Report to the Social Services Appropriations Subcommittee

Recommendation Regarding Implementation of a Medicaid Statewide Preferred Drug List

Prepared by the Division of Medicaid and Health Financing

January 18, 2021

UTAH DEPARTMENT OF HEALTH

EXECUTIVE SUMMARY

In May 2020, the Office of the Legislative Auditor General released a Performance Audit of Medicaid's Pharmacy Benefit Oversight. One of the recommendations in this report stated,

> "We recommend the Department of Health research and provide a report to the Social Services Appropriations Subcommittee and any other pertinent legislative committees regarding the potential savings, benefits, and costs from creating a statewide preferred drug list."

In addition, the following intent language passed in **H.B. 6002 Supplemental Budget Balancing and Coronavirus Relief Appropriation** by the 2020 Sixth Special Session of the Utah Legislature:

> *"Notwithstanding the intent language in Item 144 of Chapter 8 of Laws of Utah 2020 Fifth Special Session, The Legislature intends that the Department of Health start a statewide preferred drug list in Medicaid beginning no sooner than July 1, 2021."*

Recommendation

Based on the study conducted by the Department, the Department recommends not moving to a Statewide Preferred Drug List (PDL) effective July 1, 2021.

In addition, the Department recommends permanent restoration of the ongoing funding reduction that was taken and then restored one time for SFY 2021.

Moving to a Unified or Statewide PDL is a complicated undertaking. The State would likely experience direct cost reductions from increased drug rebates. However, these cost reductions would likely be offset by rate increases for Accountable Care Organizations (ACOs) that would be needed because the Statewide PDL would require ACOs to pay for more costly brand name drugs rather than generics. Because a Statewide PDL would likely increase ACO pharmacy costs, the State would need to increase appropriations for the ACOs to maintain actuarially sound rates for the ACOs. In order to obtain federal match for Medicaid costs, the State's rates must be approved by the Centers for Medicare and Medicaid Services (CMS). CMS will not approve rates that cannot

be certified as actuarially sound. Rates that are insufficient and not approved by CMS place the ACO model in jeopardy. In addition, the State and ACOs will incur additional one time and ongoing administrative costs for the implementation and maintenance of a Statewide PDL. These administrative costs would further offset savings.

The study found the following potential cost savings/reductions:

IMPACT OF STATEWIDE PDL IMPLEMENTATION[1]

	Low Estimate (in millions)		**Midpoint Estimate (in millions)**		**High Estimate (in millions)**	
	Total Funds	General Fund	Total Funds	General Fund	Total Funds	General Fund
Reduced Costs from Increased Rebates	$6.0	$1.4	$6.2	$1.4	$6.4	$1.5
Increased Costs from Increased ACO Rates	$5.9	$1.4	$8.1	$1.9	$10.3	$2.4
Net Additional General Fund Costs (or Savings)		$0.0		$0.5		$0.9

Based on this information and the budget cuts taken by the legislature, the Department will need to seek a restoration of the ongoing budget cut that was taken.

[1] Other implementation and on-going administrative costs are noted in this report but this table only reflects information provided the State by external experts.

Background

In accordance with Senate Bill 180 passed during the 2011 General Session of the Utah Legislature, Utah created ACOs to administer Medicaid health benefits to Medicaid members along the Wasatch front. As part of this initiative, a conscious decision, supported by the language in SB 180, was made to have the ACOs also administer the pharmacy benefit for their enrollees with some exceptions. Psychotropic and immunosuppressive drugs and some other drugs remained carved out from the ACO benefits.

The intent was to align incentives for prescribers and the health plans to minimize pharmacy expenditures. Including the pharmacy benefit as an at-risk component of the contracts was one of the major strategic accomplishments of the ACO model. From the beginning, ACOs created their own preferred drug lists. ACOs are required to cover all of the same drug classes as Medicaid Fee for Service (FFS); however, ACOs are allowed to choose the drugs based on their own clinical review and their ability to negotiate drug prices. The State Medicaid agency collects all primary rebates on FFS and ACO drugs. However, ACOs are allowed to retain any negotiated discounts for the drugs they cover on their PDLs. It should also be noted that this was factored into the initial ACO rates of 2013, meaning the ACO rates were reduced to account for the secondary rebates the state Medicaid agency had already been receiving for drugs being included in the ACO contracts.

In May 2020, the Office of the Legislative Auditor General released a Performance Audit of Medicaid's Pharmacy Benefit Oversight. One of the recommendations in this report stated,

> *"We recommend the Department of Health research and provide a report to the Social Services Appropriations Subcommittee and any other pertinent legislative committees regarding the potential savings, benefits, and costs from creating a statewide preferred drug list."*

The Department concurred with this recommendation and committed to submit a report to the Social Services Appropriations Subcommittee by July 1, 2021.

During the 2020 Fifth Special Session in June 2020, the Social Services Appropriations Subcommittee prioritized several budget reductions due to the impact the COVID-19 pandemic was having on the State's economy. One of those budget reductions was to implement the auditor's recommendation above, even though the Department had not conducted its study of the impacts of the recommendation. However, the Department had not had time to complete the study recommended by the auditors nor was it operationally feasible to implement this change in such a short period of time. Despite

these concerns, the recommendations were passed by the Social Services Appropriations Subcommittee and included in **Senate Bill 5001, Budget Balancing and Coronavirus Relief Appropriations Adjustments.**

After the Fifth Special Session, the Department and the ACOs expressed their concerns to the subcommittee chairs regarding this cut. During the Sixth Special Session, funding that was cut from Medicaid's budget based on the assumption that a Statewide PDL would be implemented October 1, 2020, was restored one time for SFY 2020 until a study could be completed and a recommendation could be made to the subcommittee. (**H.B. 6002 Supplemental Budget Balancing and Coronavirus Relief Appropriation**)

This report represents the efforts of the Department, in collaboration with the ACOs, to determine whether or not Utah Medicaid should move to a Statewide PDL. This study did not require additional funding and was carried out by existing Department staff and currently contracted consultants and actuaries.

Study Methodology

Many States are contemplating how to better manage their pharmacy benefit across their FFS and managed care delivery systems. A single or Statewide PDL may improve continuity of care as Medicaid members move from FFS to managed care or across managed care plans. A Statewide PDL can reduce confusion and administrative complexities for physicians and Medicaid members. In addition, a Statewide PDL has the potential to maximize federal and supplemental rebates paid to the State. On the other hand, a transition to a Statewide PDL results in increased costs for managed care plans because they may lose contracted discounts they negotiated with manufacturers and they no longer have as great of control over the drugs they are responsible to cover such as maximizing the use of generics over brand name drugs. The higher rebates the State receives come at the expense of the managed care plans having to forgo using generic drugs in some cases and using brand name drugs instead. Therefore, States must consider how managed care capitation rates need to be adjusted to account for the increase in costs for the managed care plans in order to assure rates continue to be actuarially sound in accordance with CMS managed care regulations.

In an attempt to estimate potential cost reductions, the Department engaged Steve Liles, Pharm D., Senior Director, Industry Relations, Change Healthcare Pharmacy Benefit Solutions. Mr. Liles is also the manager for the Sovereign States Drug Consortium (SSDC) which is an organization of 13 States, including Utah, that have agreed to collectively solicit and evaluate offers from manufacturers for State

supplemental and durable medical equipment (DME) rebates. Mr. Liles conducted similar studies for other States to determine the potential overall increase in rebates and increases in managed care costs by moving to a Statewide PDL. The study found that there is already a relatively high alignment in Utah between the Medicaid PDL and those used by the ACOs.

In addition, the Department engaged Milliman, Inc. to conduct an analysis of potential increases to ACO costs using the information provided by Mr. Liles using SFY 2020 data. Milliman applied this analysis to the SFY 2021 ACO rate certification to estimate the impact a Statewide PDL would have on current ACO capitation rates.

Mr. Liles estimated potential reduced costs of $6.2 million in total funds ($1.4 million in General Fund). These savings are based on estimates of how quickly and completely prescribers will adhere to the new PDL. Based on the analysis provided by Mr. Liles, Milliman estimated that if the ACO capitation rates are to remain actuarially sound and approvable by CMS, the State would need to add $8.1 million in total funds ($1.9 million in General Fund) to the ACO budget pool to keep ACO rates actuarially sound and certifiable. If rates are not actuarially sound, CMS will not approve the rates and federal match will not be available to cover ACO capitation payments. The estimates of $6.2 and $8.1 million are the midpoints of the ranges provided by Mr. Liles and Milliman.

General Fund Impact

Using the main drug classes that impact total savings, the ACO pharmacy expenditures between the traditional Medicaid population and the Expansion population from January through June 2020 were analyzed to come up with the allocation for each class. With that analysis, the percentages were weighted to Mr. Liles' projected savings in those classes to come up with the overall allocation which is as follows:

- Expansion Medicaid Population - 30.2%
- Traditional Medicaid Populations - 69.8%

Increase in Administrative Costs for the State and ACOs

In addition to the increase in costs to the ACOs by reducing their negotiated discounts with drug manufacturers and by requiring ACOs to cover more brand name rather than generic drugs, both the State and ACOs will incur additional administrative costs to operate a Statewide PDL.

State Administrative Costs

The Department will require one additional pharmacist and one additional registered nurse to process an increase in fee for service prior authorizations. The estimated ongoing cost in salary and benefit of these positions is **$243,000** in total funds (**$60,750 in General Fund**).

ACO Administrative Costs

Implementation of a Statewide PDL by the State will require additional personnel for the State and the ACOs due to the additional supervision required to manage the maintenance of a Statewide PDL and effectively coordinate activities. Implementation will require a large increase in communication with the pharmacy teams of the State and each ACO. It is estimated the existing staff will not have the capacity to continue current responsibilities and add the additional responsibilities to effectively coordinate and manage a Statewide PDL.

Administrative Expenses

- PDL:
  - Implementation Costs:
    - Pharmacy Benefit Manager (PBM) file implementation
    - Coding changes to unify the PDL by the PBM
    - Prior Authorization and Step Therapy alignment
  - Maintenance:
    - PBM file maintenance
    - Uniform utilization management criteria coordination with ACOs
    - Therapeutic category reviews to update and verify accuracy of criteria
- Communication:
  - Prescriber notification (e.g., letters)
    - Initial cost to transition existing patients
    - Ongoing costs for coverage changes
  - Member notification (e.g., letters)
    - Initial cost to transition existing patients
    - Ongoing costs for coverage changes
  - Increase in communication from prescribers/members (i.e., phone calls)
  - Increase in clinical review
    - Increase in prior authorization requests from prescribers (aligning criteria will likely require the State to add FFS prior authorization requirements to medications such as cancer treatments)
    - Increase in appeals from denials
  - Enhanced and ongoing coordination with ACOs
    - Regular review of existing criteria (e.g., new indications)
    - Review of new criteria (e.g., new medications or updates to add criteria to existing medication)

- Rebate/Discount Analysis:
  - Ongoing analysis of utilization data
  - Reconciliation of rebates collected verifying accuracy
  - State communication/coordination with manufacturers
  - ACO communication/coordination with manufacturers for discount potential

- Oversight:
  - State required review/reporting
  - ACO required review/reporting

One ACO estimates a one-time cost to update its claims system at **$110,000**. In addition, this same ACO has determined the need for four additional staff at estimated costs of **$250,000** per year. ACOs are expected to cover administrative costs using the portion of their capitation rates that is attributed to administration; however, this change would represent an increase in actual costs for the ACOs.

Pharmacy Director Workgroup

In addition to the financial analysis, the pharmacy directors from the State and each of the four ACOs met to discuss operational issues with regards to the establishment and maintenance of a Statewide PDL.

Pharmacy Director Workgroup: Cody Ball, Select Health, Shea Wilson, Molina Healthcare, Heidi Goodrich, Molina Healthcare, Leslie Rodriguez, Steward, Eric Hammond, Steward, Laura Britton, Healthy U, Dean Weedon, Utah Medicaid, Jennifer Strohecker, Utah Medicaid.

The purpose of this analysis by the Pharmacy Directors for Utah Medicaid and the four ACOs was to evaluate the impact of an aligned, Statewide PDL on the five pharmacy programs, prescribers, pharmacies, and Medicaid members. To accomplish this goal, the Pharmacy Directors from the FFS Medicaid Pharmacy Program, Select Health, Healthy U, Steward Health Choice, and Molina Healthcare (hereby referred to as “Pharmacy Director Workgroup” or “Workgroup”) met between October 26 and November 3 to identify areas of impact, share current processes, and explore/propose an approach for successful Statewide PDL implementation and management. In addition, all stakeholders expressed an interest in having active involvement in the development and management of a Statewide PDL if this is approved.

The Pharmacy Director Workgroup established the following baseline understanding of a Statewide PDL and its operational parts.

Statewide PDL Assumptions

- A Statewide PDL would assume 100% alignment of medications categorized as "preferred" or "non-preferred" on the Utah Medicaid FFS PDL.
- Medications included on the Statewide PDL will have aligned utilization management (UM) edits including, but not limited to:
    - Prior Authorization status
    - Prior Authorization criteria
    - Quantity limits
    - Step edits
    - Age edits
    - Brand to generic edits
    - 3-month supply edits
    - MME edits, or other drug specific edits as defined
- The Utah Medicaid FFS Pharmacy & Therapeutics (P&T) Committee will continue to meet at least quarterly to evaluate new drug classes for inclusion on the PDL or to review existing PDL drug classes. The P&T Committee may also be consulted on significant "negative PDL changes" to determine member impact of PDL preferred/non-preferred status and determine recommendations of grandfathering, when appropriate.
    - For Statewide PDL implementation: One representative from each ACO pharmacy program will participate as a P&T member with voting rights on P&T recommendations
- The Utah Medicaid Drug Utilization Review (DUR) Board will meet regularly at least ten times per year to evaluate clinical drug criteria, drug utilization trends, and make recommendations on drug use evaluation and prior authorization criteria.
    - For Statewide PDL implementation: One representative from each ACO pharmacy program will participate as a DUR Board member with voting rights on DUR recommendations. Additionally, it is recognized that at the onset, the five pharmacy programs may have prior authorization requirements on different drugs or drug classes. In establishing a Statewide PDL, the five plans will coordinate prior authorization requirements with consideration of impact for each plan.

Statewide PDL Exclusions

- Medications not listed on the PDL are not considered part of the Statewide PDL and may have coverage as defined by the individual ACO/FFS pharmacy program.
    - This includes both drugs and drug classes open through the point of sale system and drugs billed through the medical benefit (buy and bill or physician administered drugs).
    - Some medically managed drugs, or "J-code" drugs, billed with HCPCS codes may occasionally be listed on the Statewide PDL, but are not included in uniform PDL requirements.

- Statewide PDL exclusions also include “carve out” drug classes which are billed under the FFS pharmacy program only. This includes medications in the following classes:
    - Transplant Immunosuppressive Drugs
    - Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Drugs
    - Antipsychotic Drugs
    - Antidepressant Drugs
    - Anti-anxiety Drugs
    - Anticonvulsant Drugs
    - Hemophilia Drugs
    - Opioid Use Disorder Treatments

PDL Updates and Coordination

- Updates to drug files, including drug pricing information and drug availability (new to market drugs, new generics, and discontinued drugs) are received by each pharmacy program in a weekly drug file. Prompt review of the drug file is performed to identify any changes or updates that require action (e.g. inclusion on the PDL, exclusion from the PDL, or change in preferred / non-preferred status).
- Monthly updates will generally consist of low impact changes and will be communicated with the ACOs. If a member of the Workgroup wishes to bring any of these changes to the Workgroup for further discussion, any necessary changes can be made with the following monthly PDL update.
- Quarterly updates may also include new PDL classes, new drugs to market or other changes based on recommendations from the P&T Committee. Quarterly updates may include changes that may need to be communicated to the provider community via Medicaid Information Bulletins (MIBs).
- Annual updates occur on January 1st of each year and include an internal review of the entire PDL. ACO partners may make recommendations for the annual updates to the department no later than October 31st. The Department will review those recommendations in conjunction with confidential pricing and rebate information and make final decisions no later than December 1st. Final determinations will be communicated to the ACO partners within two business days.
- Negative formulary changes are defined as changes that impose new limitations or restrictions on the coverage of a drug. This includes “soft changes” that can have a positive financial impact and minimal therapeutic impact; and “hard changes” that can have a positive financial impact and some therapeutic impact to those on existing therapy, but is not limited to changing the PDL status of a drug from preferred to non-preferred, or UM edits as described above. Such changes should be communicated to providers. All negative formulary changes that impact providers /members will be communicated via standard outreach (phone / mail) with a transition period and consideration of grandfathering, as determined by the DUR Board.

For Statewide PDL implementation

- Clearly defined pathways for recommended PDL updates, whether weekly, monthly, quarterly, or annually will be agreed upon by the Pharmacy Director Workgroup and Medicaid leadership.
- Quarterly PDL updates will be reviewed by the P&T Committee, allowing the Workgroup attendees to weigh in on proposed changes.
- Overall, PDL updates and changes today are managed similarly across the five Medicaid pharmacy programs. The proposed pathway would align updates to the PDL across the five pharmacy programs and ensure adequate time is given to coordinate changes prior to implementation.

Critical Timeframes

Overall, the Pharmacy Director Workgroup identified two time frames of impact to consider – the Implementation Phase and the Maintenance Phase.

- The ***Implementation Phase*** defined as the time frame prior to and up to one year after Statewide PDL implementation and would incorporate impact on all facets of the Pharmacy Benefit. The Implementation Phase would require the greatest "lift", as all five Medicaid Pharmacy programs define new program requirements, design and coordinate changes with their individual Pharmacy Benefit Managers (PBMs)[2] and related pharmacy systems, and allocate resources to transition service delivery to meet Statewide PDL requirements. The experience of the Provider and the Member would be felt most during the Implementation Phase, as an aligned PDL would impact both drug prescribing patterns by providers and drug use patterns by members. This transition from five separate PDLs to one uniform coverage policy would impact some PDL classes more than others. Workload within the Pharmacy Plans may increase during the Implementation Phase.
- The ***Maintenance Phase,*** defined as the timeframe after the Implementation Phase. The Maintenance Phase is managed by clearly defined processes and quality control measures that promote close coordination between stakeholders to ensure that Statewide PDL operations achieve the intended goals. The P&T Committee would serve as a primary communication tool.

Provider Impact

- A Statewide PDL will have a significant positive impact on providers who currently have to navigate five different PDLs with differing prior authorization requirements and utilization management criteria. By unifying the PDL, providers' administrative burden is significantly reduced and patient care is streamlined across Medicaid plans.

[2] Currently, two of the ACOs utilize a PBM.

- Because of the financial savings to the State for some branded medications, the Statewide PDL will prefer some brand name medications when generic versions are available. Brand name preference is unique to Medicaid plans and may introduce confusion, although this has been a long-standing policy in FFS, to providers (and members) as the healthcare system has promoted generic substitution as the "least costly alternative". Indeed, many pharmacy systems today are auto-programmed to substitute generics except when specifically noted by the prescriber as "Brand Name Preferred". The Statewide PDL will identify such cases where brand is preferred over generic and pharmacy programming will alert "Brand is preferred over Generic" messaging to pharmacies, when filling for the generic, non-preferred product.
- There was concern that a "spillover effect" will occur, where overall Brand name prescribing will increase

Pharmacy Impact

- Pharmacists offer a critical, front-line service for Medicaid members and day-to-day pharmaceutical care, delivered through community pharmacies to Medicaid members, would be improved with an aligned approach. When evaluating prescriptions and providing clinical services to members, pharmacists familiarity with, and knowledge of, a Statewide PDL, prior authorization requirements, utilization management edits and other coverage policy promotes consistent delivery of services, thus facilitating improved pharmaceutical care.
- Branded preference may also impact pharmacy inventory, at least initially. Pharmacies may not readily stock the branded versions of drugs due to mandatory generic use requirements across other payers as well as inventory cost factors, which limit stocking expensive products on shelves. This issue would be of greatest concern during the Implementation Phase, as the Medicaid membership is transitioned to the Statewide PDL and would have less impact during the maintenance phase. For chronic medications, after initial prescriptions for a branded product are filled, pharmacies would "auto-stock" the prescription to support refills for the same medicine so that ongoing access would not be a concern.

Member Impact

- Today, the experience of the Medicaid member as he/she transitions between the five Medicaid Pharmacy programs is disconnected and lacks fluidity/uniformity. Under a Statewide PDL, the patient experience improves, as medication management can be consistently determined and received regardless of FFS/ACO status. With uniform coverage requirements, prior authorization status that is gained can easily be transitioned from plan to plan. Likewise, prescriptions that are subject to uniform utilization management edits will help the patient achieve consistency and predictability in the medications they are prescribed. Pharmacists can support patients in their disease management journey, and providers are able to spend less time consumed with "PDL differences / coverage differences" and focus on patient care outcomes.

- While the transition phase of the Statewide PDL might be challenging for some patients who may need to have changes to their drug regimen, the same problem as a result of switching plans is eliminated. A grandfathering period would smooth the transition for some identified drug changes that a member may experience.