# Medicaid Oversight and Advisory Committee

### Minutes

### <MeetMDY1> October 11, 2017

**Call to Order and Roll Call**

The<MeetNo2> Medicaid Oversight and Advisory Committee meeting was held on<Day> Wednesday,<MeetMDY2> October 11, 2017, at<MeetTime> 1:30 PM, in<Room> Room 131 of the Capitol Annex. Representative Kimberly Poore Moser, Chair, called the meeting to order, and the secretary called the roll.

Present were:

Members:<Members> Senator Ralph Alvarado, Co-Chair; Representative Kimberly Poore Moser, Co-Chair; Senators Julie Raque Adams, Danny Carroll, Morgan McGarvey, and Stephen Meredith; Representatives Robert Benvenuti III, Jim Gooch Jr., and Joni L. Jenkins.

Guest Legislators: Representatives Danny Bentley and Addia Wuchner.

Guests: Steve Miller, Commissioner, Veronica Cecil, Deputy Commissioner, and

Samantha McKinley, Pharmacy Director, Department for Medicaid Services, Cabinet for Health and Family Services; Chris Harlow, Pharm.D, President, Kentucky Pharmacists Association, St. Matthews Pharmacy; Rosemary C. Smith, R.Ph., Co-Founder, Kentucky Independent Pharmacist Alliance, Jordan Drug, Inc.; Alyson Roby, PharmD, CDE, Medica Pharmacy; Trevor Ray, PharmD, Midway Pharmacy, Independent Pharmacist; Melodie Shrader, Senior Director, State Affairs, Pharmaceutical Care Management Association; Rosmond J. Dolen, Kentucky Association of Health Plans; Kasey L. Alford, PharmD, President, CEO, Alford's Pharmacy and Drive-Thru; and Richard Ponesse, Senior Director of Trade and Finance, Industry Analytics, CVS Caremark.

LRC Staff: Jonathan Scott, Becky Lancaster, and Heather Scott.

**Approval of the Minutes from the September 20, 2017 Meeting**

A motion to approve the minutes of the September 20, 2017 meeting was made by Senator Alvarado, seconded by Representative Gooch, and approved by voice vote.

**Presentation on the Regulation and Oversight of Pharmacy Benefit Managers**

Steve Miller, Commissioner, Department for Medicaid Services, Cabinet for Health and Family Services (CHFS), stated that the Department for Medicaid Services (DMS) annual budget is $11 billion, of which $1.6 billion is for pharmacy costs. By having the pharmacy benefits handled through the managed care organizations (MCOs), Kentucky saves 10 to 12 percent or $150 to $180 million a year. DMS implemented a 90 percent medical loss ratio (MLR) for the Medicaid population in the MCOs contracts.

Veronica Cecil, Deputy Commissioner, Department for Medicaid Services, Cabinet for Health and Family Services, stated that the MCOs monthly capitation rates are developed for each contract period by an actuarial firm. MCOs utilize eligibility, use actual claim experience, and apply adjustments to the base data. In regards to the pharmacy benefit, MCOs may waive or impose lower co-payments but not exceed the maximum co-payments. DMS allows each of the MCOs to delegate authority to Pharmacy Benefit Managers (PBMs). The PBMs are a subcontractor of the MCOs. Subcontractors must comply with the provisions of the MCOs contract. MCOs must provide oversight to the subcontractor.

Samantha McKinley, Pharmacy Director, Department for Medicaid Services, Cabinet for Health and Family Services, stated that participants in the pharmaceutical supply chain may not handle the drug but have significant influence over the distribution to the consumer. The additional participants mentioned in the pharmaceutical supply chain are the health insurance payer, PBMs, group purchasing organizations (GPOs), and pharmacy services administrative organizations (PSAOs). GPOs allow the independent pharmacy to take advantage of aggregate purchasing power to obtain better discounts and rebates from manufactures. Chain pharmacies have a higher purchasing volume and have more success negotiating on their own behalf.

PBMs developed from the reimbursement side as an opportunity to confront escalating costs of the drug market. PBMs can be owned by insurance companies, health maintenance organizations (HMO), manufacturers, retail pharmacies, or private entities. Health plans contract with PBMs to process and pay for prescription drug claims for its network pharmacies. PBMs also contract with pharmacies to create networks to dispense medications. PBMs establish the reimbursement levels in those contracts. PSAOs provide services to pharmacies that include contracting, financial intermediation, and other supportive activities with PBMs. DMS contracts directly and only with MCOs for the delivery of the pharmacy benefit on a capitation basis. DMS is not a party to the other agreements in the pharmaceutical supply chain.

Deputy Commissioner Cecil stated that DMS has requirements in the MCO contracts regarding conforming to applicable law, policies, and procedures. DMS has provider network requirements that would apply to subcontractors. DMS has a required corrective action process that could result in civil money penalties or sanctions. MCO contracts contain a withhold provision, where DMS may withhold a portion of its monthly capitation payment until the violation is corrected.

In response to questions from Senator Alvarado, Ms. McKinley referenced the DMS contracts with MCOs. MCOs are held responsible for any violations made by one of its subcontractors, such as PBMs. Commissioner Miller stated that the state law requiring a notice of change in rates does apply to MCOs. Ms. McKinley stated that if PBMs do not notify its pharmacies of a change in rates, MCOs would be responsible for the violation. She stated that she did not explore the amount of money spent on the oversight of the pharmaceutical supply chain. Deputy Commissioner Cecil stated that in regards to the MLR, costs are not broken out specifically for the pharmacy costs. When the actuary sets the MCOs’ capitation rates, the pharmacy costs are in the aggregate of the 90 percent MLR. The actuary will look at the outliers and evaluate the information to ensure there is cost efficiency in the development of the rates.

In response to questions from Senator Meredith, Deputy Commissioner Cecil stated that DMS manages the MCOs and MCOs have oversight of the PBMs. Commissioner Miller stated that DMS runs metrics on each of the MCOs on a monthly basis. DMS is not aware of PBMs being out of compliance with MCOs’ contracts. CVS Caremark has over 50 percent of the Medicaid pharmacy business in the Commonwealth. Deputy Commissioner Cecil stated that there is no contract or provision that prohibits a company from owning a pharmacy and becoming a PBM. PBMs providing oversight for its own pharmacies could be a federal trade issue. Commissioner Miller stated that there is not a means to give local providers ownership of the process and have things mandated by the State under the state plan amendment that DMS is operating under. Providers could come together and work with MCOs on a risk sharing plan. A number of changes would need to happen that are not anticipated and not a part of the 1115 Kentucky HEALTH waiver that is pending approval from the Centers for Medicare and Medicaid Services (CMS).

In response to questions from Representative Bentley, Commissioner Miller stated that DMS monitored the drug costs paid, national studies of the prices, and costs being incurred by MCOs that determined the 12 percent savings the PBMs provided to the Commonwealth. Outside the Medicaid population there may be more savings and DMS is closely monitoring the savings created by the MCOs.

In response to questions from Senator Carroll, Commissioner Miller stated that determining if MCOs are efficient depends on the how efficiency is measured. There are different levels of complaints that DMS receives on the MCOs. Deputy Commissioner Cecil stated that DMS does not track violations made by PBMs. The PBMs’ complaints are channeled through the Department of Insurance (DOI). Medicaid providers disagree as to which of the MCOs is the best and worst at providing benefits. Commissioner Miller agreed that more MCOs bring about more administrative burdens for all departments.

In response to questions from Senator Alvarado, Commissioner Miller stated that access to local pharmacies for Medicaid members would be an issue if the independent pharmacies stopped participating in the MCOs’ plans.

In response to questions from Senator Meredith, Commissioner Miller stated that DMS is not privy to the details of the contracts between independent pharmacies and the PBMs and PSAOs.

In response to questions from Representative Bentley, Commissioner Miller stated that it would require a total restructure within DMS to carve out pharmacy benefits from the MCOs’ contracts. A restructure would require an increase in the internal amount of people, skill sets, and administrative costs.

In response to questions from Senator McGarvey, Commissioner Miller stated that DMS did not anticipate that four of the five MCOs would be using the same PBM. Deputy Commissioner Cecil stated that each of the MCOs has a different contract with its PBM.

**Presentation on Independent Pharmacy Reimbursement Challenges**

 Rosemary C. Smith, R.Ph., Co-Founder, Kentucky Independent Pharmacist Alliance, Jordan Drug, Inc., stated that DMS does not have direct contracts with PBMs. Kentucky Medicaid cannot provide sufficient oversight over how the PBMs are treating Kentucky pharmacy providers. PBMs determine the amount that pharmacies will be reimbursed for each medication dispensed with no oversight from Kentucky Medicaid and often with no oversight from the MCO. PBMs, who own pharmacies and are direct competitors with independent pharmacies, are allowed to determine what the independent pharmacies are paid per drug. PBMs can require that a Medicaid recipient must purchase a drug from the PBMs mail order pharmacy with no oversight from DMS.

In 2016, Senate Bill 117 recognized that three years after the passage of Senate Bill 107, PBMs were not supplying an updated list of what PBMs would pay pharmacists to dispense each medication. Senate Bill 117 clarified that PBMs were to supply pharmacists with the list in a readily available format. Senate Bill 117 required PBMs to notify pharmacists if they had been underpaid. Senate Bill 117 required PBMs to be licensed by the DOI to conduct business in Kentucky. She stated that the MCOs’ and PBMs’ profits should not come at the cost of putting local pharmacies out of business.

Chris Harlow, Pharm.D, President, Kentucky Pharmacists Association, St. Matthews Pharmacy, stated that the passage of Senate Bill 117 creates greater transparency in generic drug pricing and will soon be fully implemented. The PBMs continue to cost taxpayers, patients, and pharmacists money and cause for concern. He is asking for immediate action to address chronic under reimbursement by MCOs with CVS Caremark as their PBM. PBMs determine reimbursement rates for retail pharmacists, establish formularies, and determine which drugs require prior authorizations. Effective in January 2017, Senate Bill 117 required DOI to license PBMs and mandated additional transparency requirements so that pharmacists could have better knowledge of what they will be reimbursed when dispensing generic drug. PBMs are not complying with provisions of the statute. Dr. Harlow has not received notifications of reimbursement changes or dispensing fee changes that meet the requirements of Senate Bill 18, passed in 2016. He encourages DMS and DOI to strengthen oversight of MCOs and PBMs before more independent pharmacies have to close.

The Food and Drug Administration (FDA) does not recognize one definition of a specialty drug instead each of the PBMs determine which drugs are defined as a specialty drug. The PBMs prohibit retail pharmacies from fulfilling prescriptions for specialty drugs that are often high cost drugs and could be safely and effectively dispensed by retail pharmacists. Patients are required to have the high cost medication dispensed by a mail order pharmacy that is often owned by the PBMs. PBMs that are determining reimbursements are also the competition, no one entity should be allowed to participate on both ends of the transaction.

In response to questions from Senator Alvarado, Dr. Smith stated that pharmacists do not always know what the reimbursement will be at the time a claim is processed to fill a prescription. There are situations where a reimbursement is reduced after the drug is dispensed. There are a number of fees in clawbacks when a claim is adjudicated. Money is taken back from pharmacies as Direct and Indirect Remuneration (DIR) fees. CMS has established National Average Drug Acquisition Cost (NADAC) pricing. CMS has specified that between $9 and $13 is the cost of filling a prescription. She stated that is routine not to be notified of changes in reimbursements, pricing, or contracts.

In response to questions from Representative Benvenuti, Dr. Harlow stated that an independent pharmacist sees more surprises with reimbursements in the commercial business than in Medicaid. Dr. Smith stated that she still has fee-for-service Medicaid patients in eastern Kentucky. Independent pharmacies previously had one formulary and a set rate. Before 2011, if there was an issue with pricing and a maximum allowable cost (MAC) appeal was made, the appeal was answered within hours or days. Fee-for-service Medicaid has gone to NADAC pricing plus $10.64. Some MCOs now have a .35 cent dispensing fee which is unsustainable for independent pharmacists. Kentucky Independent Pharmacist Alliance (KIPA) was started with more than 520 pharmacists but 50 to 60 pharmacists have now closed their businesses. Many independent pharmacies are on the brink of closing because of the drop in reimbursements.

Alyson Roby, PharmD, CDE, Medica Pharmacy, stated that Medicaid patients represent more than 25 percent of her overall business. She has experienced a 105 percent drop in reimbursement from Passport. The day CVS Caremark took over as Passport’s PBM, her reimbursement dropped 74.8 percent and her dispensing fee dropped 77.5 percent. Four of the five MCOs that are reimbursing below acquisition costs all have CVS Caremark serving as its PBM. The number of prescriptions that are reimbursed one dollar or less above the acquisition cost has increased, effectively eliminating the right to appeal. The acquisition cost does not include the cost of the vial, the label, the cost of submitting a claim for reimbursement, nor does it include labor costs associated with preparing and dispensing a drug. If she rejects the PBMs’ contracts, she will lose the opportunity to provide care to patients in all the other health plans affiliated with the network, which could include the state employees plan and other major employer plans.

Dr. Roby stated that for a pharmacy to assist Medicaid patients with medication adherence, provide appropriate medication counseling, and other health care services necessary to improve overall health, it must receive adequate reimbursements from the PBMs to maintain necessary staffing levels. Spread pricing is simply the difference between what the health insurance plans pays for the drug and what the pharmacy is reimbursed for dispensing the drug. The average spread is between $8 and $10. Pharmacies are not able to determine what is being paid for a prescription claim until weeks or months after a claim has been submitted. The independent pharmacies’ competitors are determining reimbursements for independent pharmacies. CVS Caremark owns a PBM, retail pharmacies, and a mail-order pharmacy. Other PBMs own mail-order pharmacies only. PBMs should not be allowed to participate on both sides of the transaction. Kentucky Medicaid should prohibit its MCOs from contracting with PBMs who own or operate a retail or mail order pharmacy to reduce apparent conflicts of interest. DMS should require transparency in generic drug reimbursement to include a reasonable dispensing fee. DMS should also conduct an audit of the PBMs to better understand if the taxpayers are saving money.

Trevor Ray, PharmD, Midway Pharmacy, Independent Pharmacist, stated that his pharmacies’ Passport reimbursement above actual drug acquisition cost dropped 86 percent when CVS Caremark took over as the PBM for Passport. The dispensing fee dropped from $2 to .45 cents and the number of below cost reimbursement for generic drugs went from 4 percent to 32 percent. Passport claims are 25 percent of his overall business and approximately 80 percent of Passport claims are for generic medications. MAC appeals were filed with CVS Caremark, all of the appeals were denied, and then complaints were filed with DOI. DOI expressed to him that there was very little more it could do until proposed regulations went into effect. In Kentucky Medicaid, MCOs allow its PBMs to put pharmacies into an existing national network of plans. The only way an independent pharmacy can say no to Kentucky Medicaid is to drop out of the entire network.

He stated that the MAC lists being used by several MCOs that have CVS Caremark as its PBM, continue to reimburse pharmacies under cost on 30 percent to 50 percent of generic drugs. Senate Bill 117 clearly recognized that a pharmacist should never be reimbursed for less than the generic drug can be purchased for from a licensed wholesaler in Kentucky. CMS evaluates the pricing for drugs monthly and publishes the new pricing to be used as each drugs NADAC price. When CMS suggested NADAC pricing, it recognized that this new option was going to reduce drug reimbursement to very close to acquisition cost. CMS also advised that the dispensing fee would need to be increased to fairly and adequately reimbursement pharmacists for their professional services. Kentucky Medicaid adopted a dispensing fee for Medicaid fee-for-service within that suggested range of $9 to $13. Unlike Medicaid fee-for-service, under the jurisdiction of DMS, the MCOs through its PBMs are paying his pharmacy close to acquisition cost for the drugs, but continue to have a dispensing fee of .20 to .35 cents.

Dr. Ray referenced a review performed by many pharmacies which found that Passport, Aetna, and CareSource are reimbursing at or below NADAC without the adequate professional dispensing fee recommended by CMS. The MCOs and its PBMs are paying pharmacists based on an unsustainable model. PBMs will claim they save the MCOs money by administering pharmacy benefits, but no one seems to be able to verify the savings. Moving outpatient pharmacy benefits away from MCOs to the jurisdiction and authority of Kentucky Medicaid would enhance drug pricing transparency and stabilize reimbursements for all pharmacies.

In response to questions from Senator Carroll, Dr. Smith stated that West Virginia has carved out pharmacy benefits from its Medicaid managed care organizations. Dr. Ray stated that Texas redirected prescription benefits through PBMs and put 40 to 50 independent pharmacies out of business. DMS could contract directly with PBMs to eliminate going through MCOs and have direct oversight of PBMs. Prior to 2011, Kentucky Medicaid directly contracted with PBMs.

In response to questions from Representative Bentley, Dr. Ray stated that Medicaid contract language specifies that in order to have Medicaid MCOs and PBMs operate that there should have specific BIN and PCN numbers. The intent would be that one could discontinue business with one of the MCOs or PBMs without discontinuing business with the other MCOs or PBMs.

**Presentation on Pharmacy Benefit Manager Process and Legislative Initiatives**

Melodie Shrader, Senior Director, State Affairs, Pharmaceutical Care Management Association, stated that PBMs are health care companies that contract with insurers, employers, and government programs to administer the prescription drug portion of the health care benefit. PBMs work with insurers and employers to perform a variety of services to ensure high-quality, cost efficient delivery of prescription drugs to consumers. PBMs offer a set of core services to clients designed to contain drug expenditures such as; claims administration, pharmacy network management, negotiate and administer product discounts, mail-service pharmacy and specialty pharmacy services. PBMs save plan sponsors and consumers an average of 35 percent compared to expenditures made without pharmacy benefit management. The plan sponsor or MCOs have the final say when creating a drug benefit plan with PBMs. The number of independent pharmacies has not decreased but increased at a rate higher rate than chain retail pharmacies in Kentucky.

Independent pharmacies contract with PSAOs to provide many services such as; negotiating with PBMs for reimbursement rates, audit services, purchasing, office services, and marketing. PSAOs allow the independent pharmacies to be competitive with a chain drug store. MAC lists standardize the reimbursement amount for identical products from various manufacturers, regardless of each manufacturer’s price. PBMs develop and maintain its own confidential MAC lists based on proprietary methodologies. In Senate Bill 17, PBMs are required to be licensed at DOI. The commissioner has authority to suspend, revoke, or refuse to renew a license. Since the enactment of Senate Bill 117, pharmacists have been utilizing the maximum allowable cost appeal process with pharmacy benefit managers.

In response to questions from Senator Meredith, Ms. Shrader stated that PBMs compete with each other and information is proprietary regarding reimbursements. PBMs must go into the marketplace to survey prices, review invoices, and evaluate the costs that manufacturers are selling products. Each company must come up with a pricing mechanism that fairly represents the acquisition costs plus an additional margin. There is an external appeal processes so that if an independent pharmacy was reimbursed under the MAC list and not the acquisition cost then the independent pharmacy could appeal to the DOI. The law requires that with any changes or appeals that are justified, the drug price is immediately and retrospectively corrected. PBMs must reimburse the pharmacy that made the appeal and the entire network. If a MAC list did not accurately reflect the market price then all of the pharmacies within the network would appeal.

 In response to questions from Representative Gooch, Ms. Shrader stated that PBMs cover approximately 256 million Americans. The PBMs’ tools and services used are standard with government plans, Medicaid, Medicare, as well as private employers. Independent pharmacies are partners to the PBMs. PBMs need independent pharmacies in its network to help provide services to the clients.

In response to questions from Representative Moser, Ms. Shrader stated that it could be possible for Kentucky Medicaid to work directly with only one PBM. However, that would need to be studied by DMS because that pricing model may not be the most cost effective.

In response to questions from Representative Bentley, Ms. Shrader stated that PBMs do make money in administration fees. Each of the PBMs’ clients dictate in contract how PBMs are managed or how transparent PBMs will operate. Some clients come with a defined number of dollars but want to make sure benefits and employees are covered. PBMs are a vendor for the client. In regards to using a trade name drug with an incentive rebate or a generic drug, determinations are made by the client.

In response to questions from Senator Alvarado, Ms. Shrader agreed that PBMs should abide by the state laws as written.

In response to questions from Senator Carroll, Ms. Shrader stated that the MAC list is designed to encourage efficient shopping. PBMs would have to present data that shows when the claim was processed that particular drug could be bought at the PBMs’ MAC price. Drug prices change frequently because it is considered a commodity. Kasey L. Alford, PharmD, President, CEO, Alford's Pharmacy and Drive-Thru, stated that it took months to have one prescription appealed and justified through DOI. Since August there have been dramatic cuts in Passport prescription reimbursements. To cover all overhead, independent pharmacists are requesting to use a NADAC Plus model. In an appeal, PBMs do not have to show where the drug could be purchased for MAC price.

Patrick O’Connor, Deputy Commissioner of Policy, Department of Insurance, stated that Medicaid and MCOs’ appeals make up the majority of the appeals received. Since September, the anticipated number of appeals is in the thousands. The main issue of the appeals is the reimbursement from Medicaid MCOs or PBMs. To appeal a reimbursement, DOI has a form on its website that pharmacists can fill out and submit by prescription. The form requires specific information regarding the prescription, the National Drug Code (NDC), the pricing that was used, the date of fill, MCOs at issue, and the plan at issue. DOI is improving the communications between all groups involved to facilitate a process that works more efficiently.

In response to questions from Senator Carroll, Deputy Commissioner O’Connor stated that the pricing methodology that is used by PBMs in reimbursement is defined in KRS 304.17A-162. PBMs can disclose the sources of information used to create the MAC list. However, the methodology or how the PBMs use those sources when coming up with numbers on the MAC list is not disclosed, it is considered proprietary and confidential information. In determining the price for a drug, there could be multiple generics of the same drug, multiple manufacturers, purchased at different price levels on the date of fill. The pharmacist is going to use the cheapest generic that works with the plan MAC list.

In response to questions from Representative Benvenuti, Ms. Shrader stated that CVS Caremark does not have a direct contract with DMS but does have contracts with MCOs in Kentucky. Kentucky is an any-willing-provider state and contracts have to be built on market based principles. The MCOs have a MLR required by contract, at least 90 percent of every dollar must be paid out in claims. If the price to providers increases then DMS will have to increase the amount of dollars available.

In response to questions from Senator Meredith, Deputy Commissioner O’Connor stated that there are multiple MAC lists for each health benefit plan, for Medicaid, and for the MCOs.

**Presentation on Pharmacy Benefit Managers, Managed Care, and Legislative Oversight**

Rosmond J. Dolen, Kentucky Association of Health Plans, stated that the PBMs’ responsibilities include; processing pharmacy claims, developing drug formularies, operating programs to manage utilization, operating mail order systems, creating and managing pharmacy networks, managing the appeal process, negotiating and collecting supplemental rebates. In general, the United States does not regulate prescription drug prices. A statutory provision in the Medicaid program allows states to use many of the same prescription drug management tools available to insurers in the private sector. In a study from the Menges Group in April of 2015, found $2.06 billion net savings in state and federal expenditures in Federal Fiscal Year (FFY) 2014 for states whose Medicaid contracts included pharmacy benefits.

In response to questions from Senator Meredith, Ms. Dolen stated that she is not aware if the PBMs are required to meet a 90 percent MLR. The PBMs are held to an aggregate number. She is not aware who provides compliance accountability to PBMs. MCOs and insurers in the state are partners in providing access and quality of care to the Medicaid members. PSAOs contract on behalf of the independent pharmacies entering into agreements with PBMs.

In response to questions from Senator Carroll, Richard Ponesse, Senior Director of Trade and Finance, Industry Analytics, CVS Caremark, stated that the only requirement regarding the percentage of money received from MCOs to fill prescription benefits, is the open and free market. CVS Caremark is competing against other PBMs to win business. CVS Caremark agrees that it has the majority of the pharmacy business because it provides the lowest net cost to the plan sponsors who hire CVS Caremark. He does not know the total Medicaid profit margin in Kentucky. He is confident that if DMS eliminates PBMs it will increase pharmacy costs. On average, CVS Caremark reimburses large chains 20 to 25 percent less than independent pharmacies.

**Adjournment**

 There being no further business, the meeting was adjourned at 4:51 PM.