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340B Opportunities Under The Patient Protection and Affordable Care Act (PPACA)

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Introduction

The Federal 340B drug pricing program can provide significant savings in outpatient pharmaceutical costs for Disproportionate Share Hospitals (DSHs or DSH hospitals). These savings contribute directly to the bottom line for providers operating in an increasingly difficult environment to serve an increasingly vulnerable population. Established in 1992 under the Veteran's Health Care Act and administered by the Health Resources and Services Administration (HRSA), the program generates savings through an up-front manufacturer's discount. As a condition of participation in Medicaid, the program requires pharmaceutical manufacturers to sell most outpatient drugs to participating 340B providers (known as "covered entities") at a discounted rate. Covered entities include DSH hospitals (those with a DSH *adjustment percentage* of more than 11.75%), Federally Qualified Health Centers, and other designated federal grantees.

The savings that can be generated under 340B take on additional importance in the current climate of cuts in federal and state funding for Medicaid and an increase in the provision of uncompensated care. The good news is that health reform and other recent legislative action and guidance appear to set the stage for potentially expanded opportunities for DSH hospitals under the program for DSH hospitals.

Background

The 340B discount is one of the deepest discounts in the industry. A June 2011 survey of 281 DSH hospitals, conducted by Safety Net Hospitals for Pharmaceutical Access (SNHPA), reported that hospitals spent an average of 27% less on outpatient drugs as a result of the 340B program,

with an average savings of \$4.4 million annually¹. Drug manufacturers are bound under their agreement with HRSA to sell drugs to covered entities at or below the “340B ceiling price.” The 340B ceiling price is set at or below the best price in the market, or at a discount equal to the Average Manufacturers Price (AMP) less a minimum rebate percentage of 23.1%, for most brand name drugs. If a manufacturer’s price for a brand name drug is less than the AMP less 23.1%, it must offer the drug to 340B entities at the lower price. Covered entities are also able to directly negotiate prices lower than the ceiling price. In addition, the 340B Prime Vendor Program (PVP), operated under the HRSA Office of Pharmacy Affairs (OPA), obtains volume discounts by aggregating purchases of 340B drugs for multiple 340B providers.

It is important to note that this program was designed to provide relief directly to providers that serve a large proportion of uninsured and underinsured patients, with the stated legislative intent being to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”² Participating providers bill the patient’s insurance company for the full price of the drug which is obtained at 340B pricing, with the income differential retained by the provider. The intent of the 340B provision is for providers to use the savings to increase access to pharmacy services for uninsured populations. The SNHPA survey mentioned above also investigated how hospitals have used the savings to offset low reimbursement from under-insured commercial, Medicaid and Medicare patients. These initiatives included developing medication therapy management (MTM) and disease management programs, increasing pharmacy staffing and enabling the pharmacy to maintain sufficient inventory.

Expansion of 340B through Health Reform

Two recent developments have increased the opportunity for additional 340B savings by expanding the scope of the program while addressing compliance and pricing transparency issues.

First, the Patient Protection and Affordable Care Act (PPACA) contained a number of provisions to enhance the 340B program:

- Expands eligibility to include critical access hospitals, sole community hospitals and rural referral centers with DSH adjustment percentages of $\geq 8\%$, and freestanding cancer centers with DSH adjustment percentages $\geq 11.75\%$.

¹ Demonstrating the value of the 340B Program to Safety Net Hospitals and the Vulnerable Patients They Serve
6/29/2011 Safety Net Hospitals for Pharmaceutical Access

² House Report, No. 102-384, Part II, page 12, 102nd Congress, Second Session (1992)

- Requires the Office of Pharmacy Affairs (OPA) to publish ceiling pricing and actual pricing data submitted by drug manufacturers, to perform spot checks of transactions and to address identified discrepancies in pricing.
- Changes the discount methodology by increasing the Medicaid rebate percentage, which will likely result in deeper 340B discounts (from 15.1% to 23.1% for most brand name drugs; to 17.1% for clotting factors and pediatric drugs; and from 11% to 13% for generics).
- Institutes a number of integrity provisions for both drug companies and covered entities, including the authority to impose fines on manufacturers for violations of 340B rules, increased price transparency, new processes for dispute resolution and recovery of overcharges, and civil penalties for providers knowingly violating the prohibition against diversion of 340B drugs.
- Directs the Government Accounting Office (GAO) to prepare a report to Congress by September 2011 addressing recommendations for further program expansion, assessing whether the program hinders access to drugs in other settings and whether providers are using 340B savings to further the *intent* of the program.

Secondly, HRSA and the OPA issued a new rule in March of 2010 which allowed hospitals to sign agreements with multiple contract pharmacies for filling 340B prescriptions. Previously limited to the hospital's outpatient pharmacy and a contract with a single retail pharmacy, DSH hospitals are now free to negotiate contracts with contract pharmacy administrators or directly with retail chains such as CVS and Walgreens. The ability to reach more 340B eligible patients in a wider geographic area creates new savings opportunities for 340B providers.

What's Ahead for the Program?

The door to even further expansion of the 340B program to include inpatient drugs has also recently been opened. A provision addressing this modification was briefly included in H.R. 4213, the Unemployment Extension Act, in December, 2010. This has been opposed by the pharmaceutical industry and, not surprisingly, the provision was pulled before final passage of the bill. More recently, H.R. 2674 was introduced, which, among other industry fixes to the 340B provisions of PPACA, calls for the extension of the program to include inpatient drugs. The bill was sent to the Health Subcommittee on 8/1/2011.

The eventual answer will likely lie in the soon to be released GAO report mandated by PPACA. The report is expected to make recommendations regarding further program enhancements and to provide direction to the Office of Pharmacy Affairs in resolving outstanding issues including the definition of a "patient" under the program. This contentious definition has been

the subject of ongoing debate since 2007 when published guidance was interpreted by the provider community as too restrictive and was subsequently withdrawn by HRSA. A new definition has been submitted to the Office of Management and Budget for review, and is anticipated to be published shortly. While some industry insiders warn of the potential for a more restrictive interpretation, the patient definition is generally expected to be relaxed upon publication of the new definition. The Office of Pharmacy Affairs has recently indicated that it is not likely to publish the new guidance until at least the issuance of the GAO Report.

Realizing the Potential for 340B in Disproportionate Share Hospitals

The recent expansion to the 340B program presents potential new avenues for savings. However, there are a number of reasons that new participants, as well as providers that have been participating for years, are not optimizing use of the program, including:

- Lack of understanding of complex rules and regulations which are open to interpretation;
- Resultant staff belief that all opportunity is being captured;
- Unfamiliarity with the key aspects of pharmacy management and procurement critical to the 340B program;
- Difficulty in the management of inpatient/outpatient inventory controls; and/or
- Availability of adequate resources to effectively manage the program.

Gaining an understanding of the full scope of the program rules and regulations and performing an assessment of your 340B program can identify and quantify the extent to which your facility is utilizing the program to achieve maximum savings. Perhaps more importantly, it will provide valuable direction in the development of potential additional 340B savings.

Issues for analysis include the following:

- *What components of the hospital are participating in 340B?* Any provider-based facility under Medicare regulations can be included in the program. This would include provider-based home health agencies, infusion therapy, oncology clinics, hospice, etc.
- *Which patients are considered eligible under 340B?* The current definition of a patient according to HRSA requires that the individual: has an established relationship with the covered entity, has their medical records maintained by the covered entity, and receives health care services from professionals who are either employed by or under contract or arrangement with the covered entity. A careful Interpretation of this definition can include situations which might not be apparent at first glance, including prescriptions written on discharge, specialist referrals in certain cases, home health patients, employees and other classes of patients.

- *Are you taking advantage of the multiple contract pharmacy opportunity to increase utilization and revenue?* Contract arrangements should be analyzed to ensure that a high percentage of all eligible prescriptions are filled by the 340B contract pharmacies, savings that accrue go to the 340B provider and that required annual independent audits are being conducted.
- *Are there innovative models that can be adopted which have the potential to increase access to low cost pharmaceuticals for vulnerable populations, while increasing hospital savings through 340B?* Options could include off-site clinic models, providing onsite care at non-340B partner facilities, and other models.

As health care reform and other deficit reduction strategies are implemented, the 340B Drug Discount program remains a vehicle for increased savings. BESLER Consulting and our affiliated strategic partners have been involved at the State and provider level in identifying opportunities for efficiency and cost containment initiatives. To learn how we can assist your hospital in reviewing or establishing a 340B drug program, please contact Leslie Dykman at (732) 392-8316 or ldykman@besler.com.