MEDI-CAL DRUG REVIEW POLICY AND PROCEDURES

This document represents the drug evaluation policies and procedures in effect in the Department of Health Care Services (Department), Medi-Cal Pharmacy Benefits Division.

POLICY

This document applies to the review of those drugs that would be dispensed by pharmacy providers to Fee-For-Service (FFS) Medi-Cal beneficiaries and any drug approved by the federal Food and Drug Administration (FDA) for the treatment of cancer, AIDS, or an AIDS-related condition. It incorporates criteria and time frames mandated by statute and shall be used by the Medi-Cal Contract Drug Advisory Committee (MCDAC) and Department staff to make recommendations and decisions regarding addition, deletion, or retention of drugs on the Medi-Cal List of Contract Drugs (List).

Drugs Eligible for Review

The Department will not begin a drug petition review unless the product has received approval for marketing by the FDA *and* the product is available on the market. State law provides that any drug approved by the FDA for the treatment of cancer must be added to the List; therefore, such drugs are exempt from the review procedures outlined in this document.

Medi-Cal Contract Drug Advisory Committee

State law (W & I Code Section 14105.4) specifies that the MCDAC, appointed by the Department Director, make recommendations to the Department as to the addition or the deletion of any drug from the List. These recommendations are to be in accordance with the five evaluation criteria below.

Drug Evaluation Criteria

Welfare and Institutions (W&I) Code Section 14105.39(c)(1) and (2) establishes the drug evaluation criteria as follows:

1. The safety of the drug.
2. The effectiveness of the drug.
3. The essential need for the drug.
4. The potential for misuse of the drug.
5. The cost of the drug.

The deficiency of a drug when measured by one of these criteria may be sufficient to support a decision that the drug should not be added or retained, or should be deleted

from the list. However, the superiority of a drug under one criterion may be sufficient to warrant the addition or retention of the drug, notwithstanding a deficiency in another criterion.

These five criteria are further defined in Section 51313.6 of Title 22, California Code of Regulations as follows:

1) *Safety*. "... the relative freedom from side effects and is determined by reviewing the contraindications, precautions, warnings, adverse effects, and drug interactions associated with the use of the 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."

2) *Efficacy.* "... 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.* "... the availability of a drug through the Medi-Cal List of Contract Drugs is necessary to protect life or 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 factors 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.* "... the opportunity for unjustified, inappropriate, irresponsible, or improper use of a drug. Evaluation of unjustified, inappropriate, or irresponsible use may take into account such factors as utilization of a drug where there is insufficient medical necessity for its use; continued use of a drug despite loss of effectiveness; 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."

   Note: The Department considers off-label use a "misuse potential" only when the use of the product is inappropriate according to the medical community. Medical literature, staff, academic, and provider experience is utilized to confirm what off-label uses are inappropriate.

5) *Cost.* "...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 comparisons between two or more drugs, and may take into account, but is not limited to, difference of unit cost as defined in Section 51513(a)(13), differences of cost of total treatment, or cost of alternative methods of treatment."

It is the policy of the Department that evaluation of the cost criterion shall include:

- Off-label use of drugs
- Pharmacoeconomic data presented by the manufacturer related to the comparison of:
    - two or more treatment alternatives having identical outcomes (Cost-Minimization Analysis),
    - treatment alternatives which have different cost and treatment outcomes associated with them (Cost-Benefit Analysis), or
    - total health care system costs of treatment alternatives having similar treatment outcomes (Cost-Effective Analysis).
- Pharmacoeconomic models/studies, based on the following guidelines:
    - Studies used to support pharmacoeconomic claims must be of sufficient scientific rigor to ensure confidence in the claimed effects.
    - Study designs and measurements must reflect current scientific standards.
    - Baseline data should reflect the population covered by the Medi-Cal program.
    - Baseline data should reflect the Medi-Cal program.
    - Cost data should reflect the Medi-Cal program's reimbursement methods.
    - Realistic offsets for drug displacement (including single-source and multi-source drugs) should be included along with data quantifying therapeutic category growth.

Records Retention

The Medi-Cal Pharmacy Benefits Division (Division) will retain all records associated with recommendations and decisions regarding addition, deletion, or retention of drugs on the List for a period of three years or for the duration of the contract that added or retained the reviewed drug, whichever is greater.

DRUG REVIEW PROCEDURES

The Department may review individual drugs as Individual Drug Petitions (IDP) or as part of a Therapeutic Category Review (TCR) for addition to either the List or the Preferred Prior Authorization (PPA) list as outlined below.

Individual Drug Petition Review Procedures

A manufacturer, physician, or pharmacist may request an IDP review of a drug, or the Department may initiate an IDP review as well.

Petitions

The Division Chief, or designee, receives each petition submitted by manufacturers, physicians, or pharmacists and either:

(1) assigns a pharmacist to coordinate the review with a group of drugs on a flow basis, or

(2) defers the petition to a TCR if such a review is currently scheduled or is planned.

Manufacturer-initiated petitions for FDA-approved, P-rated (Priority Review) drug products are given expedited review by the Department. (See "Fast-Track Review," below.)

To be considered complete, the petition package must contain at least the following information regarding the drug product:

- A letter specifically requesting that the drug be added to the List.
- The FDA classification as to chemical type and therapeutic potential (e.g., 1P, 3S, etc.) designating the drug product *at the time of approval.*
- A copy of the FDA approval letter.
- The FDA's approved labeling (e.g., product package insert, product monograph).

The above minimum information is sufficient for the Department to *initiate* the review and evaluation of a single drug petition. However, the Department will require additional information during the review process.

In order to expedite the drug evaluation, manufacturers are encouraged to provide the Department as early as possible in the review process:

- Detailed therapeutic information (e.g., clinical studies), and,
- Cost information (e.g., the current Average Wholesale Price (AWP) for all package sizes as reported by First DataBank, the Average Manufacturer Price per the federal Medicaid rebate agreement, pharmacoeconomic studies, etc.).

Initial Notification

The Department will notify manufacturers by mail when review has been initiated on petitioned products. The notification will include at least the following:

- Identification of the regulatory/statutory five criteria (safety, efficacy, essential need, misuse potential, and cost) used to evaluate the drug.
- Specification of manufacturer contract negotiation time frames and Department expectations regarding the manufacturer's business proposal.
- Information on how to handle manufacturer contacts with the MCDAC and associated time frames, unless MCDAC review is not required. (While petitions for the addition of new drug strengths, dosage forms, and product formulations of already-listed drugs do not generally go to the MCDAC for review, occasionally, the Department may seek their advice.)
- Identification, phone number, and e-mail address for the Department pharmacist assigned to coordinate the review.

Analytical Process

The Department will send a letter to the MCDAC within 90 calendar days of the date of the petition requesting their review of the petitioned drug(s) and will send a copy of the letter to Pharmaceutical Research and Manufacturers of America (PhRMA). The letter to the MCDAC includes, at least, the following:

- Generic name, brand name, FDA approved indications for use, and manufacturer of the drugs to be reviewed.
- A statement specifying that the review must be based on the regulatory/statutory five criteria of safety, efficacy, essential need, misuse potential, and cost of each drug.
- A statement recognizing that the required evaluation of the cost will be done without access to manufacturer rebate data, due to its confidential nature.
- The response time frame (30 calendar days).
- An enclosed form to indicate, on a drug-by-drug basis, recommendations and comments and with a space for the member to certify, by signature, that his or her recommendation for each drug is based on consideration of the evaluation criteria required by state law.
- A statement requesting that members identify any overriding criteria relative to their recommendations in the comments section of the form.

After receiving the recommendations from the MCDAC, the Department will schedule and conduct a meeting, at the manufacturer's option, with manufacturer representatives. The Department's representatives at the meeting will generally include senior manager(s) from the Pharmacy Benefits Division and the staff pharmacist who has been assigned to coordinate the review; other Division staff may also attend. The purpose of this meeting is to discuss therapeutic considerations, pharmacoeconomic studies, and the business proposal by the manufacturer. During the meeting, the manufacturers will be required to bring at least two copies of the presentation materials. **Please note that the copies provided will be kept for reference and must be identical to the actual presentation materials. This requirement is mandatory. If any information presented is not provided via hard copy during the presentation, the information will not be considered for evaluation of the product. There are no exceptions.**

The Department may also seek additional input from healthcare providers, provider organizations, schools of pharmacy, or other entities. Additionally, the Department may receive unsolicited input.

Evaluation

The Division's staff next will conduct an internal meeting to review and evaluate the drug products. The pharmacist assigned to the review will initiate discussion of each drug product. The format to be used for documenting consideration of each drug product shall include the following information at a minimum:

- Generic name, brand name, FDA rating, and manufacturer of the drugs.
- Recommendations of each member of the MCDAC.
- Recommendations of other entities contacted for input and unsolicited input if appropriate.
- Brief documentation of each of the five regulatory/statutory criteria of safety, efficacy, essential need, misuse potential, and cost.
- Manufacturer's input.
- Pertinent medical literature or other information.
- Department staff analysis.

Negotiations

Following the Department's evaluation of a petitioned drug based upon the five evaluation criteria, a counter offer, along with other clinical and business proposals as deemed appropriate, may be presented to the manufacturer.

The manufacturer will have 30 business days to accept, reject, or present an alternative to the Department's counter offer. Such responses should be communicated to the pharmacist assigned to the drug petition. If the manufacturer fails to respond within the 30 business days, the Department will conclude that the manufacturer is rejecting the counter offer or cannot provide the requested information. The assigned pharmacist will update the group and a decision will then be made whether or not to add the petitioned drug to the list.

Decision

The pharmacist assigned to coordinate the review will initiate final discussions on the drug product if the manufacturer has offered any additional information and business proposals. Upon completion of these discussions, a decision will be made whether or not to add the petitioned product to the List.

Decision Notification

The Department then will send a letter regarding the decision to the manufacturer of the drug product with identification and explanation of the five-regulatory/statutory criteria upon which the decision was made and will send a copy of the letter to the members of the MCDAC.

The Department will send a contract to the manufacturer if it decides to add a manufacturer's drug to the List. Once the Department receives the contract signed by the manufacturer's representative, the Department's pharmacist staff will develop an Operation Instruction Letter (OIL) to instruct the Department's fiscal intermediary to distribute Medi-Cal bulletins to inform providers of any changes to the List and to take any necessary action for processing provider claims for these drugs.

Manufacturers may contact the pharmacist who coordinated the review to find out the proposed effective date of the drug product addition. ***The effective date to add a drug will not be official until the Medi-Cal provider bulletin is published. Therefore, manufacturers must not announce or market an effective date prior to Medi-Cal bulletin publication. The Department reserves the right to take administrative action and delay the addition of a drug when a manufacturer prematurely announces or markets the drug as being on the List. ***

Appeals

State law provides that a manufacturer denied a contract because of an IDP review, may appeal that decision with the Director within 30 calendar days of the date of the written notice of the Department's decision. Within 30 calendar days of the manufacturer's appeal, the law requires the Director to request a recommendation regarding the appeal from the MCDAC. The committee must provide this recommendation in writing to the Director within 30 calendar days of the Director's request. The Department will schedule a meeting with the manufacturer and the

Department's Deputy Director of Health Care Policy, or designee, to review any additional information supplied with the appeal. The Department will not consider new financial business proposals during the appeal process. However, the appeal process can include further discussion and clarification of the manufacturer's most recent financial business proposal or any proposed fiscal effect that the addition of the drug would have on the Department. The Director must issue a decision within 30 calendar days of the MCDAC recommendation.

Preferred Prior Authorization

State law provides that a manufacturer of a drug not added to the List may request inclusion of the drug on the PPA drug list [W & I Code Section 14105.39(f)]. See PPA section.

Fast-Track Drug Petition Review Procedures

New drugs approved by the FDA which are designated P-Priority Review, will be evaluated by the Department within 120 days of receipt of a manufacturer petition (unless the manufacturer requests, in writing, an extension of the evaluation period) subject to the following conditions:

1. The petition is complete (see above under "Petitions").
2. The manufacturer responds to requests for information (including counter offers) within reasonable time frames specified by the Department (at all steps in the review and negotiation process).

This 120-day time period for P-designated drugs will include the above Individual Drug Petition Review Procedures. This includes submitting the drug to the MCDAC, evaluating the petition request according to the statutorily required criteria, and initiating negotiations with manufacturers, if applicable.

Therapeutic Category Review Procedures

Therapeutic Category Reviews (TCRs) are self-initiated by the Department and conducted in accordance with W & I Code Section 14105.37. Much of the process is the same as that for IDPs.

Initial Notification

The Department may develop a TCR schedule annually and make it available to the public upon request. A copy will be mailed to the local representative of PhRMA and the MCDAC. The schedule will include a disclaimer statement that it is subject to change with adequate notification.

The first day of the 120-day negotiation period for a TCR will be the date of the letter from the Department notifying affected manufacturers of the start of the TCR. A copy of this letter will be sent to PhRMA and will include, at least, the following:

- Identification of the TCR and subcategories, if any, and the drug products involved.
- Reference to pertinent state law.
- Identification of the regulatory/statutory five criteria of effectiveness, safety, essential need, misuse potential, and cost of the drug.
- Specification of manufacturer contract negotiation time frames and Department expectations regarding the manufacturer's business proposal.
- Information on how to handle manufacturer contacts with the MCDAC and associated time frames.
- Identification and phone number for the Department pharmacist assigned to coordinate the TCR.

If, within 30 days of notification, a manufacturer does not enter into negotiations for a contract, the Department may suspend or delete from the List, or refuse to consider for addition, drugs of that manufacturer in the selected therapeutic categories.

Analytical Process

The Department will send a letter to the MCDAC one week after manufacturer notification, requesting their review of the TCR drugs; a copy will be sent to PhRMA. The letter will include, at least, the following:

- Generic name, brand name, and manufacturer of the drugs to be reviewed.
- A statement specifying that the review must be based on the regulatory/statutory five criteria of effectiveness, safety, essential need, misuse potential, and cost of each drug.
- A statement recognizing that the required evaluation of the cost will be done without access to manufacturer rebate data, due to its confidential nature.
- The response time frame (usually 30 calendar days).
- An enclosed form to indicate, on a drug-by-drug basis, recommendations and comments and with a space for the member to certify, by signature, that his or her recommendation for each drug is based on consideration of the evaluation criteria required by state law.
- A statement requesting that members identify any overriding criteria relative to their recommendations in the comments section of the form.

The Department may also seek additional input from healthcare providers, provider organizations, schools of pharmacy, or other entities, as part of the TCR. Additionally, the Department may receive unsolicited input.

After receiving the recommendations from the MCDAC, the Department will schedule and conduct a meeting with each manufacturer, at the manufacturer's option, between 45 and 60 days from the start of the TCR. The Department's representatives at the meeting will generally include the senior manager(s) from the Pharmacy Benefits Division and the staff pharmacist who has been assigned to coordinate the TCR; other Division staff may also attend. The purpose of this meeting will be to discuss therapeutic considerations, pharmacoeconomic studies, and the manufacturer's business proposal, such as whether the manufacturer will offer rebates in addition to the federally mandated rebates. During the meeting, the manufacturers will be required to bring at least two copies of the presentation materials. Please note that the copies provided will be kept for reference and must be identical to the actual presentation materials. This requirement is mandatory. If any information presented is not provided via hard copy during the presentation, the information will not be considered for evaluation of the product. There are no exceptions.

Evaluation

The Division's staff next will conduct an internal meeting to review and evaluate the drug products. Discussion of each drug product will be initiated by the pharmacist assigned to the TCR, and will include at least the following:

Generic name, brand name, and manufacturer of the drugs.

Discussion of each of the five regulatory/statutory criteria of safety, efficacy, essential need, misuse potential, and cost.

- Manufacturer's input.
- Pertinent medical literature or other information.
- Department staff analysis.
- Recommendations of each member of the MCDAC.
- Recommendations of other entities contacted for input and unsolicited input if appropriate.

Negotiations

State law (W&I Code Section 14105.37) provides that:

- If, after 120 days from the initial notification, a contract is not executed for a drug currently on the List, the Department may suspend or delete the drug from the List.

- If, within 120 days from the initial notification, a contract is executed for a drug currently on the List, the Department shall retain the drug on the List.
- If, within 120 days from the date of the initial notification, a contract is executed for a drug not currently on the List, the Department shall add the drug to the List.
- The Department shall terminate all negotiations 120 days after the initial notification.

Following the Department's review of the drugs based on the five evaluation criteria, the Department may present a price counter offer to the manufacturer. The manufacturer may accept, reject, or present an alternative to the counter offer within the time frame requested by the Department. Manufacturers' acceptance of contract offers must be completed within the 120 days and no offers may be accepted beyond the 120 days.

Decision

Prior to the end of the negotiation period, the Department staff will present their initial recommendations to the Director for approval.

Decision Notification

After receiving approval from the Director, the Department will send a letter indicating the decisions for every product included in the TCR to all of the manufacturers whose products were reviewed, and will send a copy of the letter to the MCDAC and PhRMA. A more detailed identification and explanation of the five-regulatory/statutory criteria upon which the decision was made regarding a specific manufacturer's drug will be available upon written request from that manufacturer.

When the decision is that a manufacturer's drug will be added to, or retained on, the List, the Department will send a contract to the manufacturer. Once the Department receives the contract signed by the manufacturer's representative, the Department's staff will develop an Operation Instruction Letter (OIL) to instruct the Department's fiscal intermediary to distribute Medi-Cal bulletins to inform providers of any changes to the List and to take any necessary action for processing provider claims for these drugs.

Manufacturers may contact the pharmacist who coordinated the TCR to find out the proposed effective dates of the drug product addition. The effective date to add a drug is not official until the Medi-Cal provider bulletin is published. Therefore, manufacturers must not announce an effective date prior to Medi-Cal bulletin publication. The Department reserves the right to take administrative action and delay the addition of a drug when a manufacturer prematurely announces or markets the drug as being on the Medi-Cal List of Contract Drugs.

Any proposed deletions of drugs from the List as a result of the TCR are subject to the public hearing process pursuant to provisions of W & I Code Section 14105.38.

Appeals

State law provides that a manufacturer denied a contract as a result of the TCR may appeal that decision with the Director within 30 calendar days of the date of the written notice of the Department's decision. Within 30 calendar days of the manufacturer's appeal, the law requires the Director to request a recommendation regarding the appeal from the MCDAC. The committee must provide this recommendation in writing to the Director within 30 calendar days of the Director's request. The Department will schedule a meeting with the manufacturer and the Department's Deputy Director of Medical Care Services, or designee, to review any additional information supplied with the appeal. The Department will consider no new financial business proposals during the appeal process. However, the appeal process can include further discussion and clarification of the manufacturer's most recent financial business proposal or any proposed fiscal effect that the addition of the drug would have on the Department. The Director must issue a decision within 30 calendar days of the MCDAC recommendation.

Preferred Prior Authorization

State law provides that a manufacturer of a drug deleted from, or not added to, the List may request inclusion of the drug on the list of PPA drugs [W & I Code Section 14105.39(f)]. To ensure that the health needs of Medi-Cal beneficiaries are met, statute also requires the Department to evaluate these requests using the Drug Evaluation Criteria.

PPA list evaluations follow the Fast-Track Drug Petition Review Procedures (see above). Though not required, the Department may seek additional input from the MCDAC. Additionally, the Department may initiate the review of one or more drugs for addition to the PPA list.

Additional Provisions

W&I Code Section 14105.37 also provides for suspension or deletion of any drug from the List as follows:

- The Department may suspend or delete any drug from the List at the expiration of the contract term or when the contract between the Department and the manufacturer of that drug is terminated.
- In the absence of a contract, the Department may suspend or delete any drug from the List.
- Any drug suspended from the List pursuant to this section or W & I Code Section 14105.35 shall be subject to prior authorization, as if that drug were not on the List.
- Any drug suspended from the List pursuant to this section or W & I Code Section 14105.35 may be deleted from the List in accordance with W & I Code Section 14105.38.