Report to the Health and Human Services Interim Committee and Social Services Appropriations Subcommittee

Expansion of 340B Drug Pricing Programs

Volume 18

Prepared by the Division of Medicaid and Health Financing

August 21, 2012

UTAH DEPARTMENT OF HEALTH

Table of Contents

H.B. 74 –Expansion of State Medicaid 340B Drug pricing program	1
Feasibility of Additional Disease Management Programs	1
Senate Bill 180 in the 2011 Utah Legislative General Session	2
Potential Cost Savings	3
Necessary Amendments and Waivers	4
Projected implementation of 340B programs	4
Fill-and-Bill and Buy-and-Bill at 340B Pricing	4
Disease Management	5
Association for Utah Community Health	5

H.B. 74 –Expansion of State Medicaid 340B Drug pricing program

The 2008 Legislature directed the State Medicaid agency to expand program use of savings under the 340B drug pricing program. Specifically, the Department of Health shall determine:

- The feasibility of developing and implementing one or more 340B pricing programs for a specific disease, similar to the hemophilia disease management program;
- Whether the 340B program results in greater savings for the department than other drug management programs for the particular disease. The Department shall report regarding:
    - Potential cost savings to the Medicaid program from the expansion of use of the 340B program;
    - Amendments and waivers necessary to implement increased use of 340B pricing;
    - Projected implementation of 340B pricing programs;
- The Department shall work with the Association for Utah Community Health to identify and assist community clinics that do not have 340B drug pricing programs to determine whether:
    - Patients of the Community Health Center would benefit from establishing a 340B drug pricing program on site or through a contract pharmacy;
    - The Community Health Center can provide 340B drug price savings to the Health Center's Medicaid patients

Previous versions of this report have provided explanations and descriptions of program requirements, limitations, expectations, and obstacles. Attention should be directed to these earlier versions for information concerning those details. This version will focus on progress since the previous report.

Feasibility of Additional Disease Management Programs

Designing a disease management program and securing approval from the Centers for Medicare and Medicaid Services (CMS) presents challenges. Program staff submitted a final draft State Plan Amendment (SPA) to the Denver Regional CMS office in May of 2010 for review. The SPA included six disease states: hemophilia, multiple sclerosis, cystic fibrosis, rheumatoid arthritis, hepatitis C, and Crohn's disease. That draft was reviewed by CMS in both the Regional and the Central CMS offices and received a tentative approval.

With the passage of Health Care Reform, CMS expressed some uncertainty surrounding the best method for implementing an expanded disease management program. At various points in the past, CMS separately asked that the State consider:

- Medical Homes provisions contained in the legislation as a vehicle for implementing the proposed disease management program,
- implementing solely through a State Plan amendment,

- eliminating the need for a1915(B)(4) Waiver,
- giving enhanced attention to the cost effectiveness requirements of a waiver,
- altering the need for a request for proposal, and
- consulting with the Indian tribes prior to approval being granted.

Following additional discussions between the state and CMS, CMS determined that many of its suggestions were not feasible. CMS provided the state with a request for additional information and ultimately decided that three processes are needed along with tribal consultation:

1. A request for proposal (RFP),
2. A 1915(B)(4) Waiver, and
3. The cost effectiveness portion of the waiver.

CMS does not have a template for this waiver type as they have never approved one like this before. The template provided needs to be extensively adapted to this situation and CMS has to collaborate on that requirement.

While follow-up with CMS has occurred almost quarterly since that submission, practical implementation and further pursuit of this SPA has declined as a result of other Medicaid pharmacy priorities (e.g., ACO's) that have a direct impact on this initiative.

Senate Bill 180 in the 2011 Utah Legislative General Session

With the passage of Senate Bill 180 in the 2011 Utah Legislative General Session, Medicaid prepared and submitted an 1115 Waiver application to CMS which, if approved, will convert the existing managed care model to one of Accountable Care Organizations (ACOs). The ACOs are anticipated to include most pharmacy services. ACOs will operate in the four Wasatch Front counties. Individuals in rural areas will continue to be served under the fee-for-service model. Mental health therapeutic classes of drugs (e.g., atypical anti-psychotics, psychotropic drugs) have been excluded from the waiver request and subsequent ACO management.

Various components for handling the pharmacy benefit portion of the ACO model have been discussed with the ACOs as well as CMS. Aspects relating to claims processing, data transfer, and Medicaid regulation compliance must be configured. Accommodation of the Mental Health benefit presents challenges for the ACOs, Medicaid, and future 340B drug program parameters. For example, some ACOs desire to use 340B acquired drugs for their pharmacy benefit. A mental health carve-out means that utilization tracking has to be separate for those drugs that are provided as 340B, those that are not provided as 340B, and those that are not provided though the ACOs.

The Deficit Reduction Act of 2005 requires Medicaid to collect rebates on physician administered drugs even when provided under Managed Care Organizations. The Affordable Care Act of 2010 requires Medicaid to collect rebates on all pharmaceuticals provided under Managed Care Organizations.

In the future, providing Medicaid pharmaceutical care through an ACO model along the Wasatch Front would greatly reduce the population base for expansion of 340B drug pricing programs under fee-for-

service. In all cases, Medicaid is still required to track and report utilization to ensure that required rebates are collected. Consequently, new ACOs will have mandatory utilization reporting requirements.

The feasibility of expanding disease management into other disease states will be greatly reduced if clients along the Wasatch front become part of an ACO in the future. This may impact the willingness of 340B providers to bid for other disease management programs (lacking economies of volume).

The state has been working with CMS to obtain approval of the 1115 Waiver request titled *Utah Medicaid Payment and Service Delivery Reform*. CMS denied the original 1115 Waiver application, but said that portions of the initial submission could be done through a 1915(b) Waiver as a Managed Care Organization. The state is working through changes to the 1915(b) Waiver for the physical health portion of the business and Medicaid staff are also working with CMS on a separate 1915(b) Waiver for disease management.

Potential Cost Savings

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals. Significant savings on pharmaceuticals may be seen by those provider entities that participate in this program. The 340B program is operated under the jurisdiction of the Office of Pharmacy Affairs (OPA). A component of the Health Resources and Services Administration (HRSA), of the U.S. Department of Health and Human Services (HHS), the Office of Pharmacy Affairs has three primary functions:

1. Administration of the 340B Drug Pricing Program, through which certain federally funded grantees and other safety net health care providers may purchase prescription medication at significantly reduced prices.
2. Development of innovative pharmacy services models and technical assistance, and
3. Service as a federal resource about pharmacy.

In all of its activities, OPA emphasizes the importance of comprehensive pharmacy services being an integral part of primary health care. Comprehensive pharmacy services include:

- patient access to affordable pharmaceuticals,
- application of "best practices"
- efficient pharmacy management, and
- the application of systems that improve patient outcomes through safe and effective medication use.

The interest that HRSA (a sister agency to CMS under HHS) maintains in Medicaid 340B programs stems from the fact that all parties involved must take strict measures to ensure that drug manufacturers are not exposed to a “double” rebate and that 340B purchased drugs are not provided to patients who do not qualify as a patient of the 340B participating facility (note: the simple act of filling a prescription at a 340B facility is not sufficient to establish that relationship). Medicaid drug expenditures are entitled to a manufacturers rebate back to Medicaid. Drugs reimbursed to a 340B covered provider entity under the OPA program are prohibited from being subject to any rebate.

All savings to Medicaid from implementing a 340B based program come entirely from the providers. Additional revenues from the 340B program were intended to help 340B providers offset losses resulting from the high volumes of discounted and free medical services provided to the uninsured and underinsured, which volumes qualify them for participation in the program. A change requiring 340B providers to fill prescriptions and bill Medicaid at 340B cost pricing requires providers to share all of their savings with Medicaid and would essentially eliminate that revenue, thus discouraging provider participation. Therefore, it becomes important to find a means to maintain provider interest.

340B pricing information is not accessible directly to Medicaid, as this information is considered proprietary. Cost savings were originally calculated based on estimated 340B prices. Bill Von Oehson, president and general counsel of "The 340B Coalition," a national organization of safety net Disproportionate Share Hospitals (DSH) based in Washington D.C. maintains that 340B prices are on average AWP (Average Wholesale Price) minus 49 percent. The actual price varies by drug product. There is little question that potential cost savings exist. Those savings are not always easily calculated given the constraints of the system, such as 340B requirements, CMS approvals, and availability of willing contractors. Medicaid delayed revising savings calculations pending the outcome of CMS review of the 1115 Waiver application, and continues to do so as negotiations for the 1915(b) ACO waiver are undertaken.

Necessary Amendments and Waivers

There are several distinct components for the 340B program. The medical component pertains to pharmaceutical services provided in a physician's office setting (e.g., hospital clinics, community clinics). The point-of-sale (POS) component pertains to prescriptions obtained through a pharmacy. A third component, referred to as disease management, is administered through a POS setting with some medical services also provided.

In previous reports, the Division has addressed the third component, expansion of the current 340B Disease Management program, which includes the management of additional disease states. As reported under the section addressing feasibility, the Division, has, in the past, involved itself in negotiations with CMS to finalize a SPA, waiver, and RFP for disease management. The Division included the disease management expansion program as part of the original 1115 Waiver request titled *Utah Medicaid Payment and Service Delivery Reform*. The value of a Medicaid disease management program with an ACO model running in the state will be limited to the non-ACO catchment areas of the state. Pursuit of disease management under remaining fee-for-service contracts is being revisited, especially since the serviceable populations are located in sparsely populated rural counties.

Projected implementation of 340B programs

Fill-and-Bill and Buy-and-Bill at 340B Pricing

Previous reports have detailed the opportunities and obstacles for implementing "fill-and-bill" and "buy-and-bill" arrangements with providers (please refer to previous reports for more detail).

Negotiations with hospital providers and other 340B covered entities continue in hopes of obtaining additional savings. Although the net gain is less than a full 340B discount, the net result will be additional savings to the Medicaid program and preserving interest in the program by the participating 340B providers.

To aid in this process, Utah Medicaid commissioned a dispensing fee survey. The survey will provide Medicaid with the information necessary to establish a specific 340B dispensing fee. Dispensing fee differentials are likely to be identified, and the state plans to submit a State Plan Amendment to CMS for approval of any new proposed dispensing fees. Since the November 2011 report, the State has secured a vendor and the survey is underway and anticipated to be completed in the near future. With information from the dispensing fee survey, Medicaid will begin negotiations with 340B entities in order to have the pharmacy 340B providers fill-and-bill at 340B pricing. Medicaid would put an edit in the claims payment system to ensure those providers are billing at 340B costs and that those claims are not included in the rebate invoicing program.

Disease Management

The process through which Freedom of Choice Waivers are approved by CMS has proven to be lengthy. Such was the case with the original hemophilia program. Given the pace of the CMS approval process, the efforts required to submit a 1915(b) Waiver application, and resulting changes to the disease management model presented by the ACO waiver (e.g., smaller population base), it is difficult to estimate a completion date for expansion of the disease management program.

Association for Utah Community Health

The Association for Utah Community Health (AUCH) is an organization of 340B qualifying community health centers, federally qualified health centers, and family planning clinics. There are 29 covered entities in the AUCH organization. AUCH pharmacies charge 340B clients the cost of the 340B drugs plus a five dollar co-pay, providing a great benefit to their patients. Medicaid patients of the 340B AUCH providers do not use the 340B program and, in fact, are sensitive as to whether 340B purchased drugs are used since using 340B drugs would change their co-pay (Traditional Medicaid clients may not pay copays greater than three dollars).

A 340B covered entity by definition buys 340B drugs for use in the facility. All covered entities provide 340B purchased medications, at least in the physicians' offices, whether or not pharmacy services are available onsite or through a contracted pharmacy. Most AUCH members have onsite pharmacies or have a contracted pharmacy. Presently, covered entities can elect whether or not they will choose to fill-and-bill with 340B purchased drugs for their Medicaid patients. To date, two have elected to do so.

Past negotiations with the AUCH organization focused on methods to make obtaining medications attractive for the Medicaid client while maintaining the revenue for the covered entity. Similar to other 340B providers, as stated previously, the contracted pharmacy retailers providing services to 340B AUCH clients have also voiced discontent with participation unless reimbursement issues (e.g., higher dispensing

fees or co-pays) are addressed. Results from the dispensing fee survey should help resolve those concerns. A cost settlement approach has not been discussed with the AUCH organization since coordination of the required programming among the covered entity, the contracted pharmacy, and the Medicaid agency is beyond the scope of their systems and resources at this time. AUCH has indicated to Medicaid that its organization of covered entities will, however, work towards fill-and-bill participation pending satisfactory resolution of reimbursement issues such as an increase in the current dispensing fee.