340B Benefits Some, Not Others

Money Redirected Through Expansion

By Ron Schleif, Bruce Edelen, and Mary Lou Bowers

Recent legislative and marketplace changes are considerably increasing the impact 340B price discounts will have on pharmaceutical manufacturers. With the expanded insurance coverage for the nation's indigent population, provided by the Affordable Health Care Act (ACA), it will become easier for hospitals to become eligible to qualify for the drug discount program. While the recent addition of the ACA's eligibility for freestanding cancer clinics has had minimal negative impact on pharmaceutical companies, the orphan drug exclusion has had minimal positive benefit for these same organizations. Clearly, the 8% increase in the 340B price discount affects hospital profit margins in the positive, and that discount will increasingly be applied to certain oral medications as hospitals increase their use of outpatient and contract pharmacies. Furthermore, the acquisition of community oncology practices by hospitals with 340B pricing is leading to a rapid growth in the number of cancer patients treated per 340B hospital. For pharmaceutical companies this shifts patients toward a channel with a much lower net effective selling price. And these newly acquired patients will have minimal, if any, effect on the hospital's ability to qualify for 340B, even if every newly acquired patient is fully insured through commercial health plans.

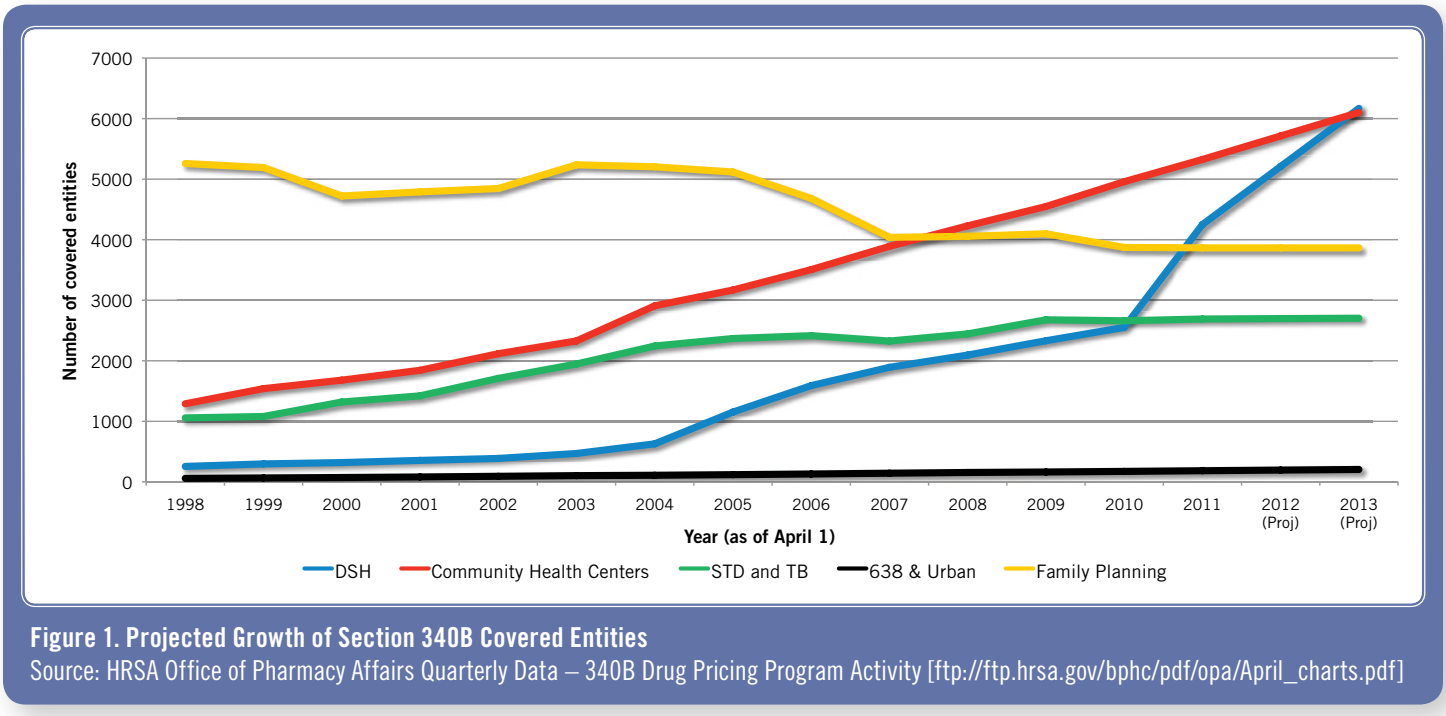

Figure 1. Projected Growth of Section 340B Covered Entities
Source: HRSA Office of Pharmacy Affairs Quarterly Data – 340B Drug Pricing Program Activity [ftp://ftp.hrsa.gov/bphc/pdf/opa/April_charts.pdf]

Oncology Reimbursement Management and The Pritchard Group examined the impact of the ACA on the 340B Drug Pricing Program and their results are compiled in a recent report, some of which is detailed below. Before getting to the salient points from the report, let's first understand 340B more comprehensively.

340B Definition and Logistics

Established under the Veterans Health Care Act of 1992, 340B enables specific government-supported facilities to stretch scarce federal resources, reach more eligible patients, and provide more comprehensive services by limiting the cost of outpatient drugs. Originally, 11 different types of organizations benefitted from the program including, federally qualified health centers (community health centers), family planning centers, black lung clinics, tuberculosis clinics, state-operated AIDS drug assistance programs, Ryan White Care Act programs, hemophilia treatment centers, homeless clinics, Urban Indian clinics, Native Hawaiian health centers, and disproportionate share hospitals (DSHs).

The discounts (estimated to be 20%–50%) offered by 340B resulted in significant savings for these providers; and have had a direct financial impact on qualifying hospitals/clinics and pharmaceutical companies. The discounts also have indirectly impacted community practices, physicians, distributors, GPOs, retail and specialty pharmacies, Medicaid, commercial payers, and the way patients receive care.

Last year, the ACA altered the 340B Program in three major ways by:

- Adding 5 types of hospitals that can participate (ie, children's hospitals, cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals)
- Exempting orphan drugs
- Raising the statutory price discount from 15.1% to 23.1%

Disproportionate share hospitals provide substantial outpatient services to cancer patients, the proportion of which varies by cancer type and stage. As Figure 1 shows, DSH growth is likely to accelerate well into the future as more and more sites qualify for participation.

In order to participate in the 340B program a hospital must meet three criteria:

- Government ownership or government control
- Sign a written certification
- Possess the necessary level of Medicare disproportionate share

The first criterion is usually met one of two ways: a) the hospital is owned by the city, county or state; or

b) the hospital is a private non-profit hospital with a government contract to provide healthcare services to low income individuals who are not entitled to benefits under Medicare or Medicaid—all that is required is a one-page statement signed by the state or local government official certifying that a contract exists and meets 340B standards.

The second criterion is a certification signed by the hospital stating non-participation in Group Purchasing Organizations (GPOs) for covered outpatient drugs.

The final criterion of meeting the necessary Medicare DSH adjustment percentage is often the primary determinate as to whether the hospital can participate. While a very small minority of hospitals qualify as "Pickle" hospitals (urban hospitals with greater than 30% of inpatient revenues from state or local subsidies to cover costs for the Medicaid-ineligible), the vast majority of DSHs qualify because of the number of inpatient days for patients covered by Medicaid and patients covered by both Medicare Part A and SSI (Supplemental Security Income, or disability). When the formula below is calculated for a DSH the result must be greater than 11.75% in order to qualify for that quarter.

$$\text{DSH Patient \%} = \frac{\text{Medicare \& SSI Days}}{\text{Total Medicare Days}} + \frac{\text{Medicare (non-Medicare Pt A)Days}}{\text{Total Patient Days}}$$

Even though the 340B Program only pertains to outpatient services, the above eligibility formula is based on inpatient services. What's more, the basis is not services provided to the uninsured, but inpatient services provided to Medicaid and Medicare patients.

Thus, the increased insurance coverage provided by ACA will actually make it easier for most hospitals to qualify for 340B. Since the ACA provides insurance predominantly through Medicaid, the numerator will grow by 35–40 million patients post-2014, making it considerably easier for hospitals to exceed the 11.75% threshold.

This formula is also the reason why a hospital's acquisition of community oncology practices has no impact on its ability to qualify for 340B. The acquisition has minimal, if any, effect on the inpatient services that determine eligibility, thus enabling the hospital to leverage 340B price discounts as they buy community practices.

Impact on Cancer Centers

Since the ACA enactment, only 2 of the 11 designated cancer research centers (City of Hope and University of Miami) have attained 340B eligibility as freestanding cancer centers (Table 1.) A study by Avalere Health in May 2010 found that of the remaining 9 centers, 1 did not qualify due to the criterion of ownership/control (USC Kenneth Norris Cancer Center is owned by USC, a private research university), and the other 8 were unlikely to qualify due to the disproportionate share criterion (all had adjustment percentages less than 5%). No further impact of 340B discounts is expected from these designated comprehensive cancer centers unless the ACA driven Medicaid growth in 2014 more than doubles their Medicaid inpatient days.

Salient Points From the Report

From interviews with all 340B key stakeholder groups and analysis of data concerning the use of 340B discounts, the Oncology Reimbursement Management and Pritchard Group report projected the following:

Pharmaceutical Companies Will Lose Profits

Of primary concern for the pharmaceutical industry is the fact that 340B pricing benefits are applied to both indigent and fully insured patients. The industry is subsidizing inefficiencies in healthcare delivery that go far beyond the indigent.

The level of discount applied in 340B pricing can, at times, be eye-popping. This was true prior to implementation of the ACA, but ACA raised the discounts even more. Currently, for branded therapies other than clotting factors/pediatric drugs, the discount is the greater of:

$$\text{AMP} - [\text{Medicaid Best Price Discount \%} + (\text{Price Increase \%} > \text{CPI-U})]$$

or

$$\text{AMP} - [23.1\% + (\text{Price Increase \%} > \text{CPI– U})]$$

So the minimum discount is 23.1% off of the Average Manufacturer Price (AMP). It can, however, increase into the 60% to 80% range depending on:

Table 1. 11 Comprehensive Cancer Centers	Location	340B Participation
City of Hope National Medical Center	Duarte, CA	Since Q4, 2010
USC Kenneth Norris Jr. Cancer Hospital	Los Angeles, CA	No
Dana Farber Cancer Institute	Boston, MA	No
Memorial Hospital for Cancer and Allied Disease	New York, NY	No
Roswell Park Memorial Institute	Buffalo, NY	No
American Oncologic Hospital – Fox Chase	Philadelphia, PA	No
The University of Texas M.D. Anderson Cancer Center	Houston, TX	No
Fred Hutchinson Cancer Research Center	Seattle, WA	No
Arthur G. James Cancer Center Hospital and Research Institute	Columbus, OH	No
University of Miami Hospital and Clinics	Miami, FL	Since Q1, 2011
H. Lee Moffitt Cancer and Research Institute Hospital, Inc.	Tampa, FL	No

Source: CMS - Medicare PPS Excluded Cancer Hospitals; HRSA Office of Pharmacy Affairs 340B Covered Entity Database

what the price increase strategy has been versus the Consumer Price Index for All Urban Consumers (CPI-U); and if additional discounting has led to a Medicaid Best Price discount greater than 23.1%.

Even though AMPs are not publically available, it is possible to approximate 340B pricing using the Wholesale Acquisition Cost (WAC) and Average Sales Price (ASP). The assumptions are that ASP approximates AMP and that price increases to AMP and WAC are proportional.

Using Rituxan as an example (Table 2), the 23.1% discount would lower Rituxan's selling pricee $133.16 from the current ASP of $576.44. Added to this discount would be the amount the price increases have exceeded the CPI-U over the life of the compound. Since Rituxan's launch in 1997, the WAC has increased 88% while the CPI-U has increased only 40%. This more than doubles the discount, adding $150 to create a total discount of $284.75 or 49% off of ASP. This means instead of the $4,600 per dose for the average patient the manufacturer would receive just over $2,300. And that assumes the Medicaid Best Price is not greater than a 23.1% discount, because if it is, that higher percentage will be substituted and the manufacturer realizes even less than $1,500 per dose.

Table 2. Rituxan 100 mg Discount			
ASP Data for Q3 2011	$576.44		
AMP as of 7/1/2011 (assume AMP = ASP)	$576.44		
Statutory Minimum Discount Percentage	23.1%		
Statutory Minimum Discount Dollars	**$ 133.16**		
		WAC	**CPI-U**
Price at Launch (12/1997)		$318.00	161.3
Price as of 5/1/2011		$599.07	226.0
Percent Increase		88%	40%
Additional Discount Due to Price Increases > CPI	**$151.59**		
TOTAL 340B DISCOUNT DOLLARS	**$ 284.75**		
TOTAL 340B DISCOUNT PERCENTAGE	**49%**		
FINAL 340B PRICE	**$291.69**		

Source: Q3 1996 Red Book; Reimbursementcodes.com; U.S. Dept. of Labor - Bureau of Labor Statistics CPI-U History Table

When drug discounts ranging from 23% to 50% or more are given to a steadily growing number of hospitals, and these hospitals are also growing the number of cancer patients treated in their outpatient centers, the only outcome for pharmaceutical companies is lower profits. Certainly there are strategies that can be employed to minimize these losses, but the discounts will impact the net-effective selling price and overall profits.

›› Hospitals and Community Health Centers Will Use 340B as a Life Preserver

Hospitals and community health centers will come under increasing budget pressures as federal and state governments' lower payments to healthcare providers as a means to manage budget crises. 340B price discounts will be one benefit eligible providers will leverage to the maximum. The greater the margin to be gained by applying 340B to commercial patients, the more the provider will be able to weather cuts in other areas.

›› The Orphan Drug Exemption to 340B is More of a Drug Inclusion

Specific to oncology, the orphan drug exemption could be a significant benefit to pharmaceutical companies if applied to all 340B entities. This would provide relief from the substantial 340B discounts and the growing number of entities.

The ACA did provide exclusion for orphan drugs; however, it is only applied to new entity types added in the ACA (rural referral centers, critical access hospitals, sole community hospitals, and freestanding cancer hospitals). Of these, freestanding cancer hospitals are the only entities where excluding orphan drugs from 340B discounting would be significant to cancer compounds. When looking across all 340B hospitals of significance to cancer compounds, there were 3,082 DSHs, 145 children's hospitals, and 5 freestanding cancer hospitals sites eligible for 340B during the second quarter of 2011. Of these, the 3,227 DSHs and children's hospitals will receive 340B discounts on orphan cancer drugs, and only the 5 freestanding cancer sites (University of Miami has 4 eligible sites) are excluded.

To further dilute any pharmaceutical company benefit of the orphan drug exclusion, CMS has proposed that the exclusion for orphan drugs be limited to only those patients with "the rare condition or disease for which that orphan drug was designated." So for products with multiple indications where only one is for the orphan designation, the exclusion benefit may be minimal. Under the CMS proposal for example, if Taxol was still a single-source product today its orphan designation for AIDS-related Kaposi's sarcoma would avoid 340B discounts to the above entities for that use, but not when Taxol is used in lung, breast, ovarian or any other types of cancer. Of course it will be interesting to see how challenging CMS' proposal is to implement for 340B hospitals without an excellent EHR system.

›› Oral Cancer Therapies Can Escape 340B

Oral cancer therapies may not be exempted in the ACA legislation, but they can escape 340B discounting when the prescriptions are filled by any pharmacy outside the 340B institution's services. So pharmaceutical companies with oral cancer therapies that employ a closed system of specialty pharmacies will have much more control of their fate.

Orals utilizing an open pharmacy system will be subject to an increasing 340B impact. Directors and administrators of 340B entities understand that to get the maximum benefit from their 340B eligibility, they need to be the organization supplying the medications. Supplying Part D medications means competing with other supply channels: retail pharmacy, chain stores, mail order and specialty pharmacies.

Outpatient pharmacies within 340B eligible institutions are improving their marketing tactics, but greater success is likely to come from these institutions partnering with other pharmacies via contracts, and sharing some of the value 340B discounts offer. Since April '10, 340B eligible sites have been able to contract with more than one pharmacy. This increased presence within the community will make it much easier for patients to access their medications from 340B entities. The attractive economics in supplying these medications and the ability to now contract with multiple pharmacies are factors that will contribute to the growth in contract pharmacies. In Figure 2, the Office of Pharmacy Affairs has made the following predictions for the growth in use of contract pharmacies by 340B entities.

›› Physicians Will Shift Their Employment to Hospitals

Practice acquisition and consolidation is being driven by the stress providers are feeling as a result of the current reimbursement environment. These consolidated networks result in an expansion of the 340B environment and contribute to the erosion of the traditional private practice model. Payers, both private and public, are driving healthcare delivery to large networks of providers that only institutions can manage.

While the number of 340B sites and pharmacies will grow in the future, so will the number of patients going through these sites. Hospitals are acquiring community practices; oncologists fresh out of their fellowship are increasingly likely to work at a hospital or institution as opposed to a community practice; and the Accountable Care Organizations (ACOs) fostered by the ACA will place hospitals as the natural focal point of these initiatives. Within 2 years, hospitals are likely to treat as many cancer patients as community practices, reversing a trend that began in the early 1990s.

Looking Foward

Since the 340B Drug Pricing Program was initiated in 1992 the impact on stakeholders associated with the program was reasonably predictable. However, with the enactment of the ACA, questions are being raised as to what extent the ramifications of the ACA on 340B stakeholders (pharmaceutical companies, physicians, and hospitals, as well as pharmaceutical company initiatives) will entail. The 340B program will continue to evolve, and stakeholders need to not only understand how future changes will affect them, but how they can affect the future changes.

Some aspects of the future for 340B are, however, quite clear:

- Does 340B go away when the approximately 35 million uninsured gain insurance coverage in 2014 through the ACA?
  Answer – No.
- Will it become more difficult for hospitals to qualify for 340B once indigent patients have insurance coverage? Answer – No.
- Does it become increasingly difficult for hospitals to qualify for 340B when they acquire and incorporate community oncology practices and their commercial patients? Answer – No.

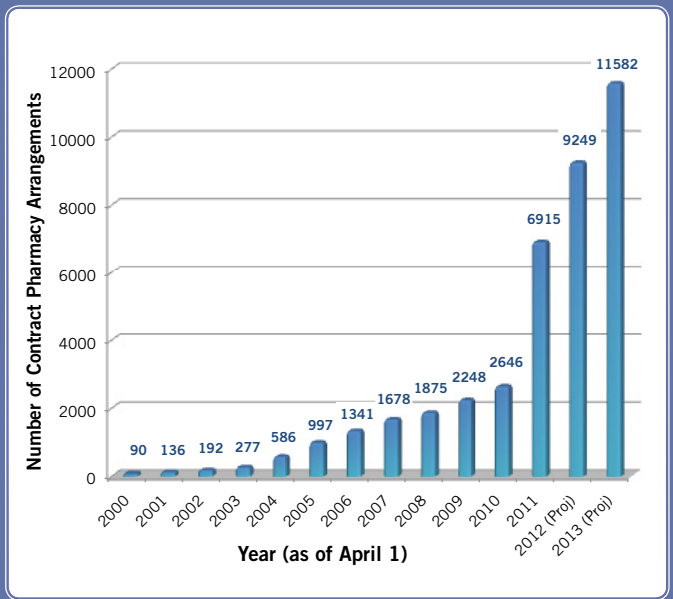

Figure 2. Growth of 340B Contract Pharmacy Arrangements
Source: HRSA Office of Pharmacy Affairs Quarterly Data – 340B Drug Pricing Program Activity [ftp://ftp.hrsa.gov/bphc/pdf/opa/April_charts.pdf]

- What will the impact to pharmaceutical companies be of allowing freestanding cancer hospitals to access 340B pricing? Answer – Very minimal.
- Is having orphan drug status a safe haven for oncology products? Answer – No.
- Should manufacturers of oral cancer therapies be worried about 340B? Answer – They should be thoughtful.
- Will the amount of discounts really become that substantial? What difference does a few percent make? Answer – Yes. RS BE MLB

About the Contributors

Ron Schleif is co-founder of Oncology Reimbursement Management, a consulting firm focused exclusively on helping clients navigate through oncology pricing, access, and reimbursement. More than half of his 30 year career in the pharmaceutical industry has focused within oncology, where he has held management and senior management roles in strategy, brand development, sales, marketing and Six Sigma initiatives.

Bruce Edelen is co-founder of Oncology Reimbursement Management and is an expert in all aspects of optimizing access and reimbursement for cancer therapies. During his 30+ years in the pharmaceutical industry Bruce has been instrumental in developing the pricing and contracting strategy for oncology marketed products, and has played pivotal roles in the pricing, reimbursement, and access strategies developed for pipeline oncology products.

Mary Lou Bowers is President and CEO of The Pritchard Group, LLC and a recognized authority in provider strategy, operations, and reimbursement. Her focus has been to assist hospitals, physicians, payers and industry with navigating toward their optimum return for nearly four decades. Prior to her practice as a consultant, she held senior leadership positions in physician practices and associations, hospitals and hospital systems, and health insurance companies. Additionally, Ms. Bowers works extensively to promote understanding of the regulatory impact on healthcare operations.