Meeting with the
Medi-Cal Pharmacy Drug Contracting Branch
Frequently Asked Questions (FAQ)

You have been invited to meet with Medi-Cal regarding your petition to add a drug to our List of Contract Drugs (List). Meeting with Medi-Cal can be challenging. Many manufacturers have no idea what to expect or how to prepare when they schedule an appointment to present a drug to us, or what goes on in the actual presentation. This document contains some frequently asked questions that will help you prepare for your meeting with Medi-Cal. Much more detailed information is available in the Medi-Cal Drug Review Policies and Procedures.

Q: How long is the meeting?

Typically we schedule the meeting room for one and one-half hours. This leaves time for a one-hour presentation, plus questions. There generally will not be an opportunity for a second meeting, so budget your time carefully.

Q: Do you provide audio-visual equipment?

No, we have no audio-visual equipment available. Our meeting rooms have only electrical outlets and a screen. You must provide your own projectors, laptops, extension cords, etc.

Q: Who will attend from Medi-Cal?

Typically the pharmacist who has been assigned to your drug will attend, sometimes with other pharmacists. Occasionally staff from other DHCS programs may attend. If you have handouts for your presentation, please bring enough copies for the Medi-Cal staff attending.

Q: Whom should we bring to the meeting?

That is up to you. We typically meet in various conference rooms in our building, as necessitated by scheduling. Most of our meeting rooms will hold six to ten people. Medi-Cal usually assigns one or two persons to attend, leaving four to eight persons that the manufacturer can bring. It has been our experience that bringing more people than this does little to enhance a drug's presentation. Please be sure to tell the pharmacist assigned your drug how many you plan to bring, in advance, so that we can schedule an appropriately sized room.

Some manufacturers send the drug's product manager, attorneys, local, regional and national sales managers, pharmacoeconomists, and financial experts. Others send only one or two people as spokespersons. Most will bring one or two California physicians who are experts on the disease their drug is meant to treat, and who can discuss the drug from the perspective of treating Medi-Cal patients.

Whoever you send, they should be prepared to address our Five Criteria and to come prepared with a business proposal. It might also be desirable to bring your state rebate manager (see below under "Why does Medi-Cal need this information regarding rebate payments?")

Q: What should we talk about?

The Department must evaluate your drug using our five criteria – Safety, Efficacy, Essential Need, Misuse Potential, and Cost. The persons you bring to this meeting should concentrate on addressing these criteria, e.g., what makes this drug safer or more effective than other drugs Medi-Cal has on its List? Why does Medi-Cal need this drug, if other similar drugs are already on the List? What are the chances that prescribers will misuse this drug (i.e., prescribe this drug when equally efficacious but less expensive drugs are available)? What makes this drug cost-effective to Medi-Cal? We discuss the Cost criterion in more detail later in this document.

With regard to the Cost criterion, Medi-Cal expects you to make a business proposal that addresses the State's need to control costs in its rapidly expanding Medi-Cal drug benefit. Usually that will involve an offer of a rebate paid to the State, over and above the federal rebate required by the Federal Centers for Medicare and Medicaid Services (CMS).

Q: What should we bring to our meeting?

Bring a sample of the product where possible and practical. A placebo sample is preferred – we just want to see what the product looks like.

If possible, mail or e-mail us a copy of any presentation materials (e.g. PowerPoint slides) one week in advance to give the Department time to prepare**. Please also bring at least two copies of the presentation materials to your scheduled meeting. 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 your product. There are no exceptions.**

Bring information on your current and planned marketing efforts for this product, including direct-to-consumer marketing. Bring examples of your marketing materials. Let us know to whom you will be promoting this product in the medical community, e.g., family practitioners, neurologists, allergists, etc.

Always bring your written business proposal. If you can send this in advance, that can be particularly helpful.

Bring your company's history regarding payment of rebates to Medi-Cal. For example, what is the amount Medi-Cal has billed you, both for CMS and state supplemental rebates? How much has your company paid us? How much has your company disputed? What steps has your company taken to resolve any disputes quickly and fairly?

Q: Why does Medi-Cal need this information regarding rebate payments?

It is much better to anticipate and correct rebate payment problems before they occur, rather than afterward. The dispute resolution process is terribly expensive, both in terms of uncollected rebates, and also in terms of use of Medi-Cal and manufacturer staff resources. For this reason, we review companies' rebate payment history to try to avoid these problems before they occur. This is why it might be advisable to bring your state rebate manager to answer our questions regarding your company's rebate payment history.

Q: We don't like disputes either. How can we avoid them?

Some products, by their very nature, tend to generate more disputes than others do. Many disputes cannot be avoided, but manufacturers will save themselves some rebate headaches if they know how the products are used and how the products should be billed. For example:

Drugs that are sold as powder for injection often generate disputes. While the pharmacy should bill these products as "eachs," they often bill in ccs of the final product. For example, a pharmacy bills us for 5 cc, instead of 1 vial. Medi-Cal's rebate invoice to the manufacturer then shows a quantity of 5, forcing the manufacturer to pay too much in rebates, or to dispute our invoice.

Kits are 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 by the pharmacist. A pharmacist trying to bill for the product won't know if he or she should bill one kit, or 60 capsules.

Products that are dispensed in units with fractional quantities (e.g., 2.5 cc ampules, 16.8 gm canisters) tend to create disputes. Prior to October 1, 2002, pharmacies submitted claims in whole numbers (a 16.8 gm inhaler canister was billed as 17 gm, a 2.5 ml ampule was billed as 3 mls).

Effective October 1, 2002, Medi-Cal standardized on the National Council for Prescription Drug Programs Version 5.1 Telecommunications Standard (NCPDP 5.1) to process pharmacy claims transactions. This is important because under this new standard, pharmacy providers no longer round fractional quantities to whole numbers. A 16.8 gm inhaler canister is billed as 16.8 gm, not 17. A box of 25 x 2.5 cc vials is billed as 62.5 cc, not 75. This should help reduce errors and disputes that occur due to rounding errors. You should be aware of this change when working with Medi-Cal utilization data.

Don't propose complicated schemes for rebate calculation. Rebate calculations that involve market share, DACON, and similar variables only invite later disputes. Keep things simple. (See next question.)

Q: What information do you need in our business proposal?

For each NDC number of the product in question, please provide us with the following information:

- The Average Wholesale Price (AWP).
- The Average Manufacturer's Price (AMP) as reported to CMS.
- The daily consumption (DACON) for the various strengths of your product(s), as reported by IMS, Verispan, or another acceptable source.
- The proposed rebate you are offering us expressed as a percentage of AMP. Be sure to specify if your rebate will be paid in addition to the CMS rebate, or if it is to be a combined CMS plus state supplemental rebate. See Examples 1 and 2 on the Sample Pricing Calculations spreadsheet.
- Alternatively, you may make a net price offer, meaning that Medi-Cal's cost after rebate will be a net, fixed dollar amount. See Examples 3 and 4 on the Sample Pricing Calculations spreadsheet, as noted above.

We ask that you make your business proposal simple to understand, and simple to administer. We have seen many business proposals where, for example, rebate would increase if a drug's market share exceeded a certain value; or where the rebate would be X% with one competitor on the List, but would be Y% if two competitors were on the List, etc. These kinds of proposals, while creative, are very difficult to administer both for Medi-Cal, and also for the manufacturers' accounting departments. Avoiding these kinds of excessively creative approaches will prevent many rebate administration and dispute problems in following years.

Q: What happens after our meeting?

The pharmacist assigned to your drug will present the drug to the other professional staff in the office, addressing the five criteria. The group will discuss the Medi-Cal Contract Drug Advisory Committee's (MCDAC) recommendations as well. A decision will then be made. The choices typically are 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. We generally give the manufacturer a week to respond to our counter-proposals.

While review of drugs is one of our most important activities here at Medi-Cal, it is by no means our only activity. Our pharmacists are extremely busy. Thus, it may be as long as several months after your meeting with Medi-Cal before we get back to you with a response. You may call the pharmacist assigned to your drug periodically to check on its status.

It is our goal to complete our review of your product on the following schedule:

P Drugs - Drugs that recently have been given a priority ("P") review by the federal Food and Drug Administrations (FDA) are given priority in our reviews also. We seek to complete these reviews within 120 days of petition. This is a very tight time frame, both for the Department and for you, the manufacturer, so please 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 our standard review procedures. We seek to complete these reviews within 240 days. Realistically, though, review times sometimes exceed 240 days.

Q: How does Medi-Cal calculate cost?

It's important to remember that we at Medi-Cal view cost as our cost, i.e., the amount of money we pay to pharmacies for your product. Many companies make comparisons on their products based on wholesaler acquisition cost, or WAC. But Medi-Cal doesn't pay pharmacies at WAC. We pay for most drugs at Average Wholesale Price (AWP) minus 17% percent (AWP – 17%), plus a dispensing fee. For examples of how we calculate cost, see the Sample Pricing Calculations spreadsheet.

Please review it carefully.

Q: How do I know which drugs are already on the Medi-Cal List of Contract Drugs?

The Medi-Cal List of Contract Drugs is published online in our Pharmacy Provider Manual.

Q: Where can I learn about the other aspects of the Medi-Cal Pharmacy Program?

The Pharmacy Provider Manual is the most comprehensive reference on the Medi-Cal pharmacy program, and contains answers to many questions. To view the manual, go to Medi-Cal's website. On the top of the page, under Publications, you will find a link labeled "Provider Manuals". Scroll down to "Pharmacy" and you will find the links to the Pharmacy Provider Manual.

Q: Can I get a copy of the contract we will need to sign with Medi-Cal?

Ask the pharmacist in charge of your drug's review for a copy of our boilerplate contract. It is important to have your company review our boilerplate contract language ahead of time so that if your product is added to the List, the boilerplate contract can be signed quickly.

Q: How can I get data on Medi-Cal utilization of our product, and of our competitor's products?

There are several sources for this information:

- You can download monthly and quarterly reports of fee-for-service pharmacy drug utilization, in National Drug Code (NDC) order on our website, free of charge.

- The CMS website has quarterly drug utilization for most states, including California, going back to 1991. There is no charge for this information. The files are in ASCII text format, and are too large to fit into an Excel spreadsheet, so you will need to have some basic computer and database skills to work with the files. We have had success working with these files in Microsoft Access and in dBASE.

Q: I have more questions. Where can I get answers?

Call the pharmacist assigned to review your drug. He or she can answer your questions.

Again, we encourage you to carefully read our Medi-Cal Drug Review Policies and Procedures document, which explains many of these points in much greater detail than given here. If you don't have a copy of that document, please request a copy from your assigned pharmacist, or download it from the Internet using the link above.