COLORADO DEPARTMENT OF HEALTH CARE POLICY & FINANCING

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John W. Hickenlooper, Governor • Susan E. Birch MBA, BSN, RN, Executive Director

November 9, 2011

The Honorable Cheri Gerou, Chair
Joint Budget Committee
200 East 14th Avenue, Third Floor
Denver, CO 80203

Dear Representative Gerou:

This report is in response to Legislative Request for Information 5 which states:

The Department is requested to submit a report by November 1, 2011 to the Joint Budget Committee regarding the Department's efforts to ensure that pharmaceuticals are purchased at the lowest possible price. In the report, the Department is requested to provide cost and savings estimates that may occur on a quarterly basis if the Department did the following:

- *(a) tracked changes in the price of pharmaceuticals;*
- *(b) checked the availability and price of generic drugs and compared those prices to the cost of brand drugs after rebate;*
- *(c) reviewed and updated the state's maximum allowable cost list; and*
- *(d) compared pharmaceutical costs of the state Medicaid program to available pharmacy price lists.*

Please note that the Joint Budget Committee requested that the Department submit a total of 11 different requests for information on November 1. These reports are in addition to the Department's FY 2012-13 Budget Request, which is also due on November 1. Due to the volume of information due concurrently, the Department has not been able to submit all reports simultaneously. The Department hopes to work with the Joint Budget Committee in future years to alleviate some of the issues caused by the concurrent deadlines.

If you require further information or have additional questions, please contact the Department's Budget and Finance Office Director, John Bartholomew, at john.bartholomew@state.co.us or 303-866-2854.

Sincerely,

Susan E. Birch, MBA, BSN, RN
Executive Director

Cc: Senator Mary Hodge, Vice-Chair, Joint Budget Committee
Senator Pat Steadman, Joint Budget Committee
Senator Kent Lambert, Joint Budget Committee
Representative Jon Becker, Joint Budget Committee
Representative Mark Ferrandino, Joint Budget Committee
Senator Brandon Shaffer, President of the Senate
Senator John Morse, Senate Majority Leader
Senator Bill Cadman, Senate Minority Leader
Representative Frank McNulty, Speaker of the House
Representative Amy Stephens, House Majority Leader
Representative Sal Pace, House Minority Leader
John Ziegler, Staff Director, JBC
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COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

REPORT TO THE JOINT BUDGET COMMITTEE

COST EFFECTIVE ACQUISITION OF PHARMACEUTICALS

NOVEMBER 1, 2011

The Department engages in multiple activities to ensure pharmaceuticals are purchased at the lowest possible price. The lowest possible price is considered the lowest price that can be paid without creating a barrier to access for clients. Of the additional activities suggested in the Joint Budget Committee's request for information, the Department anticipates that only the expansion of net-cost comparison between brand and generic drugs will generate additional savings. As system changes are necessary to obtain data to generate a savings estimate, a fiscal impact is not included in the Department's response.

The Department's methodology for pharmacy reimbursement is undergoing significant changes. The Department is engaged in a redesign of the pharmaceutical reimbursement methodology with the primary objective of realigning reimbursement with the actual ingredient costs and dispensing costs incurred by pharmacies. This change in methodology is anticipated to generate savings and is discussed in greater detail throughout the report. The Department's FY 2012-13 R-6: "Medicaid Budget Reductions" accounts for these savings.

Each strategy proposed by the Joint Budget Committee is addressed in the sections that follow.

Tracking Changes in the Price of Pharmaceuticals

The Department does not anticipate any additional costs or savings from enhancing its tracking of changes in the price of pharmaceuticals as this is already an integral part of the Department's pharmaceutical reimbursement methodology.

The Department retains a contractor which tracks changes in the price of pharmaceuticals on a weekly basis. The pricing information is used as an input in the pharmaceutical reimbursement methodology; each drug's price is adjusted to reflect weekly changes in ingredient cost. Weekly adjustments to drug pricing help ensure prices stay as closely aligned with provider costs as possible which, in turn, ensures pharmaceuticals are obtained in a cost-effective manner. In cases where the ingredient costs of drugs are decreasing, the weekly price adjustments result in reduced expenditure. In cases where the ingredient costs of drugs are increasing, the weekly price adjustments ensure the reimbursement rate is sufficient to prevent any access issues for clients. This is an important mechanism for containing costs in the Medicaid program. When a client does not have sufficient access to pharmaceuticals, the condition they are being treated for can exacerbate resulting in expenses incurred in other, more costly settings such as the emergency room or hospital.

As price fluctuations are already being tracked on a weekly basis and each drug's reimbursement adjusted accordingly, there is no further opportunity to achieve cost savings through the monitoring of drug pricing within the current reimbursement methodology.

Checking the Availability and Price of Generic Drugs and Comparing Those Prices to the Cost of Brand Drugs after Rebate

The Department believes there are additional savings to be achieved through expanding net-cost comparison analysis done on brand and generic drug pricing. In fact, this type of comparison is the basis for savings achieved through the Preferred Drug List (PDL) program, described in

detail below. While the Department does not yet have the ability to perform this type of analysis on a large scale, the Department is in the process of completing system changes which will allow this type of analysis. When this information is available, the Department intends to use the results to guide future policy to the extent possible.

The Department implemented the PDL program in 2008 as a mechanism to promote clinically appropriate utilization of pharmaceuticals in a cost effective manner. The process considers safety, effectiveness, clinical outcomes, and costs in an attempt to drive utilization to the most proven cost-effective agents in drug classes where multiple therapeutic options are available. The PDL drug classes are reviewed on an annual basis, with the various drug classes divided among four quarterly reviews. Following each Pharmacy and Therapeutics (P&T) Committee review of the medications, the Department's costs are modeled to compare net costs of the drug based on utilization from claims data, current product reimbursement, the current federally mandated unit rebate and available supplemental rebates offered. Within the clinical context recommended by the P&T Committee, preferred products are selected that will maximize benefit and value to Medicaid enrollees, while minimizing expenditure. This comparison is essential for all PDL associated savings and cost avoidance.

Although the Department is currently engaged in and expanding the scope of the comparison of product net-costs to ensure pharmaceuticals are acquired at the least cost, there are considerable limitations.

- Federal Financial Participation: Under the State Plan, the Department must provide coverage of all products that meet the definition of a "covered outpatient drug". Prior authorization of products is allowed under certain conditions, but access to branded products that meet this definition must be maintained.

- Product availability is unpredictable; numerous products are unavailable to hospitals and providers due to shortages and supply chain issues. Generic manufacturers are often unable to meet market demands with consistent supply. If policy decisions have been made to take advantage of a generic product's savings, and the manufacturer has supply chain issues, either potential savings is lost by covering a more costly alternative, or client therapy is interrupted.[1]

- Generic drugs are not always cheaper. The federally mandated rebate base percentage is much higher for branded drugs than generics. In addition, market exclusivity is often granted to one generic manufacturer for the first six months of generic availability. Until the market becomes competitive with multiple generic options, the generic option may be more costly to the program.

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[1] On October 31, 2011, President Obama issued an executive order aimed at addressing shortages in drug supplies. The order requires the Federal Drug Administration (FDA) to obtain advanced notice of potential shortages, requires the FDA to expedite regulatory reviews that can alleviate or mitigate a potential drug shortage, and requires the FDA to report irregular types of market behavior that may lead to drug shortages.

- Not all drugs have generic equivalents and not all drugs have therapeutic alternatives. The cost-effectiveness consideration is limited to situations where alternatives exist. Further, if clinical factors are not considered, costs may be shifted to other benefits (physician administered products, increases in medical visits, increases in utilization of emergency services, etc.).

Despite the challenges described above, the Department feels that there is significant utility in the expansion of net-cost comparison analysis of brand and generic drug prices. The fluctuation in drug prices, generic availability, and federal rebates necessitate seamless monitoring on a broader level.

Review and Updating of the State's Maximum Allowable Cost List

Due to recent changes in the reimbursement methodology for pharmaceuticals, there are no immediate costs or savings associated with the expansion of the State Maximum Allowable Cost (SMAC) list.

Historically, the Department utilized Average Wholesale Price (AWP), a pricing statistic provided by First DataBank, as the primary component of the reimbursement methodology for drug ingredient costs. Under the AWP based reimbursement methodology, the SMAC list was an effective mechanism for generating savings as it allowed for targeted price reductions on specific drugs. However, following a lawsuit, First DataBank ceased to publish AWP data. As a result, it became necessary to develop a new pharmaceutical pricing methodology.

The Department is in the process of developing a reimbursement methodology which reimburses pharmacies at a level that is commensurate with both ingredient costs and the costs of dispensing drugs. This methodology relies heavily on SMAC pricing (based on average acquisition cost, discussed further below). As the new reimbursement methodology utilizes a SMAC price for all drugs that SMAC pricing data is available, there is no opportunity for further expansion of the SMAC list to generate additional savings.

While expanding the SMAC list does not present further opportunity for savings, in bringing reimbursement to a level that more closely approximates actual costs incurred by pharmacies, the Department anticipates savings of $4,000,000 through the change in reimbursement methodology. These savings have been accounted for in the Department's FY 2012-13 R-6: "Medicaid Budget Reductions" request.

Comparing Pharmaceutical Costs of the State Medicaid Program to Available Pharmacy Price Lists

There are no immediate costs or savings associated with comparing Medicaid pharmaceutical reimbursement to other available drug pricing lists.

With First DataBank no longer publishing the Average Wholesale Price (AWP) list, it has been necessary for the Department to evaluate multiple pricing lists to determine the most appropriate replacement for the AWP based methodology. While the Department is utilizing State

Maximum Allowable Cost (SMAC) and Wholesale Acquisition Cost (WAC) pricing in the interim period, the Department is developing a new pharmaceutical reimbursement methodology based on the Average Acquisition Cost (AAC). The AAC reimbursement methodology is not based on national pricing benchmarks but instead the acquisition costs incurred for a drug by Colorado pharmacies. The pricing statistic will be obtained by the Department's contractor through a statewide survey of pharmacies costs done annually and funded using existing Department resources. On a weekly basis, the contractor will update the Department's AAC price list based on relative percentage changes in national acquisition cost data. The data will be representative of acquisition cost data from a wide range of wholesalers and manufacturers that state pharmacies utilize to purchase their inventories. The Department believes that a methodology based on AAC pricing will best align reimbursement with the ingredient costs and the cost of dispensing the drug for Colorado pharmacies. This effectively sets prices at the lowest possible level without risking barriers to access for clients. As a result, no additional costs or savings are expected from comparing Medicaid pharmaceutical reimbursement to other pharmacy price lists.