Division of Medicaid and Health Financing

Expansion of 340B Drug Pricing Programs

Volume 14

Report to

The Utah Legislature's

Health and Human Services Interim Committee

and

Social Services Appropriations Subcommittee

Submitted

August 17, 2011

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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 May 2011 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 on May 3, 2010 for review. The SPA includes the following six disease states: hemophilia, multiple sclerosis, cystic fibrosis, rheumatoid arthritis conditions, hepatitis C, and Crohn's disease. That draft has been reviewed by CMS in both the Regional and the Central CMS offices and has received a tentative approval. Follow-up with CMS occurred in June, August and October 2010, January and May of 2011.

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,
- dropping 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 recent suggestions were not feasible. CMS provided the state with a request for additional information and ultimately decided that three processes now need to be done 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.

Since the February report, additional consultations with CMS have taken place to discuss details involving the necessary requirements. The feasibility of additional disease management programs is likely since approval of this SPA looks promising. After additional reviews with the CMS central office of our existing Disease Management Contract, other conference calls will be scheduled by CMS to discuss the next steps.

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 manage care model to one of Accountable Care Organizations (ACOs). The ACOs are anticipated to include pharmacy services. ACOs will only be operating in the four Wasatch Front counties. Individuals who are 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.

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 required rebates are collected.

The feasibility of expanding disease management into other disease states is greatly reduced as clients along the Wasatch front will be 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).

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. 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 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 has delayed revising savings calculations pending the outcome, extent, and scope of CMS approvals.

Necessary Amendments and Waivers

There are several distinct components for the 340B program. The medical component deals with pharmaceutical services provided in a physician's office setting (e.g., hospital clinics, or community clinics). The point-of-sale (POS) component, deals with 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. Since the previous report, the Division has included the disease management expansion program as part of the 1115 Waiver request titled *Utah Medicaid Payment and Service Delivery Reform*.

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 the previous report for more detail.)

Approval of the 1115 Waiver will have an impact on 340B programs administered by the state. Mapping specific areas of impact is difficult until final approval of the 1115 Waiver is obtained. Nevertheless, further negotiations with hospital providers are being scheduled in hopes of obtaining additional savings. Even though 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 staff is acquiring a dispensing fee survey. The agency is currently exploring available resources and associated costs for this survey. The survey will provide Medicaid with the information necessary to establish a specific 340B dispensing fee. If dispensing fee differentials are identified, the state would need to submit a State Plan amendment

to CMS for approval of the new dispensing fees. Since the May 2011 report, the State has determined that the dispensing fee survey will occur and is now looking into selection of a survey vendor.

Once a provider has been identified as being a 340B provider, 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

Freedom of Choice Waivers have proven to take a long time to work through the approval process with CMS. Such was the case with the original hemophilia program. Given the pace of the process with CMS in working to expand the disease management program and the fact that it is part of the recent 1115 Waiver application, it is difficult to estimate the completion date at this time.

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 (Medicaid clients cannot pay more than three dollars for a co-pay).

Past negotiations with the AUCH organization focused on methods to make it 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. A cost settlement approach has not been discussed with the AUCH organization at this time.

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; none have elected to do so. AUCH has indicated to Medicaid that its organization of covered entities will, however, work towards participation pending satisfactory resolution of reimbursement issues such as an increase in the current dispensing fee.