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Title 22@ Social Security

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Division 3@ Health Care Services

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Subdivision 1@ California Medical Assistance Program

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Chapter 3@ Health Care Services

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Article 4@ Scope and Duration of Benefits

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Section 51313.6@ Drug Evaluation Criteria

51313.6 Drug Evaluation Criteria

(a)

The Director shall use the following criteria when evaluating drugs to add to and to delete from the Medi-Cal List of Contract Drugs. The Director may restrict usage of any drug or therapeutic category of drugs on the Medi-Cal List of Contract Drugs. The Director's decision shall be made upon consideration of all of the five criteria specified below in items (1) through (5), without regard to the order in which the criteria are presented. The examples recited under each criterion shall not be exhaustive of those factors which may be considered. (1) Cost. For the purpose of this section, cost means the potential fiscal impact of the proposed change on the Medi-Cal drug program or the Medi-Cal program. Evaluation of cost may involve a single drug or comparison between two or more drugs, and may take into account, but is not limited to, differences of unit cost, differences of cost of total treatment, or cost of alternative methods of treatment. (2) Efficacy. For the purposes of this section, efficacy means the speed, duration, and extent to which a drug will alleviate, control or cure a medical condition. Evaluation of efficacy may involve a single drug or comparisons between two or more drugs, and may take into account such factors as efficacy of alternative methods of treatment. (3) Essential Need. For the purpose of this section, essential need means that the availability of a drug through the Medi-Cal List of Contract Drugs is necessary to protect life or to prevent significant disability. Evaluation of essential need may involve a single

drug or comparisons between two or more drugs, and may take into account such facts as the availability of alternative methods of treatment, the incidence, severity and prognosis of the medical conditions for which a drug is indicated; whether a drug is a lifesaving agent or palliative in effect; or whether a drug may provide treatment for a medical condition not adequately treated by any marketed drug. (4) Misuse Potential. For the purpose of this section, misuse potential means the opportunity for unjustified, inappropriate, irresponsible, or improper use of a drug. Evaluation of unjustified, inappropriate, or irresponsible use may involve a single drug or comparisons between two or more drugs, and may take into account such factors as utilization of a drug where there is insufficient medical necessity for its use; continued utilization of a drug despite loss of effectiveness; utilization of a drug where more efficacious or more safe drugs are available; utilization of a drug where the drug is a mixture and less than the total number of active ingredients may suffice; or utilization of a drug where a less costly but equally safe and efficacious drug may be used. Evaluation of improper use may involve a single drug or comparisons between two or more drugs, and may take into account such factors as utilization of a drug in a manner that deviates from approved medical, legal, or social standards. (5) Safety. For the purpose of this section, safety means relative freedom from side effects and is determined by reviewing the contraindications, precautions, warnings, adverse effects, and drug interactions associated with the use of a drug. Evaluation of safety may involve a single drug or comparisons between two or more drugs, and may take into account such factors as safety of alternative methods of treatment, or the relationship of safety of a drug to the severity of prognosis of the medical conditions for which the drug is indicated.

Cost. For the purpose of this section, cost means the potential fiscal impact of the proposed change on the Medi-Cal drug program or the Medi-Cal program. Evaluation of cost may involve a single drug or comparison between two or more drugs, and may take into account, but is not limited to, differences of unit cost, differences of cost of total treatment, or cost of alternative methods of treatment.

(2)

Efficacy. For the purposes of this section, efficacy means the speed, duration, and extent to which a drug will alleviate, control or cure a medical condition. Evaluation of efficacy may involve a single drug or comparisons between two or more drugs, and may take into account such factors as efficacy of alternative methods of treatment.

(3)

Essential Need. For the purpose of this section, essential need means that the availability of a drug through the Medi-Cal List of Contract Drugs is necessary to protect life or to prevent significant disability. Evaluation of essential need may involve a single drug or comparisons between two or more drugs, and may take into account such facts as the availability of alternative methods of treatment, the incidence, severity and prognosis of the medical conditions for which a drug is indicated; whether a drug is a lifesaving agent or palliative in effect; or whether a drug may provide treatment for a medical condition not adequately treated by any marketed drug.

(4)

Misuse Potential. For the purpose of this section, misuse potential means the opportunity for unjustified, inappropriate, irresponsible, or improper use of a drug. Evaluation of unjustified, inappropriate, or irresponsible use may involve a single drug or comparisons between two or more drugs, and may take into account such factors as utilization of a drug where there is insufficient medical necessity for its use; continued utilization of a drug despite loss of effectiveness; utilization of a drug where more

efficacious or more safe drugs are available; utilization of a drug where the drug is a mixture and less than the total number of active ingredients may suffice; or utilization of a drug where a less costly but equally safe and efficacious drug may be used.

Evaluation of improper use may involve a single drug or comparisons between two or more drugs, and may take into account such factors as utilization of a drug in a manner that deviates from approved medical, legal, or social standards.

(5)

Safety. For the purpose of this section, safety means relative freedom from side effects and is determined by reviewing the contraindications, precautions, warnings, adverse effects, and drug interactions associated with the use of a drug. Evaluation of safety may involve a single drug or comparisons between two or more drugs, and may take into account such factors as safety of alternative methods of treatment, or the relationship of safety of a drug to the severity of prognosis of the medical conditions for which the drug is indicated.