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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE
AD-HOC Committee on Pharmaceutical Benefit Managers (PBMs) Regulation

Meeting Summary

DATE: June 4, 2003

TIME: 9:00 a.m. – 12 noon

LOCATION: 400 Street, Suite 4070
Sacramento CA 95814

Ad Hoc Committee Members: Bill Powers, Public Member
Andrea Zinder, Public Member (absent)
Caleb Zia, Ex-Officio Member

Board Member and Facilitator: Dave Fong, Pharm.D.

Staff Present: Patricia Harris, Executive Officer
Ronald Diedrich, Deputy Attorney General

Introductions

Board member Dave Fong stated that the purpose of the ad-hoc committee is to gather facts to determine whether PBMs should be regulated. This means the board must demonstrate that the purpose of regulation is necessary to protect the public and ensure patient safety. Another reason to regulate would be if the PBM activities were considered the practice of pharmacy.

The committee held its first meeting in March. This second meeting is to explore the development of formularies, the requirements of the Pharmacy & Therapeutics (P & T) Committees including the qualifications of its members, the process used by the PBM to select the drugs that are on the formulary and how cost factors in this selection process. It was explained that a formulary is a pre-approved list of prescription drugs established by the PBM through a P & T Committee process.

Dr. Fong added that his role is facilitator for this ad hoc committee. The committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. He also explained that Board President John Jones asked former public board member Caleb Zia to continue to serve on this committee as an ex-officio member.

Dr. Fong stated that guest speakers were invited to speak on the topic of formulary development.

Department of Managed Health Care (DMHC)

Warren Barnes, Legal Counsel at DMHC stated that they regulate Knox-Keene health care service plans. DMHC's experience with PBMs is indirect with no authority to regulate PBMs, IPAs or medical groups. However, the department's regulation of health care service plans has a significant indirect effect on PBMs because PBMs subcontract with health care service plans to manage the pharmacy benefit for its enrollees. The department does not regulate the financial solvency of the PBM nor any of the activities that the PBM is engaged in.

California does not require that a health care service plan provide an outpatient drug benefit. However, if the health plan provides this benefit, then DMHC regulates the benefit. The plan must cover all medically necessary drugs. Historically, pharmaceutical benefits have been provided on a two-tier basis. Currently, the vast majority of health plans have added a third tier of prescription drug coverage that includes any drug that is basically FDA approved and its prescribed use is consistent with standards of practice. With a three-tier plan, patients have broad access to and choice of prescription drugs, but pay different co-payments (i.e. the lowest co-pay is for generic drugs; the next highest co-pay is for formulary or preferred drugs; the highest co-pay is for "non-preferred" and non-formulary drugs).

While DMHC does not regulate the development of a formulary, the health plan must offer an appeal process for non-covered drugs based on medical necessity. This is an independent medical review by a neutral third party. Mr. Barnes reported that state approval is required for the drug benefit design and any significant changes to the plan design or administration of the program. If a plan has a prescription benefit and wants to either limit the benefit in any way or exclude any drug, then it has to submit a material modification to DMHC to get approval for the change. The material modification is a formal process that requires approval before the change to the prescription benefit can be implemented. If the plan can prove that DMHC approved a change, then the enrollee cannot appeal a plan's decision for non-coverage.

Mr. Barnes noted that the Department of Insurance regulates insurance companies that provide health benefits. Self-funded employer welfare benefit plans (which also provides drug benefits) are under the jurisdiction of the U.S. Department of Labor, which regulates activities such as claims payment, member appeals and coverage decisions. While PBM activities related to such plans are governed by the client's compliance with these standards, these other agencies do not have the same regulatory oversight over drug benefits, as does the DMHC. However, it was noted that the Department of Labor recently issued regulations that were specific to medical exceptions and non-covered benefits including pharmacy benefits that require the PBM or employer to accept complaints, appeals, and grievances.

Department of Health Services – Medi-Cal

Doug Hillblom, Chief of the Medi-Cal Contracts Section, spoke on the Medi-Cal fee-for-service program for prescription drugs. He stated that it is a prior authorization program that is

permitted by the federal Medicaid laws. This means every drug product is available to Medicaid beneficiaries through prior authorization. California has a list of contract drugs that do not require prior authorization. This is a supplemental contract to the CMS Medicaid rebates. California has the largest supplemental rebate program in the nation.

The federal Medicare program has a different purpose than a PBM. Medi-Cal's purpose is to ensure access for eligible patients while controlling costs. In many instances, Medi-Cal will have multiple products in a class of drugs while the private insurer may have one. A private insurer may have a co-payment arrangement. While Medi-Cal does have a co-payment of $1 per prescription, if the beneficiary cannot afford the $1, the provider cannot deny service.

California has in law a list of 5 criteria that must be used to review every drug. They are: essential need (what is the essential need of that drug product as compared to the current list of drugs), safety (safety of comparable products), efficacy, misuse potential (more appropriate alternative than costly use as first line for therapy), and cost. He stated there are two processes for review. The first review involves the therapeutic category. Information on the each drug is reviewed for the five criteria. If there is not any substantial therapeutic difference, then all the drugs will be placed on the formulary. If there is a substantial cost difference, then it will not be placed on the formulary. However, the physician can still prescribe the drug but must obtain a treatment authorization review (TAR) for approval to prescribe the drug.

The provider submits the TAR, which must include the diagnosis and the drug therapy that has been tried or considered. A pharmacist then reviews the TAR. Approximately 220,000 TARs are received a month. The review process takes 24 hours and approximately 10% are rejected.

Dr. Hillblom explained that the Medi-Cal process is open. What is not open is the contract information. This is proprietary information because disclosure would limit the manufacturer's ability to be competitive in the marketplace. DHS also has a Medi-Cal Advisory Committee comprised of physicians and pharmacists that advises DHS on formulary issues.

DHS is able to lower the price of drugs due to its ability to move market share. However, unlike the private sector, Medicaid has state and federal mandated price controls.

Mr. Hillblom stated that Medicaid is guaranteed rebates. Drug prices are based on the best price. The best price is based on the market place. For example, a PBM negotiates a price with a drug manufacturer for an innovator drug that is the lowest price in the nation. This negotiated price then becomes the best price for Medicaid. Then Medicaid takes the average manufacturer's price minus 15.1 percent and compares it to the best price. Whichever rebate is greater becomes the Medicaid rebate. This is the initial point of negotiations for the supplemental rebate. The drug manufacturer has a contract with the federal government that discloses the best price and to ensure compliance, the manufacturer may be subject to audit by the Office of the Inspector General.

Concerns were raised about comparing the Medicaid program to the commercial market. Because the rules for Medicaid are so restrictive, all drugs are placed on prior authorization and

then negotiated off to be placed on the formulary. To require a prior authorization for private healthcare would be costly. While the goals for the public and private sector are the same to provide quality and affordable prescription benefits, the private insurer does this with a formulary and an appeal process for medically necessary drugs not covered by the formulary.

Caremark – PBM

Joel Yargerman introduced himself as the Chief Medical Officer for Caremark, Chair of Caremark's P&T Committee and a licensed California physician. Caremark administers the pharmacy benefits for CalPERS. Caremark has a network of 55,000 pharmacies.

Dr. Yargerman discussed the October 2000 document title *Principles of a Sound Drug Formulary System* as a template for his presentation. He stated that Caremark uses this document as the basis for its formulary process. He emphasized that the P&T committee process is not just developing a list of drugs. It is an ongoing, day-to-day management process for quality and cost control to ensure patient access to good medical care. The committee meetings are live and regular. There are special meetings in addition to scheduled monthly and quarterly meetings and Caremark has an infrastructure that supports this process.

The goal of the formulary process is to provide patients with the highest quality of care with minimal hassle to the physician and a system that supports the doctor-patient relationship. Caremark has a P & T Committee with a diverse and demographically represented membership. It is a 17-member committee. There are 13 voting members that are active practitioners. Eleven are physicians and 2 members are pharmacists. The 4 non-voting members are Caremark employees. The members are kept anonymous so that the pharmaceutical industry does not know who is on the committee.

The P & T Committee has a standardized series of documents that are used to review all the medical information for every single formulary decision. There is a cadre of pharmacists who are the power behind developing all the data that P&T voting committee reviews. The pharmacists develop significant monographs, perform extensive literature searches, and review all the research on each drug. If the committee doesn't have a member with expertise in a specific area, then they have a guest consultant who is and who can provide in-depth review.

Once the P & T Committee makes a decision and the quality of the drugs being considered therapeutically equivalent, then cost becomes a factor. If there is a product that is proven clinically and scientifically better, that drug is placed on the formulary even if it is more expensive.

A comment was made that there is an ongoing hassle factor for pharmacists when a prescription drug is no longer covered on the formulary or the co-pay has changed. Usually the patient is unaware of the change at the time the prescription is being filled. Caremark responded that when a drug is removed from the formulary for safety reasons, this information is immediately communicated to the plan, the patients and the providers. While Caremark added that it has a communication system in place to keep everyone informed of any changes, they agreed that

there is always room for improvement. Until the entire prescribing and dispensing process is electronic, it is going to be difficult to completely eliminate this problem. However, Caremark felt that by using a tiered formulary system, very few drugs are not covered and while the drugs might be available but at a different co-payment, this system tends to remove some of the hassle factors as well.

Caremark stated that it has a national formulary and drug lists that are fine tuned even further for some clients. Ultimately, it is the client who decides on the drug benefit design. Only a small percentage of Caremark's clients make changes to the preferred product listing. These changes are typically found in the lifestyle drugs.

The PBM clients (who are the employers) also look at how the PBM manages the plan. The clients are identifying the value of the preferred product listing process and look to see if the PBM has misaligned incentives or relationships with the pharmaceutical manufacturer. Caremark is an independent PBM and is not associated with a pharmaceutical manufacturer. Caremark's business model demonstrates the importance of quality first and then focuses on the financial value of the process. Caremark encourages generics and mail service because of the deeper discounts. The clients usually have consultants that advise them on the benefit design. The client looks to see how the PBM manages the product component and the utilization and what clinical management programs are in place to ensure appropriate drug therapy. Today the clients are much more sophisticated and the PBM must demonstrate its value on a variety of fronts.

Concern was expressed regarding the relationship of some PBMs with the drug manufacturers and that the rebates or cost savings are not being passed on to the client. It was expressed that formulary decisions are based on cost factors only after the safety, efficacy and therapeutic need have been established. It was stated that the drug manufacturer is the vendor, while the employer is the client. It is the PBM's responsibility to get the best price for its client. Caremark's business model negotiates with pharmaceutical companies and takes their discount arrangements in the form of a discount from cost of goods sold. Dr. Yargerman stated that they do not accept administrative fees. Caremark builds a financial package depending on each individual client's needs and what is competitive in the marketplace that provides the best benefit design for the client.

Dr. Y. stated that it his and Caremark's perspective that the guidelines and process that they follow to develop a formulary is so highly unbiased and clinically credible because the physicians and pharmacists of the P&T Committee make the decisions. The pharmacists and physicians should be making the formulary decisions separate and apart from any financial considerations and negotiations. It is in the best interest of the client to develop a formulary based on quality and then separately and independently negotiate the price. The PBM is able to do this and keep prices competitive for the client through an effective formulary process.

Additional Comments
It was suggested that the Board of Pharmacy take a leadership role and facilitate meetings with employers, PBMs, and providers to improve communications so that the "noise" is minimized at the pharmacy level. It was noted that there is such a coalition at the national level that involves many of the national pharmacy organizations.

A statement was made that employers have not been represented at these meetings and it is unknown if they are unhappy with PBMs and the process. Dr. Fong responded that the Pacific Business Group and CalPERs were invited.

A comment was made that the committee also has not heard from the unhappy patients who learn that a drug that was covered last month is no longer covered, or is covered but at a higher co-pay. It is the pharmacist and pharmacy personnel that are on the receiving end of the patient's unhappiness, not the PBM. It is the pharmacy staff that becomes the representative of the PBM.

It was also noted that the reason for the ground swell for regulation by pharmacy providers is because they are unhappy with their inability to negotiate for the reimbursement rate. The pharmacy provider is told by the PBM -- here is the contract and you have 14 days to sign if you want to participate in the network. Also, resident pharmacies are not given the same opportunity to compete with the mail service pharmacies in a network.

The PBM must balance the needs of the employer who wants to control costs and the patient who wants access. The board's responsibility is to ensure patient safety and the quality of care and patient safety.

Recommendations
The committee stated that it would discuss recommendations at the July board meeting.