COLORADO
Department of Health Care Policy & Financing

December 1, 2014

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

Dear Senator Lambert:

Enclosed please find a legislative report to the Joint Budget Committee from the Department of Health Care Policy and Financing on the pharmacy utilization plan for FY 2014-15.

Section 25.5-5-506(3)(b), C.R.S. (2014) requires the Department to report to the Health and Human Services Committees for the House of Representatives and the Senate, or any successor committees, and the Joint Budget Committee no later than December 1, 2003, and each December 1 thereafter, on plan utilization mechanisms that have been implemented or that will be implemented by the state department, the time frames for implementation, the expected savings associated with each utilization mechanism, and any other information deemed appropriate by the health and human services committees, or any successor committees, or the Joint Budget Committee.

If you require further information or have additional questions, please contact the Department's Legislative Liaison, Zach Lynkiewicz, at Zach.Lynkiewicz@state.co.us or 720-854-9882.

Sincerely,

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

SEB/rml

Enclosure(s): Pharmacy Utilization Plan FY 2014-15

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COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

REPORT TO THE HOUSE PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEE, THE SENATE HEALTH AND HUMAN SERVICES COMMITTEE AND THE JOINT BUDGET COMMITTEE

ON

PHARMACY UTILIZATION PLAN FY 2014-15

DECEMBER 1, 2014

INTRODUCTION

The Pharmacy Utilization Plan FY 2013-14 is required by 25.5-5-506(3)(b), C.R.S. (2014) which states:

(b) The state department shall report to the Health and Human Services Committees for the House of Representatives and the Senate, or any successor committees, and the Joint Budget Committee no later than December 1, 2003, and each December 1 thereafter, on plan utilization mechanisms that have been implemented or that will be implemented by the state department, the time frames for implementation, the expected savings associated with each utilization mechanism, and any other information deemed appropriate by the health and human services committees, or any successor committees, or the Joint Budget Committee.

The Department of Health Care Policy and Financing (Department) continues to pursue reductions in pharmaceutical expenditures has implemented several utilization mechanisms to control costs while ensuring access to medications for clients who need them. These mechanisms include enforcing limits on certain drugs, placing prior authorization requirements on certain drugs, and selecting drug classes for the Preferred Drug List (PDL). The Department is also considering other utilization mechanisms to determine if they would result in cost avoidance.

The Drug Utilization Review (DUR) Board, established by the Department, reviews drug utilization issues and makes recommendations to the Department to ensure utilization of prescription drugs is clinically appropriate and cost effective. The Department evaluates the issues identified by the DUR Board and implements utilization policies that are appropriate and will achieve cost savings. In addition, the Department has contracted with the University of Colorado School of Pharmacy (SOP) to provide additional DUR analysis and make recommendations to the Department and the DUR Board. The scope of the SOP and the DUR program has been increasing over the past years and now the contract has been expanded to include more clinical reviews and assistance with prior authorization reviews. The SOP continues to provide high quality utilization and clinical recommendations to guide policy decisions. This expansion is allowing the DUR program and the Department to address medications more proactively with clinical criteria. This is becoming more evident in both the prior authorization criteria and the PDL.

As an example, the DUR program in FY 2013-14 has provided in-depth analysis in the following areas:

- **Opioid Utilization**

  The Department wanted to evaluate opioid utilization in the Medicaid population and determine if additional policy changes were needed to ensure appropriate utilization. The long-acting opioids were on the PDL but the short-acting opioids were not subject to criteria. The DUR program evaluation was conducted at three levels of analysis: the prescription level, the patient level, and the provider level. Overall, the initial evaluation suggested that many beneficiaries were using more short-acting than long-acting opioid medications primarily for two or more pain conditions, the most common being chronic bodily pain. Additionally, over 2,000

beneficiaries were receiving an average daily morphine equivalent dose in excess of 100 mg per day for the opioid prescriptions filled within a one-year period.

- **Opioid Utilization Correlating to Overdose Risk**
    - This analysis provided a method to identify high-utilizers of opioid medications and potential policy recommendations for the Department. Using definitions used by other state Medicaid Departments as well as those published in the literature, the DUR program evaluated the risk of opioid overdose taking into account the following variables: morphine equivalents, number of prescribers, number of pharmacies, days' supply, and overlap in prescriptions. The analysis was limited to morphine equivalents, number of pharmacies used, and days' supply to help identify possible criteria for the Department. Based on these three variables, the risk of overdose from opioids is over 10-fold for people who have morphine equivalent doses greater than 100mg, who use more than three pharmacies, and have more than 300 days' supply of opiates.
    - As a result of the findings, the Department implemented quantity limits on short-acting opioids. Implementation of this policy is described in more detail under, "PLAN UTILIZATION MECHANISMS TO BE IMPLEMENTED IN FY 2014-15"
- **Physician Administered Drugs**
    - This analysis looked at physician administered drugs by utilization, cost and potential interventions with a focus on Botox (onabotunilinumtoxin A). The DUR Contractor's preliminary cost avoidance analysis indicated that implementation of evidence-based prior authorizations for onabotulinumtoxin A could result in up to $1,000,000 of annual cost-avoidance based on current trends.
    - The Department has not historically put criteria on physician administered drugs. These are billed through the MMIS and the processes are different from pharmacy claims. The Department is working with the Department's utilization management vendor to implement this criteria and is working on a strategy for stakeholder input. The Department envisions the prior authorization to be in place early in the calendar year 2015.

Regarding the cost avoidance analysis contained within this Report, the Department analyzes the fiscal impact of the utilization control mechanisms by examining expenditure trends at the therapeutic class level. This captures substitution effects *within* drug classes, but does not always capture substitution effects *between* drug classes. The cost avoidance from the implementation of a prior authorization on specified drugs in a drug class may cause clients to shift to a substitute drug from a different therapeutic class instead of another drug in the same therapeutic class. The increase in the utilization for drugs in other therapeutic classes is not always measurable. This is seen with drug products having multiple approved uses, or in the instance of drugs which are prescribed off-label (for indications which are not approved by the Food and Drug Administration).

The Department's more proactive approach to the PDL and prior authorization criteria is changing the way fiscal impact is measured. The traditional method is to use historical utilization trends to extrapolate the continued medication use without criteria, and then compare to the actual use with

criteria in place. When criteria are added to drugs as they are coming to the market, there is no previous utilization to assess utilization or financial impact. The DUR program tries to target high cost drugs to ensure that utilization is appropriate upon entering the marketplace. The Department believes that having clinical criteria on high-cost drugs as they come to market results in more appropriate utilization, which also results in cost avoidance. Unfortunately, the Department does not have a reliable method by which to measure the full financial impact when we have no data to infer what the utilization would have been without the criteria in place.

During FY 2013-14 Colorado Medicaid underwent a significant expansion. In order to account for the growth in expenditures due to the addition of the expansion population, The Department calculated the average monthly total pharmacy expenditures 6 months prior to the expansion (July 2013 through December 2013) and 6 months after the expansion (January 2014 through June 2014).

The Department then used the percent difference between these two averages (approximately 40% increase) to do a one-time adjustment to the expenditures in the analysis to account for the expansion population.

The savings and cost avoidance identified in this report that reduced FY 2013-14 expenditures are already reflected in the Department's forecasts and per capita trends for Medical Services Premiums.

PLAN UTILIZATION MECHANISMS PREVIOUSLY IMPLEMENTED

In the sections that follow, the Department describes its estimates of the fiscal impact of utilization control mechanisms implemented in or prior to FY 2013-14. It is important to recognize that market factors the Department cannot account for in its analysis likely influence the fiscal impact achieved by the implementation of utilization control mechanisms. Factors may include the introduction of new drugs in the drug class, withdrawal of drugs from the market, new drugs in different drug classes that treat the same condition, or new studies regarding the effectiveness of the drug. This is particularly true for prior authorizations that were implemented more than a year ago. The Department does not believe it is possible to accurately predict the potential cost avoidance after a prior authorization has been implemented for more than a year.

Preferred Drug List

Governor Ritter signed Executive Order D 004 07 in January 2007, establishing a preferred drug list (PDL) program for Colorado Medicaid. The purpose of this program is to provide clinically appropriate medications to Medicaid clients while decreasing expenditures on pharmaceuticals. This involves selecting drugs based on safety, cost-effectiveness and clinical outcomes from classes of medications where there are multiple drug alternatives available. Since implementation of the PDL, the majority of the Department's Pharmacy Utilization Plan has switched from individual drug prior authorization mechanisms to implementing drug classes on the PDL.

The PDL achieves savings by designating preferred drugs for which migration to a more cost-effective drug and/or collection of supplemental rebates from pharmaceutical manufacturers is possible. Supplemental rebates are rebates above the federally required minimum rebate level,

which manufacturers offer to the Department in exchange for preferred status on the PDL. It is difficult to determine the exact amount of savings from the PDL that comes from supplemental rebates versus migration to preferred drugs for each drug class; however, the Department is able to provide aggregate level information. For FY 2013-14, the Department collected $8,354,188.02 in total supplemental rebates.

In some cases, the analysis indicates that supplemental rebates do not always offset the increased utilization and price of the preferred drug. The analysis does capture utilization shifts to other drugs, including higher cost newly FDA approved agents within the same drug class. It is important to note that the PDL is not a formulary. Any drug that meets the Federal requirements for a covered outpatient drug must have coverage available, and this coverage is included in the analysis.

Generic utilization is often viewed as a cheaper alternative to branded products. This is not always the case, especially in the first year of entrance to the marketplace. There are a few factors that can make the brand less expensive than the generic. Pursuant to federal law, the Department receives rebates for drugs covered, the federally required minimum rebate. The branded product can have a substantial federally-mandated rebate which makes the net cost significantly lower than any generic equivalent. Another factor that helps set price of generic drugs is the number of companies that are producing the drug. When more companies are producing the product, the price will be driven down quicker. The Department does try to forecast the financial impact of generics being introduced to the market, but it is difficult to predict. In some cases, shifting to generic utilization by way of the PDL will actually cause expenditures to rise.

PDL Classes Updated in FY 2013-14

With the maturity of the PDL, many classes have stabilized, thus limiting their capacity for additional savings. The Department generally adds new drug classes to the PDL on a quarterly basis. Existing drug classes are re-evaluated annually thereafter. For the purpose of this report, PDL reporting will be limited to those classes which have been added or changed significantly within the past two years, offering opportunity for cost avoidance.

Antiplatelet Agents – This class was originally implemented January 1, 2012. The estimated cost avoidance for FY 2013-14 totals $67,561. During this time period the drug Plavix became generic and this accounts for the cost avoidance.

Pancreatic Enzymes – This class was originally implemented January 1, 2013. The estimated cost avoidance for FY 2013-14 totals $31,942.

Protease Inhibitors for Hepatitis C – This class was originally implemented October 1, 2012. Due to new agents entering the market, during FY 2013-14 the therapeutic class was renamed *Hepatitis C Virus Treatments* and two agents were added: Olysio® (protease inhibitor) and Sovaldi (polymerase inhibitor). The estimated cost avoidance for the protease inhibitors for FY 2013-14 totals $318,262. The vast majority of the cost avoidance occurred prior to December 2013 when there were only protease inhibitors on the market. The use of these medications decreased as

prescribers anticipated the newer agents coming to market and almost completely stopped after the new agent, Sovaldi® (sofosbuvir), was released. This is explained in detail under the "prior authorizations" section below.

Oral Fluoroquinolones – This class was originally implemented January 1, 2014. The estimated cost avoidance for FY 2013-14 totals $3,452. This savings estimate is low due to generic utilization dominated before PDL addition, and this continues still. Adding this class to the PDL primarily encourages prescribers to use the existing more cost-effective products first before trying the more expensive alternatives.

Oral Antiherpetic Agents – This class was originally implemented January 1, 2014. The estimated cost avoidance for FY 2013-14 totals $61,765.

Insulins – This class was originally implemented April 1, 2014. The estimated cost avoidance for FY 2013-14 totals $701,796.

The overall PDL cost avoidance for FY 2013-14 is $1,184,778.

Prior Authorizations (PA) Implemented

Synagis® (palivizumab) – The prior authorization criteria for Synagis® have remained largely the same dating back to 2009-2010. Past estimates of cost savings have been based upon projected utilization increases found prior to the implementation of the current criteria. The estimated cost avoidance reported below is based on the criteria in place for the 2013-14 season, which spanned from 11/18/2013 until 3/31/2014. There is no estimated projection for the upcoming fiscal year due to the fact that the clinical criteria will be changing significantly. The American Academy of Pediatrics published their updated recommendations for the use of palivizumab against respiratory syncytial virus (RSV) on July 28, 2014. These newer guidelines state that palivizumab given in a series of doses during the RSV season, has a limited effect on reducing RSV hospitalizations. As a result, fewer patients will need palivizumab and the season for use will be shortened as well. The new criteria implemented by the Department will follow these recommendations and will be reported in next year's report.

FY 2013-14 estimated cost avoidance for Synagis®: $517,884

Cymbalta® (duloxetine) – This drug is on the PDL under antidepressants and fibromyalgia agents. This drug has prior authorization criteria in both locations. The fibromyalgia criteria was initially implemented July 2012, and the antidepressant criteria was amended January 2013. We can still attribute cost avoidance due to the volume of requests for Cymbalta that are evaluated each year.

FY 2013-14 estimated cost avoidance for Cymbalta: $1,348,795

Elidel (pimecrolimus) – This drug was moved to non-preferred status on the PDL beginning July 1, 2013. As a part of this move, the Department added prior authorization criteria that only allows usage after an adequate trial of a topical steroid, which is appropriate step-therapy and significantly less expensive.

FY 2013-14 estimated cost avoidance for Elidel: $397,825

Oral anticoagulants (warfarin, Xarelto, Pradaxa and Eliquis) – Beginning October 1, 2013, these agents were added to the PDL. Utilization was mostly with generic warfarin previously, and so adding this class to the PDL allowed the Department to encourage use of generic warfarin when clinically appropriate and save the newer brand name medications for cases of medical necessity.

FY 2013-14 estimated cost avoidance for Oral Anticoagulants: $171,844

Proton Pump Inhibitors (PPI) – In 2012, the DUR contractor identified substantial overutilization of proton pump inhibitors by Medicaid members. These drugs are only indicated to be taken for periods longer than 60 days for certain select populations. The criteria implemented in October 1, 2012 followed the standard of practice by requiring step down therapy for anyone taking a PPI for 60 days without one of the exception criteria. The criteria resulted in decreased use of PPIs and increased use of histamine 2 receptor antagonists, which is in line with appropriate therapy guidelines.

FY 2013-14 estimated cost avoidance for PPIs: $6,813,254

Treatments for Hepatitis C

Sovaldi® (sofosbuvir): As mentioned above, the protease inhibitors were on the PDL prior to the release of Sovaldi in December of 2013. The class was not due to be reviewed again until July and August of 2014. The Department's handling of Sovaldi during FY-2013-14 is explained below.

The expenditure during FY 2013-14 for Sovaldi® was $5,130,897. The criteria for this drug was changed on several occasions so the Department decided to also report the costs based on the approvals and denials during each time period. The costs reported below are based on actual approvals and denials of prior authorization requests. The approval costs are reported from all claims associated with patients who were approved during the corresponding time period including in some cases claims that were paid in FY 2014-15. Cost avoidance is reported based on what the cost would have been if approved.

December 14, 2013, Sovaldi® became FDA approved. The Department approved PA requests based on indications on the Sovaldi® label through January 31, 2014. This resulted in a 92.7% approval rating for this time period.

12/14/2013-1/31/2014

Cost of Approvals: $4,144,000

Cost Avoidance: $252,000

The Department calculated that Colorado's Medicaid program currently has over 5,100 clients with a known diagnosis of Hepatitis C. Using a cost of Sovaldi® alone of approximately $84,000 up to $168,000 per treatment (depending on the number of weeks of treatment), covering Sovaldi® for just these clients could almost triple the state's annual expenses on pharmaceuticals to approximately $1.2 billion. This number does not take into account existing Medicaid clients that have undiagnosed Hepatitis C infections. The latest estimate using epidemiological statistics published by the U.S. Preventative Services Task Force finds there may be as many as 9,343 clients with Hepatitis C currently enrolled in Colorado's Medicaid program. Based on those numbers, Colorado could spend as much as $1.8 billion on Hepatitis C related treatments.

February 1, 2014, the Department refined the criteria for PA approval for Sovaldi®. The Department determined criteria needed to changed based on an in depth analysis of the evidence by the Center for Evidence Based Policy (located at Oregon Health Sciences University), other sources of evidence including the California Technology Assessment Forum, and cost. The Department's DUR board needed to make recommendations on criteria per Department policy. Until that could occur, only medically necessary cases would be approved. These approvals were determined by a State pharmacist and the Chief Medical Officer. This criteria was in effect from February 1, 2014 – May 31, 2014. This resulted in an approval rate of 27.7% during this time period.

2/1/2014-5/31/2014

Cost of Approvals: $2,912,000

Cost Avoidance: $8,400,000

Although the class was not due to be reviewed until August, because of interest in Sovaldi and the need for prior authorization criteria, the Department asked the DUR Board to recommend interim criteria at their May meeting. The DUR Board reviewed clinical studies and the evidence review that had been published by the Center for Evidence Based Policy. Based on the DUR Board's recommendations and review of the evidence, the Department further refined the criteria for PA approval for Sovaldi®. This criteria was in effect from June 1, 2014 – September 30, 2014. This resulted in a 50% approval rate from 6/1/2014 through 6/30/2014.

6/1/2014-6/30/2014

Cost of Approvals: $476,000

Cost Avoidance: $672,000

The Department believes this infectious disease is a public health concern. Because of the potential devastation of Hepatitis C, treatment for people with Hepatitis C is important and we have targeted those at highest risk of developing complications. The Department is responsible for providing health care for our members while at the same time being fiscally responsible to the taxpayers of the State of Colorado. With respect to the prevalence of Hepatitis C and the high cost of treatment, balancing these two charges has become very challenging.

We need to be stewards of our limited state resources. Hepatitis C is a slow moving disease and only a small number of people who contract Hepatitis C progress to liver failure and death. The Department's solution is to treat the members that have the most advanced disease and are likely to respond to treatment, and those with an anticipated liver transplant in order to avoid an infection of the transplanted liver. Due to the slow progressing nature of the Hepatitis C virus this delay in treatment is acceptable.

Other Prior Authorizations Implemented

During FY 2013-14 there were also prior authorization criteria set for the following medications:

- Invokana – new diabetic agent
- Farxiga – new diabetic agent
- Kineret – rheumatoid arthritis agent
- Ravicti – urea cycle disorder agent
- Tecfidera – multiple sclerosis agent
- Zubsolv – opioid dependence agent
- Procysbi – nephropathic cystinosis agent
- Diclegis – agent for nausea and vomiting
- Epaned – antihypertensive agent
- Dificid – antidiarrheal agent
- Kynamro – hypercholesterolemia agent

Our cost analysis was unable to show any cost avoidance due to the extremely low utilization of these medications. With the exception of Tecfidera®, the prior authorization criteria for each medication was implemented at the time of market release of these expensive drugs, and so there is insufficient data to track utilization trends or cost avoidance. The Department believes that placing prior authorization criteria on these medications as they enter the market promotes proper utilization of these drugs and results in cost-avoidance by preventing any inappropriate use.

PLAN UTILIZATION MECHANISMS TO BE IMPLEMENTED IN FY 2014-15

The Department's focus will continue to be split between adding/managing PDL classes, educating providers regarding updates and monitoring plan utilization while implementing criteria to support safe, appropriate and cost effective use of drug products.

The Department's DUR contractor continues to provide high quality drug utilization review services. The clinically trained pharmacists who provide services under this contract offer clinical perspective and opportunities to ensure efficient utilization of the pharmacy benefit. The contract has been expanded for FY 2014-15 to allow for additional clinical reviews and assistance with prior authorization reviews and other related activities. As a part of that expansion, the team plans to implement active learning applications to better inform Colorado Medicaid providers.

The Department, in conjunction with the DUR contractor, is currently working to secure a child psychiatrist and a pain specialist to assist in matters concerning their areas of expertise. This will help the Department to better understand the complex cases often reviewed for prior authorization. It will also help to have insight into those areas in which the Department often is crafting policy or working to educate providers. This expansion will be reported in more detail in the FY 2015-16 report.

July 1, 2014:

- Testosterone products were added to the PDL.
- Prior authorization criteria was placed on midazolam nasal inhalation spray for patients with epilepsy.

At the time of this report, the estimated cost avoidance for these drugs is not available. These figures will be reported in the FY 2015-2016 report.

August 2014:

- On August 1, 2014, dosing limits were placed on short acting opioid products. The limit is a quantity of 4 units per day. Exceptions for this limit exist for acute pain scenarios, terminal illness and sickle cell anemia. At this time, there is no estimated cost avoidance for this limit introduction, as the aim of this policy change was to improve patient safety and not cost avoidance. However, the Department believes there will be cost avoidance because this policy will limit inappropriate utilization. This policy is in line with the State's mission to reduce overuse and abuse of opioids.
    - The Department is also considering criteria recommendations from the DUR program regarding naloxone and Suboxone® (buprenorphine/naloxone). As the state is currently addressing the issues surrounding opiate overdose and death, the Department asked for an in-depth analysis addressing the usage of naloxone and buprenorphine/naloxone agents in Medicaid clients.

October 2014

- Effective October 1, 2014, there were changes to the following PDL classes:
    - Oral anticoagulants
    - Thiazolidinediones
    - Newer Diabetic Agents
    - Hepatitis C Agents

  At the time of this report, the estimated cost avoidance for these classes is not available. This figure will be reported in the FY 2015-2016.

Hepatitis C Treatments:

- The landscape of Hepatitis C treatment has drastically changed since December 2013. One additional Hepatitis C treatment was recently approved by the FDA and another new agent

approval is anticipated before the end of 2014. There are a handful of Hepatitis C treatments in the pipeline and anticipated to be approved in 2015. Therefore, due to the anticipated changes, it is not possible to estimate cost savings/avoidance for the Hepatitis C Treatments for FY 2014-15.

CONCLUSION

The Department has implemented a number of drug utilization mechanisms to control costs such as adding classes to the PDL and requiring prior authorizations for drugs. In most sections of this report, the Department identifies the utilization mechanisms that have been implemented to generate cost avoidances to a specific prescription drug class, rather than attempting to identify a savings to the overall Department's pharmaceutical budget. Some mechanisms to control costs involve certain restrictions on drugs while others involve obtaining supplemental rebates from manufacturers for individual drugs.

A summary of the estimated avoided costs is listed below. Please note that cost avoidance has been reported for relevant classes that have been recently implemented or updated. Drug classes without significant change still contribute to overall cost avoidance because of the Supplemental Rebate contracting process as is shown below. The methodology for calculating the associated savings is continuing to change, and this has made it more difficult to calculate the projected cost avoidance for the future; therefore, the tables do not show estimated PDL cost avoidance for FY 2014-15.

Total Supplemental Rebates Collected (actual rebate collected during FY 2013-14 for all PDL classes)	**$**8,354,188

Summary of Savings Achieved Through Utilization Control Mechanism	**FY 2013-14**
Preferred Drug List Updates	$1,184,778
Prior Authorization Policy	$9,249,602
Total	**$10,434,380**

Preferred Drug List Savings by Drug Class	**FY 2013-14**
Antiplatelets	$67,561
Pancreatic Enzymes	$31,942
Fluoroquinolones	$3,452
Antiherpetic Agents	$61,765
Protease Inhibitors for Hep C	$318,262

Insulins	$701,796
Total Preferred Drug List Update Savings	**$1,184,778**

Prior Authorization Policy Savings by Drug Class	**FY 2013-14**
Synagis	$517,884
Cymbalta	$1,348,795
Elidel	$397,825
Oral Anticoagulants	$171,844
Proton Pump Inhibitors	$6,813,254
Total Prior Authorization Savings	**$9,249,602**