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Excluding Orphan Drugs from the 340B Drug Discount Program: the Impact on 18 Critical Access Hospitals

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Key Words: 340B Drug Discount Program, Critical Access Hospitals, Orphan Drugs

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Abstract

Purpose: The 340B Drug Pricing Program is a federal program designed to reduce the amount that safety net providers spend on outpatient drugs. The Patient Protection and Affordable Health Care Act of 2010 extended eligibility for 340B to critical access hospitals (CAHs) for all drugs except those designated as "orphan." Because this policy is unprecedented, this study quantifies the gross financial impact that this exemption has on a group of CAHs. **Methods:** Drug spending for 2010 from 18 CAHs in Minnesota and Wisconsin are reviewed to identify the prevalence of orphan drug purchases and to calculate the price differentials between the 340B price and the hospitals' current cost. **Results:** The 18 CAHs' purchases of orphan drugs comprise an average of 44% of the total annual drug budgets, but only 5% of units purchased, thus representing a very high proportion of their expenditures. In the aggregate, the 18 hospitals would have saved \$3.1 million (\$171,000 average per hospital) had purchases of drugs with orphan designations been made at the 340B price. Because CAH claims for Medicare are reimbursed on a cost-basis, the Federal government is losing an opportunity for savings. **Conclusion:** The high prevalence of orphan drug use and considerable potential for cost reduction through the 340B program demonstrate the loss of benefit to the hospitals, Federal government and the states.

Introduction

The high cost of prescription drugs is now and has been a major obstacle in containing health care costs, particularly when it comes to containing the amount public insurance pays. One program designed to help lower drug spending is the federal 340B Drug Pricing Program (340B program), which has been administered by the Health Resources and Services Administration's Office of Pharmacy Affairs (HRSA/OPA) since 1992. The 340B program requires that pharmaceutical manufacturers provide outpatient drugs at or below statutorily defined prices, known as 340B ceiling prices, to specified grantees and hospitals.¹ In essence, the discount available through 340B reduces prescription drug costs for safety net providers that serve the indigent and majority of Medicare/Medicaid beneficiaries, such as community health centers and public hospitals.

The Patient Protection and Affordable Care Act (ACA), enacted on March 23, 2010, expands the 340B program to four new entities, taking the total number of eligible entities

Corresponding author: Madeline Carpinelli Wallack University of Minnesota, College of Pharmacy 308 Harvard St, SE, 7-159 Weaver-Densford Hall Email: <u>m-carp@umn.edu</u>, Phone: 612/624-8489 from 12 to 16. The "ACA-eligible" entities, as OPA refers to them, include four categories of hospitals: free-standing cancer hospitals, Critical Access Hospitals (CAHs), Rural Referral Centers (RRCs) and Sole Community Hospitals (SCHs).² These entities are small-scale hospitals, with CAHs, RRCs and SCHs specifically serving rural communities.

Though full access to the 340B program should translate into heightened drug cost containment for these hospitals, a lastminute amendment to the ACA adversely impacts the financial benefit that 340B is intended to provide. One week following the passage of the ACA, language was added to exclude the 340B discount for drugs designated by the Food and Drug Administration (FDA) as "orphan drugs" to the ACAeligible entities, but entities previously eligible for the 340B program were not affected.³ Broadly speaking, orphan drugs are products that the FDA has designated as treatments for rare diseases. Manufacturers of orphan products receive special incentives in exchange for the research and development invested to find treatment options. However, orphan drugs are not used solely for rare diseases and are often among the most costly products on the market. As such, this exclusionary policy for the new entities translates into a significant missed opportunity for governmental savings.

Orphan Drugs

The Orphan Drug Act of 1983 was enacted to provide incentives for manufacturers to develop drugs for rare diseases that affect a small portion of the population, which is defined by the Act as affecting fewer than 200,000 people.⁴ Drugs that treat diseases affecting a larger portion of the population are also eligible under the Act if the costs of development and manufacturing are expected to exceed sales. The Act allows companies to take a 50 percent tax credit on all clinical trial costs, exempts them from some FDA user fees, and precludes competitors from obtaining FDA approval for the same drug for seven years.⁵ The intent of the Act is to foster the potential market for such drugs, which might not exist in the absence of such incentives due to the difficultly in recovering high development costs.⁶

Under the Orphan program, the FDA may confer one of two classifications on a drug: an "orphan designation" or "approved for orphan indication".⁷ The process to receive orphan designation is fairly straightforward: manufacturers must show the FDA that the product's use will be for a rare condition. Primary clinical trials are not necessary to receive this classification. As of January 2012, the FDA has granted 1,782 orphan designations.⁸ To be "approved for an orphan indication" the manufacturers undergo a more rigorous process, which includes establishing the safety and efficacy of the drug via clinical trials. Products may obtain more than one approval for orphan indication.⁹

The final interpretation of the ACA's use of the term "orphan drugs" has yet to be decided, and the financial impact of the various scenarios has not been analyzed. HRSA issued proposed regulations on May 20, 2011, which have not been finalized.¹⁰ These regulations call for the exclusion from the 340B discount to be applied exclusively for its approved indication. Pharmaceutical manufacturers opine that a drug that has orphan designation should be exempt regardless of how the drug is used.¹¹ Additionally, legislation has been introduced that calls for a full repeal of the orphan exception.¹²

Though the final policy for implementation of the exclusion has yet to be determined, the objective of this paper is to illustrate how the most conservative interpretation of the policy—a full exemption of all orphan products—has impacted a subset of the entities affected.

Purpose

To quantify the financial impact of the orphan drug exclusion policy in the 340B program for 18 critical access hospitals.

Methods

Selection of Entity Type for Review

This study reviews the invoices for drug purchases from 18 CAHs that participate in the Fairview Purchasing Network (FPN), a group purchasing cooperative operated by Fairview Health Systems in Minneapolis, MN. Sixteen of the hospitals are located in Minnesota and 2 are located in Wisconsin. This study elected to review CAHs because they represent the majority share of rural hospitals that are newly-eligible for 340B.¹³ Moreover, of the new entity types, 77 percent of organizations that have enrolled since the August 1st, 2010 start date for participation are CAHs.¹⁴

Data Collection

Invoice data for 2010 from the 18 CAHs was extracted, categorized and analyzed to identify purchases of drugs with orphan designations and to calculate the price difference between their current cost and the 340B discount for those drugs.

The invoices were initially scanned to identify only 340Beligible purchases. Line items that included products ineligible for 340B, such as vaccines, test strips and other supplies, were excluded. The resulting list of eligible purchases made by the 18 hospitals was indexed against the FDA's Orphan Drug Database to flag those drugs with an orphan designation. This indexing resulted in the identification of 111 unique orphan products.

To calculate the price differences between the hospital's current cost and the 340B price, this study utilized data maintained by FPN. The current cost to the hospitals is based on Wholesale Acquisition Cost or as negotiated by Premier, their Group Purchasing Organization. The 340B list price for the same timeframe was additionally provided through the FPN. Comparisons were made only on line items where there was both a GPO and a 340B price. Prices that were "N/A" or "\$0.00" were also not included in the analysis. The 340B program is for outpatient drugs only, yet CAHs purchasing drugs at the GPO price have not historically been required to split inventory between outpatient and inpatient settings. In the absence of such readily-available data, the authors determined that imputing 100% outpatient use was reasonable for three reasons. First, informal discussions with a number of the CAH pharmacy directors in this study and pharmacists within the FPN about the settings for which these orphan drugs are used confirmed that the vast majority of these products would be used 100% in an outpatient setting. More specifically, most of the drugs reviewed in this study are drugs that would be used in outpatient oncology clinics. Second, CAHs, by definition, provide acute care versus ongoing treatment; as such, patients with rare conditions

would likely be referred to primary and specialty providers to receive more focused care.¹³ Third, in light of this uncertain policy environment, assuming 100% outpatient use of drugs with orphan designations permitted contemplation of the most conservative implementation scenario of the statute. In other words, the findings reflect the maximum amount of lost savings available to CAHs if orphan drugs were fully-excluded from the 340B program.

Result

In 2010, the 18 CAHs' total drug purchases at the GPO price were \$22.5 million. The median annual drug expenditure by hospital was \$1.1 million, with the range spanning \$197,000 to \$3.5 million. The hospitals' expenditures on drugs with orphan designations were high, representing an aggregate 44% of drug purchases (Table 1). In sharp contrast, the aggregate quantity of orphan drugs purchased was only 5%. Due to the high costs of orphan drugs, these products represent an extremely high proportion of the 18 hospitals' expenditures in relation to the number of units purchased. A portion of this difference is explained by the fact that drugs with orphan designations are, on average, more expensive than those without. For example, considering just the 4th quarter of 2010, the average GPO cost for a drug (by NDC) with orphan designation was \$794.00 versus \$94.00 for drugs without the designation.

Based on the price differences between the 340B and GPO price for 2010, had the 18 CAHs' purchases of orphan drugs been available at the 340B price, the savings would total \$3.1 million. By hospital, this translates to an average annual orphan drug savings of \$171,000, or 14% of the average annual total CAH drug budget.

For the top 10 drugs with orphan designations purchased by the 18 hospitals, the difference between the 340B price and the GPO ranged from 12% to 48%, with a median difference of 31%. As illustrated in Table 2, the top 10 drugs with orphan designations that demonstrated the highest potential annual savings from the 340B program for the 18 hospitals were led by Remicade[®], Rituxan[®] and Herceptin[®]. Of the \$3.1 million in total savings projected for the 18 CAHs, these 10 drugs represent \$2.5 million, or 81% of the total calculated savings.

In addition to the cost differences realized at the point of purchase, statutory provisions embedded within the calculation for the 340B price include protections against price increases over time. Though the exact mechanics of the inflation protection mechanism are complex, simply put, when drug manufacturers raise prices in the commercial market faster than the rate of the Consumer Price IndexUrban, a penalty goes into effect, thus reducing the 340B price for the eligible entities. In addition to the difference in the upfront reduction in cost that the 340B program offers, purchasing drugs at the 340B price compared to the GPO price over 2010 results in savings over time. Table 1 shows the opposite direction of the GPO price over the year compared to the 340B price for the 18 hospitals' purchases for the top 5 drugs with orphan designation.

Discussion

The results show that the orphan exception for CAHs has a significantly negative financial impact on these hospitals. Expenditures on prescription drugs are a key concern across the entire health care system, particularly in light of rising pharmaceutical costs, the general state of the economy, the increasing age of the population, and growing use of costly specialty and infusion drugs, which are more likely to have orphan indications. As such, it is important to capitalize on the savings available at the 340B price for these drugs.

Aside from the reduction in costs to these hospitals and the public insurance programs who reimburse them, the orphan drug exclusion elicits a number of larger topics for discussion.

1. The Orphan Drug Exclusion Has Affected Participation in 340B

A discount of between 25%-50% off current drug costs would go a long way in mitigating the financial, staffing and sustainability challenges unique to CAHs.¹⁵ Yet, according to 340B advocacy organizations, the newly covered entities that the law intended to help are not signing up in large part due to the orphan exception.¹⁶ Prior work on the 340B experience of the rural hospitals' made eligible by the 2003 Medicare Modernization Act revealed that one of the most important factors influencing participation was expected cost savings, so the exemption is likely influencing enrollment.¹⁷ Even HRSA has acknowledged the possibility that the lack of access to 340B pricing on orphan drugs is dissuading enrollment, "we have heard during national conferences that may be the case."¹⁸

Though a CAH should consider other variables, such as implementation and compliance costs, when calculating the net effect of participation in 340B, reservations about the potential for savings on non-orphan products will likely influence the decision to participate. In the fall of 2010, the Safety Net Hospitals for Pharmaceutical Access and the National Rural Health Association partnered to advocate for a repeal of the orphan drug exemption for the new entity types. The two organizations administered a survey to 140 eligible facilities and found that 82 percent reported that the removal of the exclusion was "very important," and that expenditures on these drugs comprised a significant share of general drug budgets. $^{\rm 19}$

2. Decreased Access to the 340B Program for Savings Can Affect Patient Care

Previous studies have found that the 340B discount produces savings that are used in a number of ways, such as serving more patients, offsetting the cost of uncompensated care for the uninsured or underinsured, and increasing the scope of services offered.²⁰ A 2004 survey of 340B participants found that savings from the discount can "increase and/or improve services at the hospital, offset losses in other departments, reduce medication prices to the patient, and increase the quantity and/or variety of drugs available."²¹ In June 2011, the Safety Net Hospitals for Pharmaceutical Access (SNHPA) released a report on the value of the drug discount program to patients and hospitals. The survey of over 600 member hospitals found that the program is critical to hospital operations; the savings from the program reduce costs to patients, and increase patient access to pharmacy services.²² In summary, reducing the potential savings available to these entities impacts their ability to provide these important services.

3. Use of Drugs with Orphan Designation is not Limited to Rare Diseases

The policy to exempt orphan drugs from the 340B program for these entities does not seem to consider the total use of the drug and its market reach. Drugs with orphan designations often have more common applications, and the orphan indication may just be one of the many approved uses of the drug. As a result, the total use of an orphan product can be considerably more widespread than imagined, reducing the notion of "rare" use. In fact, 25 of the top 100 products in the US market by sales in 2009 were orphan designated drugs.²³

Orphan drugs, which include cancer treatments, blood products and other infused specialty medications, are among the most expensive products on the market and, consequently, often represent a significant share of a hospital's pharmacy budget. Through 2010, the largest clinical sub-category of drugs that have received orphan designation is oncology products.²⁴ Of the top 10 orphan drugs ranked by potential 340B savings to the 18 hospitals, nine are oncology products.

4. The Impact of the Orphan Exclusion will Increase with Time

It is also important to note that the number of drugs with orphan designations is growing and forecast to be the next generation of blockbusters for the pharmaceutical industry. The FDA is currently reviewing a record number of orphan drugs under development, increasing the total number of drugs potentially ineligible to CAHs at the 340B discount.²⁵ According to market forecasts, six of the top ten best-selling drugs in the US in 2016 will be products with orphan designations, including Rituxan, Humira, Avastin, Revlimid, Enbrel, and Remicade, representing projected sales of \$18.9 billion.²⁶

Moreover, once a product is granted orphan designation, it is always considered an orphan drug. Though the market exclusivity will eventually expire, the orphan designation will not, thereby preventing any future discounts to the CAHs under this policy.

Study Limitations

There are a number of limitations to this study. First, this study reviewed the data for a small subset of geographicallylinked hospitals that participate in a single purchasing network, eliminating the ability to generalize the findings to the rest of the CAHs in the country. It was not the objective of this research to compute a national estimate for the impact of the orphan drug exclusion at this time. Instead, the authors sought to provide numbers on the group studied as an example of the impact of this policy.

Second, this study did not conduct any multivariate analysis to account for variation in the CAH expenditures and utilization of orphan drugs. There are many variables that can influence a hospital's budgetary considerations and a complete analysis of them was beyond the scope of this initial look at the impact of a policy on a sub-set of hospitals.

Third, the authors contemplated estimating outpatient use by applying a proportional outpatient use for drugs that is reported for other outpatient services on each CAH's annual Medicare Cost Report, but imputing 100 percent utilization for the drugs with orphan designation was deemed more reasonable. Outpatient revenue estimates encompass a wide variety of outpatient services available at the hospital, so the equal application to utilization of orphan drugs is inadequate, a fact confirmed through our informal discussions with a number of CAH's pharmacy directors. At the same time, determining the *actual* outpatient use for the year by the drug would have been overly burdensome to the CAH or to FPN.

Fourth, this study only compared savings on purchases, which do not equate to the actual savings that would be realized by a CAH because of the impact of the lower pharmacy expense that would be reported on the hospital's Medicare Cost Report. This lower cost will ultimately reduce the cost-based reimbursement payments to the CAH by the Medicare program and, thus, the actual savings achieved will be somewhat less than what is reported here. However, applying the reduced costs to each institution's Medicare reimbursement formula was beyond the scope of this project. This point highlights the relationship between the costs of a CAH and the Medicare program. The orphan drug exclusion not only impacts the potential 340B savings that can be achieved by a CAH, it also creates a missed savings opportunity for Medicare.

Finally, this research does not assess the impact of the orphan exclusion policy on pharmaceutical manufacturers, as it was beyond the scope of the objectives.

Conclusion

Congress intended for the 340B program to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."²⁷ By extending the discount program to these new entity types, one could reasonably assume Congress had the same intention; yet, this study highlights how the orphan drug exception diminishes the value of participation to the entities. Given the financial impact demonstrated through this research and the current economic state, it is reasonable to conclude that the policy of excluding high-cost, commonly-used drugs from the 340B program should be reconsidered. Although this study reviewed only 18 of the over 1320 CAHs in the country, the notion of applying the average per-hospital savings of \$171,000 to all CAHs does generate critical questions about if or how this exclusionary policy should be adopted.

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	2010 Total Overall Drug	2010 Total Orphan Drug	Percent	2010 Total	2010 Total	Percent
CAH	Expenditures	Expenditures	Orphan	Overall Units	Orphan Units	Orphan
1	\$611,722	\$252,171	41%	6,224	390	6%
2	\$919,136	\$445,020	48%	10,088	469	5%
3	\$197,448	\$14,837	8%	4,737	32	1%
4	\$366,601	\$122,496	33%	4,427	165	4%
5	\$2,244,008	\$1,203,799	54%	16,465	1,213	7%
6	\$479,551	\$268,207	56%	4,337	348	8%
7	\$1,472,564	\$669,950	45%	8,866	519	6%
8	\$3,454,319	\$1,531,206	44%	27,946	1,966	7%
9	\$967,910	\$448,809	46%	8,872	731	8%
10	\$578,904	\$97,773	17%	13,302	94	1%
11	\$2,854,039	\$1,233,195	43%	19,628	1,241	6%
12	\$665,157	\$391,909	59%	4,990	339	7%
13	\$408,254	\$196,958	48%	3,483	180	5%
14	\$1,458,824	\$578,311	40%	14,561	709	5%
15	\$1,247,412	\$630,449	51%	13,568	695	5%
16	\$1,773,977	\$864,936	49%	13,845	900	7%
17	\$1,597,629	\$966,611	61%	13,689	1,023	7%
18	\$1,188,733	\$27,713	2%	14,243	42	0%
Totals	\$22,486,188	\$9,944,348	44%	203,271	11,056	5%

TABLE 1: Relationship Between Total Drug Expenditures and Total Spent on Drugs with Orphan Designations by Hospital, 2010

TABLE 2: Top 10 Drugs by 340B Savings Potential for the 18 Hospitals, 2010

NDC	Drug	Generic Description	CAH Cost, 2010	340B Cost, 2010	Total Savings Potential
50242005306	RITUXAN SDV 500MG 50ML	RITUXIMAB	\$1,630,881	\$920,535	\$710,346
57894003001	REMICADE PWD 100MG IN 20ML VL1	INFLIXIMAB	\$2,115,176	\$1,544,240	\$570,936
50242013468	HERCEPTIN MDV 440MG 20ML 1	TRASTUZUMAB	\$1,085,706	\$698,494	\$387,212
50242005121	RITUXAN SDV 100MG 10ML	RITUXIMAB	\$703,772	\$394,792	\$308,980
50242006101	AVASTIN VIAL 400MG 16ML	BEVACIZUMAB	\$864,056	\$720,943	\$143,113
63020004901	VELCADE VIAL 3.5MG D/SHIP 10ML	BORTEZOMIB	\$312,672	\$195,666	\$117,006
00002762301	ALIMTA SDV 500MG 50ML	PEMETREXED DISODIUM	\$386,546	\$271,891	\$114,656
00078038725	ZOMETA CONC VIAL 4MG 5ML	ZOLEDRONIC ACID	\$337,618	\$272,597	\$65,021
00024059120	ELOXATIN VIAL AQ 100MG 1	OXALIPLATIN	\$205,067	\$144,156	\$60,911
63459039120	TREANDA VL 100MG 20ML	BENDAMUSTINE HCL	\$384,884	\$328,306	\$56,578
			Total		\$2,534,759