenever payments have been made by this Plan with respect to Allowable Expenses in a total amount, at any time, in excess of the maximum amount of payment necessary at that time to satisfy the intent of this provision, the Plan shall have the right to recover such payments, to the extent of such excess, from one or more of the following, as the Plan shall determine: any persons to or for or with respect to whom such payments were made, any insurers, service plans or any other organizations.

(c) Contracts in force on the effective date of this rule which contain an "excess" clause, "anti-duplication" provision, or any other provision by whatever name designated under which benefits would be reduced because of other existing coverages, shall be brought into compliance with this rule by the later of the next anniversary or renewal date of the group policy or contract, or the expiration of the applicable collectively bargained contract pursuant to which they are written, if any.

NOTE: Authority cited: Section 1344, Health and Safety Code. Reference: Section 10270.98, Insurance Code.

HISTORY:

1. New section filed 5-9-80; effective thirtieth day thereafter (Register 80, No. 19).
2. Repealer of former COB regulation section 1300.67.13 and adoption of new COB regulation section 1300.67.13 filed 3-9-87; effective upon filing pursuant to Government Code section 11346.2(d). Regulation approved for consistency with CCR, title 10, sections 2232.50 through 2232.59, as required by Insurance Code section 10270.98 (Register 87, No. 11).
3. Editorial correction of printing error restoring correct wording of subsection (8) of Instructions (Register 91, No. 33).
4. Amendment of subsections (b)(4)-(b)(4)(E), new subsections (b)(4)(F)-(b)(4)(H)(2), subsection relettering, and amendment of newly designated subsection (b)(4)(I) filed 8-6-93; operative 9-7-93 (Register 93, No. 32).
5. Editorial correction of printing error in History 2 (Register 93, No. 32).

§ 1300.67.205. Standard Prescription Drug Formulary Template.

The following standards are minimum standards, and unless otherwise noted, apply to all health plan formularies subject to section 1367.205 of the Health and Safety Code. A health plan may implement additional provisions exceeding these requirements.

(a) Definitions.

(1) "Coverage document" is a health plan contract, evidence of coverage, certificate of coverage, schedule of benefits, or any other contract for health coverage between an enrollee or subscriber and health plan.

(2) "Dosage form" is the physical form in which a prescription drug is produced and dispensed, such as a tablet, a capsule, or an injectable.

(3) "Established name" is the official nonproprietary name for a prescription drug, as defined in section 111225 of the Health and Safety Code, which must appear on the label pursuant to section 111355 of the Health and Safety Code.

(4) "Exception request" is the process by which an enrollee requests and gains access to clinically appropriate nonformulary drugs as set forth in sections 1367.24, 1367.241, and 1367.244 of the Health and Safety Code.

(5) "Exigent circumstances" is 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.

(6) "Formulary" is the complete list of prescription 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.

(7) "Nonformulary drug" is any prescription drug where an enrollee's copayment or out-of-pocket costs are different than the copayment or out-of-pocket costs for a formulary prescription drug, except as otherwise provided by law or regulation.

(8) "Prescription drug" or "drug" is a drug approved by the federal Food and Drug Administration (FDA) for sale to consumers that requires a prescription and is not provided for use on an inpatient basis. The term "drug" or "prescription drug" includes: (A) disposable devices that are medically necessary for the administration of a covered prescription drug, such as spacers and inhalers for the administration of aerosol outpatient prescription drugs; (B) syringes for self-injectable prescription drugs that are not dispensed in pre-filled syringes; (C) drugs, devices, and FDA-approved products covered under the prescription drug benefit of the product pursuant to sections 1367.002, 1367.25, and 1367.51 of the Health and Safety Code, including any such over-the-counter drugs, devices, and FDA-approved products; and (D) at the option of the health plan, any vaccines or other health care benefits covered under the prescription drug benefit of the health plan product.

(9) "Product" is a discrete package of health care coverage benefits that a health plan offers for a particular policy with a specific network service area.

(10) "Quantity Limit" is a restriction on the number of doses or any other limitations on the quantity of a prescription drug a health plan will cover during a specific time period.

(11) "Strength" is the amount of active ingredient or ingredients present in each dose of a prescription drug.

(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:

(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.

(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 pla 1300.67.01 n 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.

(3) Definitions of any additional or different terms used in the formulary that are necessary to understand the outpatient prescription drug benefit. The health plan must request review and approval from the Department for all additional or different terms used in the formulary, pursuant to section 1352 of the Health and Safety Code.

(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.

(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.

(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.

(14) Notice of an enrollee's rights to step therapy as provided in subdivision (d)(2) of Rule 1300.67.24.

(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.

(17) A description of the limit on cost sharing for orally administered anti-cancer drugs required by section 1367.656 of the Health and Safety Code.

(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.

(e) Categorical list of prescription drugs.

(1) The categorical list of prescription drugs shall be organized by drug category and class based on a commonly used and widely accepted drug classification system such as the most current version of the U.S. Pharmacopeial Convention (USP) Medicare Model Guidelines or the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification. The formulary shall identify the drug classification system that is used. Prescription drugs shall be listed in drug classes consistent with the drug classification system. Prescription drugs belonging to multiple drug classes shall be listed in each applicable class. Category names shall appear alphabetically, and class names shall appear alphabetically within those categories. Brand name and generic prescription drugs shall be alphabetically listed by respective brand or established name within classes. In addition to a category and class name provided by the drug classification system, the categorical list shall include, where possible, a plain language description of the category and class.

(2) The categorical list shall include a complete list of all covered prescription drugs, including both generic and brand name drugs, and shall include, where possible, a plain language description of a prescription drug. A health plan may include prescription drugs covered only under the medical benefit of the product, provided that each such drug is clearly identified as a drug covered only under the medical benefit. A health plan may include nonformulary prescription drugs provided that each such drug is clearly identified as a nonformulary drug.

(3) The categorical list shall include columns in the following order from left to right: (A) Prescription Drug Name; (B) Drug Tier; and (C) Coverage Requirements and Limits. The column headings shall appear on the top of each page of the categorical list.

(4) In the "Prescription Drug Name" column, the proprietary name for a brand name drug shall appear in all CAPITAL letters. The established name for the brand name drug shall be placed in parentheses after the brand name in all ***bold and italicized lowercase*** letters. The established name for a generic drug shall appear in all ***bold and italicized lowercase*** letters. If a generic drug is sold under a brand name, the brand name shall be placed in parentheses after the established name in regular typeface with the first letter of each word capitalized.

(5) The "Prescription Drug Name" column shall include all covered dosage forms and strengths for each prescription drug. If there are differences in tier placement, quantity limit, prior authorization, step therapy, or other utilization restrictions or plan benefit offerings for a prescription drug based on its differing dosage forms or strengths, the categorical list of prescription drugs shall include separate rows for the dosage forms and/or strengths of the prescription drug to clearly identify the differences.

(6) The "Drug Tier" column shall identify the cost sharing tier where the prescription drug is placed, if applicable. A health plan shall use a unique tier number, abbreviation, or symbol for the following: (A) prescription drugs, devices, and FDA-approved products covered under the outpatient prescription drug benefit of the product pursuant to sections 1367.002, 1367.25 and 1367.51 of the Health and Safety Code; (B) orally administered anti-cancer drugs that are subject to the cost sharing limit in section 1367.656 of the Health and Safety Code; (C) nonformulary drugs; and (D) drugs covered only under the medical benefit. The tier abbreviations, notations or symbols shall be explained in the annotated legend or key of the formulary.

(7) The "Coverage Requirements and Limits" column shall include abbreviations, notations, or symbols for all utilization management restrictions that the health plan imposes on prescription drug coverage, including but not limited to, prior authorization, step therapy, quantity limits, and network limitations on access including specialty pharmacy restrictions, in addition to any other requirements, limits, or other relevant information applicable to the coverage provided for a prescription drug. For each prescription drug subject to quantity limits, the applicable quantity limits shall be described with specificity. Each abbreviation, symbol, or notation used in the "Coverage Requirements and Limits" column shall be explained in the annotated legend or key of the formulary.

(8) The annotated legend or key to all abbreviations, symbols, and notations used in the formulary shall appear on each page of the categorical list.

(f) Index. The index shall list each covered brand name and generic drug by respective brand name or established name in alphabetical order and include the page number for the location of the drug in the categorical list of prescription drugs.

NOTE: Authority cited: Sections 1344 and 1367.205, Health and Safety Code. Reference: Sections 1342.71, 1367.002, 1367.205, 1367.24, 1367.241, 1367.25 and 1367.656, Health and Safety Code.

HISTORY:

1. New section filed 6-25-2019; operative 10-1-2019 (Register 2019, No. 26).

§ 1300.67.24. Outpatient Prescription Drug Copayments, Coinsurance, Deductibles, Limitations and Exclusions.

(a) Every health care service plan that provides coverage for outpatient prescription drug benefits shall provide coverage for all medically necessary outpatient prescription drugs except as described in this section, subject to the requirements of Health and Safety Code section 1342.7(g).

(1) Outpatient prescription drugs are self-administered drugs approved by the Federal Food and Drug Administration for sale to the public through retail or mail-order pharmacies that require prescriptions and are not provided for use on an inpatient basis. For purposes of this section "inpatient basis" has the meaning indicated in Section 1300.67(b), and "self-administered" means those drugs that need not be administered in a clinical setting or by a licensed health care provider.

(2) Coverage for outpatient prescription drugs shall also include coverage for disposable devices that are medically necessary for the administration of a covered outpatient prescription drug, such as spacers and inhalers for the administration of aerosol outpatient prescription drugs, and syringes for self-injectible outpatient prescription drugs that are not dispensed in pre-filled syringes. For purposes of this section, the term "disposable" includes devices that may be used more than once before disposal. This section does not create an obligation for a plan to provide coverage for a durable medical equipment benefit.

(b) Standards for outpatient prescription drug benefit plans

(1) A prescription drug benefit offered by a plan shall comply with the requirements of the Knox-Keene Act and the regulations promulgated by the Director of the Department of Managed Health Care, including but not limited to Sections 1342, 1343.5, 1342.7, 1363, 1363.01, 1363.03, 1363.5, 1367(e), 1367(g), 1367(h), 1367.01, 1367.20, 1367.21, 1367.22 and 1367.24 of the Act and Section 1300.67.4(a)(3)(A) of these rules.

(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.

(4) A plan that provides coverage for prescription drugs through a mail order pharmacy shall have written policies and procedures documenting that the plan's mail order arrangements are in compliance with the requirements of the Act and this section, and applicable California and federal laws regarding pharmacists and pharmacy services. The mail order pharmacy process shall conform effectively and efficiently with a plan's processes for prior authorization for coverage of medically necessary drugs as required by the Act, and shall include standards for timely delivery and a contingency mechanism for providing the drug if a mail order provider fails to meet the delivery standards.

(5) In reviewing copayments, coinsurance, deductibles, limitations, or exclusions for compliance with Section 1367(e) and (h) of the Act, and Section 1300.67.4(a)(3)(A) of these rules, the Department's approval or disapproval may be based upon all relevant factors, including but not limited to:

(A) The type and number of enrollees affected;

(B) The clinical efficacy of the drug(s) proposed to be limited or excluded;

(C) The availability of therapeutic equivalents or other drugs medically necessary for treatment of health conditions;

(D) The specific health plan products to which the copayment, coinsurance, deductible, limitation, or exclusion will apply;

(E) The duration of the limitation or exclusion;

(F) The rationale for the copayment, coinsurance, deductible, limitation or exclusion;

(G) The projected effect of the copayment, coinsurance, deductible, limitation, or exclusion on the affordability and accessibility of coverage;

(H) The projected comparative clinical effect, including any potential risk of adverse health outcomes, based upon utilization data and review of peer-reviewed professional literature;

(I) The overall copayment structure of the product, including whether the copayment, coinsurance, or deductible contributes to the overall out-of-pocket maximum for the product;

(J) Information regarding similar copayments, coinsurance levels, deductibles, limitations, or exclusions previously approved by the Department;

(K) Evidence-based clinical studies and professional literature;

(L) The description of the copayment, coinsurance, deductible, limitation or exclusion as compared to other benefits and products in the marketplace;

(M) Any other historical, statistical, or other information that the submitting plan considers pertinent to the request for approval of the copayments, coinsurance level, deductibles, limitation, or exclusion.

(c) Copayments, Coinsurance and Deductibles

(1) A plan's prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment amount, the enrollee shall not be required to pay any more than the retail price.

(2) Proposed copayment structures or ranges, coinsurance, or deductibles submitted to the Director for approval shall be based upon a methodology that is fully described and documented, and that complies with the standards set forth in this Section. A plan may use actual cost data on prescription drugs or, for contracted services or products, nationally recognized data sources used by the plan in developing the contract rates.

(3) A copayment or percentage coinsurance shall not exceed 50 percent of the cost to the plan as described in subsection (c)(5) and (6). A percentage coinsurance shall meet one of the following additional requirements:

(A) Have a maximum dollar amount cap on the percentage coinsurance that will be charged for an individual prescription;

(B) Apply towards an annual out-of-pocket maximum for the product; or

(C) Apply towards an annual out-of-pocket maximum for the prescription drug benefit.

(4) In addition to compliance with this subsection (c), copayments and coinsurances shall comply with the standards identified at subsection (b), including that they shall be reasonable so as to allow access to medically necessary outpatient prescription drugs, and the Department's determination may be based on all relevant factors as provided in subsection (b)(5).

(5) The "cost to the plan" means the actual cost incurred by the plan or its contracting provider to acquire and dispense a covered outpatient prescription drug, without subtracting or otherwise considering any copayment or coinsurance amount to be paid by enrollees. The cost to the plan may include average cost calculations as described in this section, and shall include all discounts and other prospective cost and pricing arrangements, as applicable. Plans shall account for any rebates and other retrospective cost and pricing arrangements for outpatient prescription drugs by verifying that the rebates and other retrospective cost and pricing arrangements for outpatient prescription drugs are applied by the plan to reduce costs for the plan's subscribers.

(6) Compliance with the requirement not to exceed 50 percent of the actual cost to the plan may be met by various methods including the three methods described below. A plan may propose a different method, which shall be filed

with the Department prior to implementation by the plan and supported by information and documentation sufficient to satisfy the Department as to the validity of the calculation methodology.

(A) Average Cost in Each Tier. This copayment represents the average plan cost per drug in a tier and is calculated in the following manner:

1. The copayment is for one tier in a multi-tier prescription drug benefit. (EXAMPLE: the Name Brand tier.)

2. Add together the plan's cost for all the drugs in that tier. (EXAMPLE: the Name Brand tier covers X drug which costs the plan $50 per prescription, Y drug which costs $100 per prescription, and Z drug which costs the plan $75 per prescription-added together for a total cost of $225.)

3. Divide the cost determined according to 2 above by the total number of drugs in that same tier. (EXAMPLE: there are 3 drugs in the Name Brand tier which cost the plan $225, $225/3 = $75.)

4. The copayment may not exceed 50 percent of the average cost of drugs in the tier to which it applies. (EXAMPLE: 50% of $75 = $37.50. The copayment for the Name Brand tier may not exceed $37.50.)

(B) Weighted Average Cost in Each Tier. This copayment is the same as the average per tier except that the prescriptions actually covered by the plan are used in the calculation.

1. The copayment is for one tier in a multi-tier prescription benefit. (EXAMPLE: the Name Brand tier.)

2. Calculate the number of prescriptions for drugs in that tier actually covered by the plan. (EXAMPLE: the plan covered the cost of 10 prescriptions in the Name Brand tier.)

3. Add together the cost for all the drugs covered in 2 above. (EXAMPLE: the plan covered three prescriptions for X drug (3 x $50= $150), three for Y drug (3 x $100 = $300) and four for Z drug (4 x $75 = $300). $150 + $300 + $300 = $750 total cost for prescriptions in that tier covered by the plan.)

4. Divide the total cost determined according to 3 above by the number of prescriptions from step 2. (EXAMPLE: $750/10 = $75.)

5. The copayment may not exceed 50 percent of the weighted average cost of drugs in the tier to which it applies. (EXAMPLE: 50% of $75 = $37.50. The copayment for the Name Brand tier may not exceed $37.50.)

(C) Weighted Average Cost Across All Tiers. This copayment is the same as the weighted average per tier except that there is one copayment calculated using the number of prescriptions for all tiers covered by the plan.

1. The copayment is for all tiers in a multi-tier prescription benefit. (EXAMPLE: the Name Brand tier and the Generic tier.)

2. Calculate the number of prescriptions for drugs in that tier actually covered by the plan. (EXAMPLE: Ten prescriptions under the Name Brand tier (three for X drug, three for Y drug and four for Z drug, ten prescriptions under the Generic tier (three for drug A, three for drug B and four for Drug C for a total of twenty drugs.)

3. Add together the cost for all the drugs covered in 2 above. (EXAMPLE: the ten Name Brand drugs cost $750 (from previous example) plus the Generic drugs, three for A drug (3 x $5 = $15), three for B drug (3 x $10 = $30) and four for C drug (4 x $15 = $60) (Generic total = $105) ($750 + $105 = $855 cost for all the drugs covered in the Name Brand and Generic tiers.)

4. Divide the total cost across tiers determined according to 3 above by the number of prescriptions from step 2. (EXAMPLE: $855/20 = $42.75)

5. The copayment may not exceed 50 percent of the weighted average cost of drugs in all the tiers in the prescription drug benefit to which it applies.

(EXAMPLE: 50% of $42.75 = $21.38. The copayment for all tiers may not exceed $21.38.)

(d) Limitations

Plans that provide coverage for outpatient prescription drug benefits may apply the following limitations:

(1) A plan may impose prior authorization requirements on prescription drug benefits, consistent with the requirements of the Act and regulations.

(2) When there is more than one drug that is appropriate for the treatment of a medical condition, a plan may require step therapy. A plan that requires step therapy shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements of the Act and regulations. In circumstances where an enrollee is changing plans, the new plan may not require the enrollee to repeat step therapy when that enrollee is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. Nothing in this section shall preclude the new plan from imposing a prior authorization requirement pursuant to Section 1367.24 for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. For purposes of this section, "step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

(3) A plan shall provide coverage for the medically necessary dosage and quantity of the drug prescribed for the treatment of a medical condition consistent with professionally recognized standards of practice.

(A) A plan may limit the amount of the drug dispensed at any one time to a 30-day supply or, if the treatment is for less than 30 days, for the medically necessary amount of the drug.

(B) A plan may impose a requirement that maintenance drugs be dispensed in a two months or greater supply.

(C) A plan may establish a mandatory mail order process for maintenance drugs when dispensed in a three months supply or greater quantities, but shall not impose any fees or costs for mandatory mail order prescriptions other than the applicable copayment or coinsurance. A plan shall not require an enrollee to fill a prescription by mail if the prescribed drug is not available to be filled in that manner.

(D) For purposes of this section, "maintenance drugs" means those outpatient prescription drugs that are prescribed for the enrollee on a continual basis to treat a chronic condition.

(4) Plans may require enrollees who are prescribed drugs for smoking cessation to be enrolled in or to have completed a smoking cessation program, if covered by the plan prior to or concurrent with receiving the prescription drug.

(5) Other limitations that the Department may approve pursuant to Section 1342.7 of the Act and this section.

(e) Exclusions

Plans that provide coverage for outpatient prescription drug benefits are not required to provide coverage for prescription drugs that meet the following conditions:

(1) When prescribed for cosmetic purposes. For purposes of this section "cosmetic" means drugs solely prescribed for the purpose of altering or affecting normal structures of the body to improve appearance rather than function.

(2) When prescribed solely for the treatment of hair loss, sexual dysfunction, athletic performance, cosmetic purposes, anti-aging for cosmetic purposes, and mental performance. Drugs for mental performance shall not be excluded from coverage when they are used to treat diagnosed mental illness or medical conditions affecting memory, including, but not limited to, treatment of the conditions or symptoms of dementia or Alzheimer's disease.

(3) When prescribed solely for the purposes of losing weight, except when medically necessary for the treatment of morbid obesity. Plans may require enrollees who are prescribed drugs for morbid obesity to be enrolled in a comprehensive weight loss program, if covered by the plan, for a reasonable period of time prior to or concurrent with receiving the prescription drug.

(4) When prescribed solely for the purpose of shortening the duration of the common cold.

(5) Drugs that are available over the counter. A plan shall not exclude coverage of an entire class of prescription drugs when one drug within that class becomes available over the counter. A plan that seeks to exclude coverage for an entire class of drugs when more than one drug within that class become available over the counter, shall first file a notice of material modification and obtain the Department's prior approval in accordance with Section 1342.7 of the Act and this regulation.

(6) Replacement of lost or stolen drugs.

(7) Drugs when prescribed by non-contracting providers for non-covered procedures and which are not authorized by a plan or a plan provider except when coverage is otherwise required in the context of emergency services.

(8) Other categories of prescription drugs approved by the Department pursuant to Section 1342.7 of the Act and this section.

(f) Oversight of Plan and Provider Compliance

A plan shall have written policies and procedures for its outpatient prescription drug benefits, and quality assurance systems in place for the early identification and swift correction of problems in the accessibility and availability of outpatient prescription drug benefits. A contract between a health care service plan and a prescription drug benefit provider shall include provisions, terms and conditions sufficient to ensure that the standards and requirements of this regulation are met.

(g) Implementation

(1) Any exclusion or limitation on a prescription drug benefit that is not described at subsections (d) or (e) may not be applied to any plan's prescription drug benefit unless a plan has filed a notice of material modification with the Department and received approval by Order to apply the exclusion or limitation. The Order of approval may be issued subject to specified terms and conditions, or for specified periods, as the Department may determine are necessary and appropriate. Following issuance of an Order approving an exclusion or limitation, any other licensed plan may apply the same exclusion or limitation to its prescription drug benefit if it files an amendment with the Department not less than 30 days prior to implementation of the exclusion or limitation, and represents that it is exactly the same as that previously approved by Order, provides specific reference to the Order number and date issued, and addresses any specified terms and conditions upon such Order, as applicable.

(2) A plan may meet the material modification filing requirements of subsection (g)(1) with respect to exclusions and limitations contained in contracts issued, renewed or amended on or before January 1,2007, by filing within six months of the effective date of this regulation a report disclosing and describing all such exclusions and limitations on prescription drug benefits covered under all subscriber contracts subject to the requirements of Section

1342.7 of the Act. The Department will provide an expeditious review of the exclusions and limitations disclosed in the report.

NOTE: Authority cited: Sections 1342.7, 1344 and 1346, Health and Safety Code. Reference: Sections 1342, 1342.7, 1343.5, 1363, 1363.01, 1363.03, 1363.5, 1367, 1367.01, 1367.215, 1367.24, 1367.25, 1367.45, 1367.51, 1374.72 and 1375.1, Health and Safety Code; see also SB 842. ch.791, Stats. 2002.

HISTORY:

1. New section filed 11-3-2000 as an emergency; operative 11-3-2000 (Register 2000, No. 44). A Certificate of Compliance must be transmitted to OAL by 3-5-2001 or emergency language will be repealed by operation of law on the following day.
2. Certificate of Compliance as to 11-3-2000 order transmitted to OAL 3-5-2001 and filed 4-16-2001 (Register 2001, No. 16).
3. Amendment of section heading and repealer and new section and Note filed 6-26-2006; operative 7-26-2006 (Register 2006, No. 26).