MEETING WITH THE PHARMACY DRUG CONTRACTING BRANCH

Frequently Asked Questions (FAQs)

The Pharmacy Drug Contracting Branch allows pharmaceutical manufacturers to conduct a clinical presentation as part of an individual drug petition for addition to List of Contract Drugs (CDL). Below are some frequently asked questions.

1. How long is the clinical presentation?

Clinical presentations are held via web conferencing for a period of up to one hour. There will not be an opportunity for a second meeting; however, any additional correspondence will be communicated through emails or phone calls.

2. What platforms are available for web conferencing?

The Department of Health Care Services (DHCS) uses Teams, Webex and Zoom. Once the date and time are agreed upon, manufacturers are expected to initiate the meeting on one of the accepted platforms, including inviting their attendees, and the DHCS pharmacist assigned to their drug. The DHCS assigned pharmacist will distribute the meeting information to internal attendees.

3. Who will attend from Medi-Cal-Rx?

Pharmacists from the Drug Contracting Branch will attend the web conference; other DHCS staff will attend on occasion.

4. Whom should manufacturers invite to the web conference?

It is up to the discretion of the manufacturer whom to invite to the clinical presentation meeting. Some manufacturers include the drug's product manager, local, regional and/or national sales managers, and/or pharmacoeconomists. Others have only one or two representatives as spokespersons. Most include a California physician or medical liaison who is an expert on the disease the drug is meant to

treat and who can discuss the drug from the perspective of treating Medi-Cal Rx patients.

5. What should be presented during the clinical web conference?

Statute mandates petitioned drugs are evaluated on five criteria – Safety, Efficacy, Essential Need, Misuse Potential, and Cost. The presentation should concentrate on addressing these criteria, e.g., what makes this drug safer or more effective than other similar drugs on the CDL? Why does Medi-Cal Rx need this drug, if other similar drugs are already on the CDL? What are the chances that prescribers will misuse this drug (e.g., prescribe this drug when equally efficacious but less expensive drugs are available)? What makes this drug cost-effective to Medi-Cal Rx?

Regarding the Cost criterion, Pharmacy Drug Contracting expects a business proposal that addresses the State's need to control costs in its rapidly expanding Medi-Cal Rx drug benefit. This will involve an offer of a State Supplemental Rebate paid to the State, over and above the mandatory rebate required by the Federal Centers for Medicare and Medicaid Services (CMS). The business proposal is required either prior to or the day of the clinical presentation.

6. What additional deliverables are required for the web conference?

Pharmacy Drug Contracting Branch requires manufacturers to email the slide presentation to the assigned pharmacist no later than one day before the web conference. **Note that the slide presentation provided in advance will be kept for reference and must be identical to the actual presentation materials. This requirement is mandatory. Any information presented during the presentation that is not provided via hard copy will not be considered for evaluation of the petitioned drug. There are no exceptions.**

Provide information on current and planned marketing efforts for this product, including direct-to-consumer marketing. Provide examples of marketing materials. Let us know promotion targets for this product in the medical community, e.g., family practitioners, neurologists, allergists, etc.

NOTE: Please also refer to the document titled *Dos and Don'ts: Guidance to Drug Manufacturers for Advertising, Marketing and Promotional Materials*, which will be provided if your company signs a supplemental rebate agreement with DHCS.

7. How can rebate disputes be avoided?

Some products tend to generate more disputes than others.

Examples:

> Drugs sold as powder for injection often generate disputes. While the pharmacy should bill these products as "each," they often bill in ccs of the final product. For example, a pharmacy bills Medi-Cal Rx for 5 cc instead of 1 vial. DHCS' rebate invoice to the manufacturer then shows a quantity of 5, forcing the manufacturer to overpay in rebates or to dispute the invoice. Kits are also a frequent source of problems. For example, a kit might contain 60 capsules of a drug plus an administration device, all contained in a package that is not meant to be opened prior to dispensing. A pharmacist trying to bill for the product won't know to bill one kit, or 60 capsules. Products dispensed in units with fractional quantities (e.g., 2.5 cc ampules, 16.8 gm canisters) tend to create disputes.

It is the responsibility of the manufacturer to inform the Pharmacy Drug Contracting Branch if their product requires a unit conversion in cases where the CMS unit differs from the NCPDP billing unit.

Rebate calculations that involve market share, DACON (daily average consumption), and similar variables only invite later disputes. Keep things simple. (See next question.)

8. What information is needed in the business proposal?

Business proposals must be simple to understand and simple to administer. For each NDC number of the product in question, please provide the following information:

- The National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) if NADAC is not available
- The Average Manufacturer's Price (AMP) as reported to CMS
- The daily consumption (DACON) for the various strengths of product(s), as reported by IMS, Verispan, or another acceptable source.
- The package sizes, for products with special packaging such as blister packs or kits
- The proposed rebate should be expressed as a percentage of AMP. Be sure to specify if the rebate will be in addition to the CMS rebate, or if it is to be a total combined federal and state supplemental rebate as a percentage of AMP. See Pricing Template, available on the Pharmacy Drug Contracting main page.

- The proposed rebate offer must be in the same unit as the CMS rebate unit
- Alternatively, the manufacturer can propose a net cost offer (GNUP) meaning that Medi-Cal Rx's cost after rebates will be a net fixed dollar amount off the Medi-Cal Rx reimbursement cost, which is the NADAC (or WAC+ 0% if NADAC is not available).

9. Is a value-based contract option available?

Yes. DHCS has been approved by CMS to participate in Value Based Contracts.

10. How does Pharmacy Drug Contracting Branch calculate cost?

Medi-Cal Rx reimburses pharmacy providers using NADAC (plus a dispensing fee) or WAC + 0% if a NADAC is not available. For guidance on how to calculate the net cost for a product, see the Pricing Template, available on the Contracting Branch main page.

11. What happens after the clinical presentation?

The pharmacist assigned your drug will conduct a review and present the drug to other professional staff internally, addressing the five criteria and the Medi-Cal Rx Contract Drug Advisory Committee's (MCDAC) recommendations. A decision will be made to add the drug as proposed; to reject the petition and leave the drug under prior authorization; or to make a counter-proposal.

Counter-proposals usually involve a change in the proposed rebate, and sometimes a "Code 1" restriction of some type, such as limiting the drug's use to patients with a certain diagnosis, a certain age, etc. The counter-proposal is usually made over the telephone.

12. How long does the review process take?

P Drugs - At the time of petition, if the drug has been recently approved as part of a priority ("P") review by the federal Food and Drug Administrations (FDA), the Medi-Cal Rx petition review will also be given priority. Pharmacy Drug Contracting Branch seeks to complete these reviews within 120 days of petition. This is a very tight time frame, both for DHCS and the manufacturer, so be prepared to meet and answer questions on short notice.

S Drugs - Drugs that have been given a standard ("S") review by the FDA are processed through standard review procedures. Pharmacy Drug Contracting Branch seeks to complete these reviews within 240 days. Occasionally review times exceed 240 days, as each petition is unique and evaluated on a case-by-case basis.

13. How do I know which drugs are already on the CDL?

The CDL is published in our Pharmacy Provider Manual. The easiest way to see the CDL is to go to the Medi-Cal Rx website.

14. Is a copy of the boilerplate contract available to review in advance?

DHCS uses three type of contracts, Net Cost, CMS Plus (AMP-based), Total Rebate (AMP-based). All three CMS-approved boilerplate contracts are available on the Pharmacy Drug Contracting homepage. It is important to review the boilerplate contract language ahead of time so if the petitioned product is added to the CDL, the contract can be signed quickly. Be informed that the contract will be initiated by the Pharmacy Drug Contracting Branch and cannot be modified, except for the information necessary to execute the agreement.

15. Is data available for Medi-Cal Rx drug utilization?

The CMS website has quarterly drug utilization for California. There is no charge for this information.

16. I have more questions. Where can I get answers?

The pharmacist assigned to the drug petition is available to answer any additional questions. More information is available in the Medi-Cal Rx Drug Review Policies and Procedures document on the Contracting Branch main page.