

The Impact of Patient Assistance Programs and the 340B Drug Pricing Program on Medication Cost

Yelba M. Castellon, MD; Shahrazad Bazargan-Hejazi, PhD; Miles Masatsugu, MD;
and Roberto Contreras, MD

Objectives: Patient assistance programs and the 340B Drug Pricing Program promise to improve the financial stability, better serve vulnerable patients, and decrease the burden of cost for uninsured patients. Our objective is to examine the financial impact that PAPs and the 340B Program have on improving medication cost.

Study design: Retrospective analysis of medication dispensary data.

Methods: Dispensary data for uninsured patients obtaining medications at 2 community health centers were collected from February 1 to February 29, 2012. Uninsured patients were divided into 2 samples: (1) patients receiving PAP medications and (2) patients receiving 340B medications. The main outcome measured was the patient's cost savings. Cost savings were calculated based on the amount a medication would have cost had it been purchased by patients at prices found on Epocrates software (drugstore.com). A paired sample *t* test model using continuous variables was utilized to calculate confidence intervals.

Results: A total of 1420 PAP and 2772 340B individual medications were dispensed to uninsured patients in February 2012. For patients receiving PAP medications the mean \pm standard deviation (SD) for age = 52 ± 10 . Average cost was \$0.11 (95% CI, \$0.04-\$0.17) and average savings was \$617.36 (95% CI, \$581.32-\$653.40). For patients receiving 340B medications the mean \pm SD for age = 50 ± 14 . Average cost was \$11.50 (95% CI, \$10.55-\$12.45). Average saving was \$62.31 (95% CI, \$57.99-\$66.63).

Conclusions: PAPs and 340B provide significant medication savings for uninsured patient. More research is needed to establish "best practices" for the successful integration of PAPs.

Am J Manag Care. 2014;20(2):146-150

For author information and disclosures,
see end of text.

Medications play an essential role in the prevention and treatment of disease. Moreover, adherence to drug regimens has proved to be a primary determinant of successful clinical outcomes.¹ However, medication cost continues to be a common barrier to medication access. In fact, research shows that chronically ill patients report cost of medications as a cause for underusing prescription medications. One recent study found that 14% of heart failure patients with prescription drug coverage and 25% of those without medication coverage failed to fill 1 or more prescriptions because of cost.² Health economic studies in the United States demonstrate that consumption of prescribed drugs is reduced with increasing copayments.³

Medication underuse has a negative effect on healthcare outcomes.^{4,5} A recent large-scale study of elderly and welfare recipients in Canada found that the reduced consumption of essential drugs, caused by the introduction of a copayment scheme, led to an increased number of adverse events including increased emergency department visits, acute care hospitalization, long-term care admission, and death.^{6,7} Inadequate access to medications is especially problematic for the low-income and uninsured populations who often resort to alternative cost-reducing strategies such as not having medication dispensed at all, delaying until payment is possible to fill the prescription, or reducing the dose in order to make the medication last longer.⁸ In fact, recent health policy literature has cited racial and ethnic minority status, female gender, lack of health insurance, low income, disability, and chronic illness as being positively associated with cost-related nonadherence.⁹ As such, it is important to explore ways in which access to medications can be increased for these vulnerable patient populations.

In order to address these barriers and better provide low-income and uninsured patients with improved access to medications at low or no cost, safety net clinics have adopted programs such as pharmaceutical-sponsored patient-assistance programs (PAPs) and the 340B Drug Pricing Program. These programs promise to improve the financial stability of those entities, better serve vulnerable patients, and decrease the burden of cost for patients. PAPs rely on pharmaceutical manufacturers to help serve indigent populations. These philanthropic programs are sponsored by pharmaceutical manufacturers who provide eligible patients with brand name prescription medica-

In this article
Take-Away Points / p147
www.ajmc.com
Full text and PDF

tions at a low cost or at no cost based on income qualifications. Patients are typically screened for eligibility by clinic support staff. An application is then submitted to the drug manufacturer by the clinic on behalf of the patient. Medications are subsequently sent to the clinic to be dispensed to the applicant. In order to comply with eligibility requirements, patients must reapply on an ongoing basis.

The purpose of the 340B prime vendor program is to reduce the price of outpatient prescription and over-the-counter (OTC) drugs to Covered Entities including federally qualified health centers (FQHCs) and disproportionate share hospitals. Covered entities can only dispense an outpatient medication at these reduced prices to “patients” of the Covered Entity. Patients must have an established relationship with the Covered Entity such that the Entity maintains records of the individual’s healthcare and they must receive healthcare from a healthcare professional who is employed or under contractual arrangement with the Covered Entity.¹⁰ The 340B Drug Pricing Program was created in 1992 to provide financial relief to safety net organizations that provide care for the medically underserved.¹⁰ It resulted from the enactment of Public Law 102-585, the Veterans Healthcare Act, which is codified as Section 340B of the Public Health Services Act. Eligibility and enrollment for 340B is administered by the Office of Pharmacy Affairs, an arm of the Health Resource and Services Administration (HRSA). Participants in 340B must follow strict policies and procedures to ensure adherence to program eligibility guidelines. The 340B Program establishes a ceiling price, which is the maximum price a manufacturer can charge the Covered Entity. Those prices are calculated quarterly by manufacturers. Savings translate into 20% to 50% of the average wholesale price (AWP) for entities enrolled in this program.¹⁰ Medications are purchased in bulk from 340B vendors at reduced prices and dispensed to clinic patients at the time of the visit.

Dispensaries associated with safety net clinics play an important role in making medications accessible for underserved patients. They provide low-cost or no-cost medications through programs such as PAPs and 340B which promise to extend significant medication cost savings for the uninsured. While many of the studies have shown cost saving afforded to Covered Entities through participation in programs such as 340B and PAPs,¹⁰⁻¹⁴ the objective of this study is to examine the financial impact of these programs on improving medication cost for patients.

Take-Away Points

Utilization of programs such as Patient Assistance Programs (PAPs) and the 340B Drug Pricing Program can provide significant medication savings for uninsured patients. In this study, patients receiving PAP medications:

- Had a lower cost of medications per visit and a higher cost savings per visit. This can be explained by the fact that eligible PAP medications are exclusively brand name prescription drugs which are typically more expensive when compared with the cost of the same generic drug purchased through the 340B program.
- On the other hand, while the savings for 340B medications were less than that of PAPs, the 340B Program allows for purchasing both generic prescription drugs and over-the-counter drugs.

METHODS

We performed a retrospective data analysis of dispensary data for uninsured patients obtaining outpatient medications at 2 community-based FQHCs. Dispensary data were collected from February 1 to February 29, 2012. In order to be eligible for this study, patients had to meet the following requirements: They had to be (1) seen at the clinic for primary care; (2) not have third-party payer for outpatient medication benefits (patients eligible for medical or other government-sponsored outpatient pharmacy benefits were not eligible); (3) have income at or below the 100% poverty level; and (4) require a medication that is on the formulary. All patients were routinely screened for PAP eligibility. If a patient is eligible for PAP based on the medication they require and their income status, an application is submitted by the clinic support staff to the manufacturer on behalf of the patient. Medications are then mailed from the manufacturer directly to the clinic to be dispensed on-site. Patients that are not eligible for PAPs receive 340B medications, provided they meet the eligibility criteria. 340B medications are purchased in bulk at discounted prices and dispensed to patients at their purchase price. All dispensary transactions are recorded by the dispensary software.

Uninsured patients were divided into 2 samples: (1) patients receiving PAP medications and (2) patients receiving 340B medications. The main outcome measured was the patient’s cost savings. Cost savings were calculated based on the amount a medication would have cost if it had been purchased by patients at prices found on Epocrates software (drugstore.com) during the month of February 2012. A paired model using continuous variables was utilized to calculate confidence intervals (SPSS, 2010).

RESULTS

Patients served at the Community Health Center were 3% African American, 3% Asian, 81% Latino, 12% White, 1% Other. A total of 81% of the patients reported

■ **Table 1.** Demographics of Patients Served at East Valley Community Health Center

Characteristic	% of patients
Race	
African American	3
Asian	3
Latino	81
White	12
Other	1
Below Federal Poverty Level	
100%	81
101-105%	13
151-200%	3
Over 200%	3
Insurance Status	
Insured	25
Uninsured	75
Language Preference	
English	51
Other	49

■ **Table 2.** Commonly Dispensed Medications Under Patient Assistance Programs (PAPs) and 340B With Average Costs for a 1-Month Supply

PAP		340B	
Lantus	\$128.30	Metformin	\$5.15
Neurontin	\$340.22	Glyburide	\$2.87
Singulair	\$487.95	Insulin	\$8.29
Diovan	\$263.28	Hydrochlorothiazide	\$1.89
Protonix	\$529.99	Atenolol	\$1.68
Januvia	\$657.94	Simvastatin	\$2.63
Norvasc	\$271.00	Acetaminophen	\$0.68
Nasonex	\$130.99	Fluoxetine	\$2.60
Apidra	\$47.99	Amitriptyline	\$1.14
Procardia	\$433.29	Azithromycin	\$23.82

to be 100% below federal poverty level, 13% were 101% to 105% below federal poverty level, 3% were 151% to 200% below federal poverty level, and 3% were over 200% below federal poverty level. Seventy-five percent (75%) of the patients were uninsured, 25% were insured. Slightly over half (51%) of the patients spoke English as their language of preference and 49% spoke another language (see **Table 1**).

A total of 1420 PAP and 2772 340B individual medications were dispensed to uninsured patients in February 2012. The list of commonly dispensed medications under each program with average costs for a 1-month supply is included in **Table 2**.

Patients in the sample were mostly women (71.6%) with a mean +/- SD age of 50.1 +/- 27.0 years. For patients receiving PAP medications the mean +/- SD for age = 52 +/- 10. Average cost of medications per visit was \$0.11 (95% CI, \$0.04-\$0.17) and average savings per visit was \$617.36 (95% CI, \$581.32-\$653.40). For patients receiving 340B medications the mean +/- SD for age = 50 +/- 14. Average cost of medications per visit was \$11.50 (95% CI, \$10.55-\$12.45). Average savings on medications per visit was \$62.31 (95% CI, \$57.99-\$66.63).

DISCUSSION

Pharmacies associated with safety net clinics play an important role in making medications accessible for low-income and uninsured patients by providing low-cost or no-cost medications. Utilization of programs such as PAPs and 340B, FQHCs can provide significant medication savings for uninsured patients. In this study, patients receiving PAP medications had a lower cost of medications per visit and a higher cost savings per visit. This can be explained by the fact that eligible PAP medications are exclusively brand name prescription drugs, which are typically more expensive when compared with the cost of the same generic drug purchased through the 340B program. On the other hand, while the savings for 340B medications were less than those for PAPs, the 340B program allows for purchasing both generic prescription drugs and OTC drugs. In addition, there were almost twice as many 340B medications dispensed in the month of February, providing increased access to medications for patients who may not otherwise have been able to afford their medications. Both 340B and PAPs were successful in providing significant medication cost savings for patients.

Enabling patients to gain access to necessary medications allows for greater adherence to prescribed therapy and better healthcare outcomes. However, it is important to consider the limitations associated with each of these programs.

While individual studies have demonstrated cost savings to healthcare institutions,^{15,16} other studies have suggested that there are many barriers to using PAPs. In a study assessing use of PAPs by 215 safety net clinics in California, Texas, and Florida, 67% of clinics not using PAPs for eligible patients reported that PAPs applications were too time consuming and complex.^{14,17,18} In addition, clinics reported investing substantial staff resources to managing PAP applications.¹⁷ Other

potential barriers frequently cited were program requirements changing without notice, unrealistic income documentation requirements for indigent patients, frequent reapplication required by patients, and applications differing among companies.¹⁷ One study asked clinic staff to provide potential improvements to PAPs and found that 84% of respondents noted there is a need for standardization of the PAP application and reapplication process across PAP programs, and 83% recommended a standardized eligibility criteria across all programs.¹⁷ While PAP software has been developed in order to address some of these shortcomings and attempt to streamline the PAP application process, there is no single program that can meet the needs of every organization. Therefore, organizations must take a close look at their needs and compare them with the features of each program in order to find the best fit.¹⁸ In addition, the individual cost of software must also be taken into account.

Likewise, 340B provides economic benefits to participating organizations.^{11,12,19,20} However, these benefits do not come without challenges. Among the most commonly cited challenges is that eligible 340B sites must know how to interpret complex eligibility rules and 340B regulations, which are constantly changing.^{10,19} In addition, there is an increased need for price transparency and program oversight by HRSA in order to ensure drug manufacturer compliance with drug contract pricing.²¹ One article quotes a report issued by the Office of Inspector General regarding 340B that stated: "Theoretically, the government and manufacturers should calculate the same ceiling price because they use the same numbers. However, HRSA does not check and thus is unable to detect whether manufacturers perform the calculation properly and whether entities are paying the correct ceiling prices."²¹

Other limitations include the need for an onsite dispensary for participating 340B entities, although studies have shown that organizations are finding creative ways to maneuver around this obstacle by providing remote dispensing via 2-way videoconferencing.²² The clinic where this study took place struggled with finding access to "penny medications," which are medications that go on sale on a quarterly basis from the pharmaceutical manufacturers, at a cost of 1 cent. These medications are sold via the major distributors, but they are not advertised, nor are they listed under normal search functions on distributors' websites, making them difficult to purchase. Moreover, funding was limited for purchasing more sophisticated and comprehensive ordering software.

Limitations

Some of the limitations of the study were that cost savings were calculated using average market value versus other, more

affordable alternatives such as the Walmart \$4 Prescription Program. Also, drug pricing was not retrospectively graded and may not accurately represent what patients would have paid, given that online drug prices were used. In addition, fluctuating market prices made it difficult to perform this analysis retrospectively over time. Lastly, this study focused only on cost savings for patients, while to sustain a program, it should be cost-effective for the safety net clinic.

Although the 340B Program may serve as an alternative to PAPs in cases where there is limited support staff and funding, more research is needed to establish "best practices" for the successful integration of PAPs and/or 340B among safety net clinics. Future studies should further explore a cost/benefit analysis for both programs. Particularly, there is a need for comparisons of the cost-effectiveness for patients using PAPs with those for patients using other options that minimize medications costs.²³ Other issues to consider are how these programs will be impacted with the implementation of healthcare reform. Some believe that PAPs can be more costly in the long run as they encourage patients to rely on using more costly brand name prescriptions if and when they acquire insurance.

Author Affiliations: Charles R. Drew University of Medicine and Science, Los Angeles, CA (YC, SBH); David Geffen School of Medicine, University of California Los Angeles (SBH, YC); East Valley Community Health Center, West Covina, CA (MM, RC).

Source of funding: None reported.

Author Disclosures: The authors (SBH, YC, MM, RC) report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design (SBH, MM, YC); acquisition of data (BWS, MM, YC, RC); analysis and interpretation of data (SBH, MM); drafting of the manuscript (SBH, MM, YC); critical revision of the manuscript for important intellectual content (SBH, MM, YC, RC); statistical analysis (YC); provision of study materials or patients (SBH, RC); administrative, technical, or logistic support (SBH, MM, YC, RC); supervision (SBH, MM, RC).

Address correspondence to: Shahrzad Bazargan-Hejazi. Charles R. Drew University of Medicine and Science, 1731 E 120th St, Los Angeles, CA 90059. E-mail: shahrzadbazargan@cdrewu.edu.

REFERENCES

1. De Geest S, Sabaté E. Adherence to long-term therapies: evidence for action. *Eur J Cardiovasc Nurs.* 2003;2(4):323.
2. Kitchman M, Neuman T, Sandman D, et al. Seniors and prescription drugs: findings from a 2001 survey of seniors in eight states. Menlo, CA: Henry J. Kaiser Family Foundation; 2002.
3. Stuart B, Grana J. Ability to pay and the decision to medicate. *Med Care.* 1998;36(2):202-211.
4. Schafheutle EI. The impact of prescription charges on asthma patients is uneven and unpredictable: Evidence from qualitative interviews. *Prim Care Respir J.* 2009;18(4):266-272.
5. Tseng CW, Brook RH, Keeler E, Steers WN, Mangione CM. Cost-lowering strategies used by medicare beneficiaries who exceed drug benefit caps and have a gap in drug coverage. *JAMA.* 2004;292(8):952-960.
6. Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *JAMA.* 2001;285(4):421-429.

7. Piette JD, Heisler M, Wagner TH. Cost-related medication underuse: do patients with chronic illnesses tell their doctors? *Arch Intern Med.* 2004;164(16):1749-1755.
8. Schafheutle EI, Hassell K, Noyce PR, Weiss MC. Access to medicines: cost as an influence on the views and behaviour of patients. *Health Soc Care Community.* 2002;10(3):187-195.
9. Kennedy J, Tuleu I, Mackay K. Unfilled prescriptions of Medicare beneficiaries: prevalence, reasons, and types of medicines prescribed. *J Manag Care Pharm.* 2008;14(6):553-560.
10. Werling K, Abraham S, Strelec J. The 340B Drug Pricing Program: an opportunity for savings, if covered entities such as disproportionate share hospitals and federally qualified health centers know how to interpret the regulations. *Health Care Law Mon.* 2007:3-12.
11. Barlas S. The 340B Discount Drug Program at Ozarks Medical Center: an economic stimulus plan for Missouri. *PT.* 2011;36(5):280-281.
12. Bright DR, Adams AJ, Akala FO, Lengel AJ, Martin SJ, Powers MF. Implementation of a \$4 generic drug program in a 340B pharmacy. *Am J Health Syst Pharm.* 2010;67(11):929-931.
13. Harmon GN, Lefante J, Roy W, et al. Outpatient medication assistance program in a rural setting. *Am J Health Syst Pharm.* 2004;61(6):603-607.
14. Mounts VL, Ringenberg DG, Rhees K, Partridge C. Implementation of a patient medication assistance program in a community pharmacy setting. *J Am Pharm Assoc (2003).* 2005;45(1):76-81.
15. Coleman CI, Reddy P, Quercia RA, Gousse G. Cost-benefit analysis of a pharmacy-managed medication assistance program for hospitalized indigent patients. *Am J Health Syst Pharm.* 2003; 60(4):378-382.
16. Weiner S, Dischler J, Horvitz C. Beyond pharmaceutical manufacturer assistance: broadening the scope of an indigent drug program. *Am J Health Syst Pharm.* 2001;58(2):146-150.
17. Duke KS, Raube K, Lipton HL. Patient-assistance programs: assessment of and use by safety-net clinics. *Am J Health Syst Pharm.* 2005;62(7):726-731.
18. Petrarca AM, Lengel AJ, Powers MF. Comparison of patient assistance program software. *Am J Health Syst Pharm.* 2011;68(14):1331-1338.
19. Keough CL, Webster SA. 340B program presents opportunities--and challenges. *Healthc Financ Manage.* 2009;63(11):42-44, 46, 48.
20. Radford A, Slifkin R, Schur C, Cheung K, Baernholdt M. Rural hospitals: are you missing out on drug savings? *Healthc Financ Manage.* 2008; 62(6):82-85.
21. Young D. Persistent problems plague 340B program. *Am J Health Syst Pharm.* 2006;63(1):8, 10, 12.
22. Clifton GD, Byer H, Heaton K, Haberman DJ, Gill H. Provision of pharmacy services to underserved populations via remote dispensing and two-way videoconferencing. *Am J Health Syst Pharm.* 2003; 60(24):2577-2582.
23. Felder TM, Palmer NR, Lal LS, Mullen PD. What is the evidence for pharmaceutical patient assistance programs? a systematic review. *J Health Care Poor Underserved.* 2011;22(1):24-49. ■