

White Paper

Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?

RORY MARTIN, PHD, IQVIA Market Access Center of Excellence **KEPLER ILLICH, MA,** UC Davis School of Economics

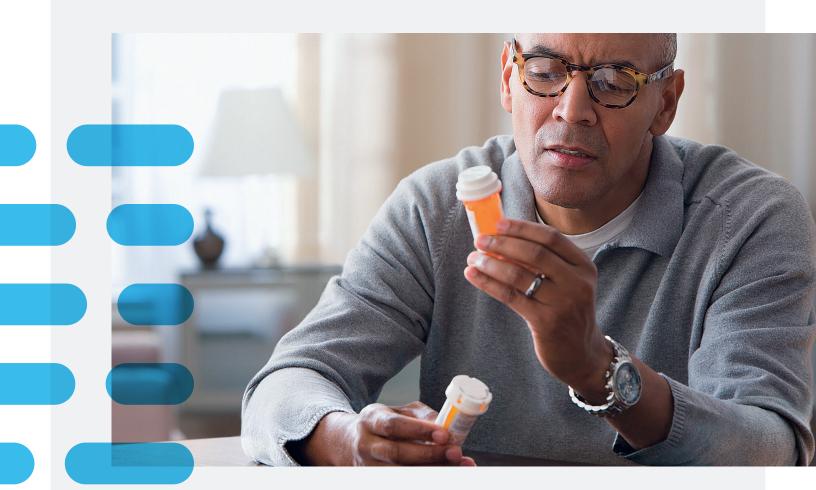


Table of contents

	Abstract	3
	Introduction	4
	340B prescription discount cards	5
)	Methods	6
,	Pharmacy claims data	6
	Challenges measuring discount sharing	6
	Estimation of 340B eligibility	6
	Testing the 340B eligibility algorithm	7
)	Identification of 340B prescription discount cards	7
	Study design for 340B discount sharing	8
١	Limitations	9
,	Results	9
	Discussion	11
	Acknowledgements	12
	Funding	12
	References	13
	About the authors	15

Abstract

The 340B Drug Discount Program is a federal program in which manufacturers provide Medicaid-like discounts on covered outpatient drugs to qualifying hospitals and clinics. This cross-sectional study examined whether 340B discounts are directly shared with patients, studying the impact of 340B eligibility on patient out-of-pocket costs at contract pharmacies. A method for estimating 340B eligibility was developed and applied to IQVIA pharmacy claims data. In addition, we developed a method for identifying claims using a 340B prescription discount card, a discount card designed to share 340B discounts with patients. The study spanned 12 months and used a national sample of pharmacy claims for branded, patient-administered drugs. The only claims segment displaying substantial evidence of patient discountsharing was the 1.4% of 340B-eligible pharmacy claims that used a 340B discount card. Here, patient out-of-pocket costs were reduced by 92.9%, with a mean reduction in patient out-of-pocket costs for 30 days of therapy of \$661.65. These findings demonstrate that 340B discount sharing at the point of sale at contract pharmacies is possible, but that most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts.

Introduction

The 340B program was created in 1992 in an effort "... to reverse the unintended, but nonetheless pernicious effects of loopholes" of another federal drug price program: the Medicaid Drug Rebate Program¹. There is ongoing debate about who should benefit from 340B program drug discounts. Hospitals and grantees assert that the purpose of 340B discounts is to allow them to provide additional services and uncompensated care². Manufacturers believe that under-served patients should directly receive 340B program value, that third-party vendors and for-profit contract pharmacies may be inappropriately benefitting from the discounts, and that additional transparency regarding the use of discounts is essential to long-term 340B program sustainability³. However, there is no requirement for providers to pass on 340B discounts to patients. In 2018, the U.S. Government Accountability Office (GAO) published a survey⁴ of hospitals and clinics participating in the 340B program ("covered entities") to explore the use of contract pharmacies: external pharmacies contracted to the hospital or clinic which deliver drugs to patients. Of 55 respondents, 30 reported they offered low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies.

When the 340B program began in 1992, drugs were delivered to patients using only entity-owned pharmacies or through clinics; contract pharmacies did not exist. In 1996 the Health Resources and Services Administration (HRSA), which administers the 340B program, recognized contract pharmacies but there was a limit of one per covered entity⁴. This was broadened in 2010 to allow an unlimited number of contract pharmacies, and today some covered entities have contract pharmacy networks spanning hundreds of outlets.

The flow of 340B revenue from manufacturer to patient via multiple stakeholders is illustrated in Figure 1. In 2021, manufacturers supplied \$94B of product dollarized at WAC⁵. Wholesalers generate revenue

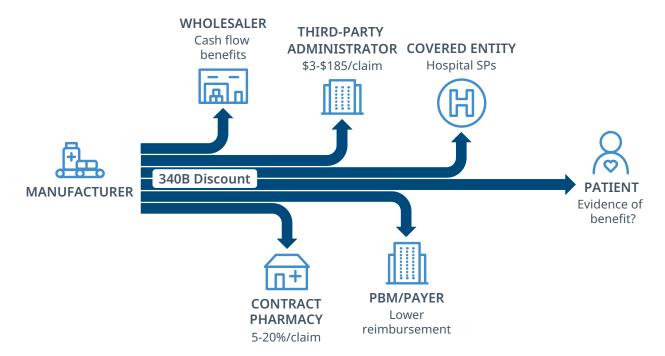
from 340B primarily from cash flow benefits from 340B chargebacks⁶. Pharmacy dispensing fees may be paid as a percentage of actual acquisition cost (e.g., 5% for generics up to 15% for specialty products⁷) or as a percentage of profit. Third-party administrators charge fees for set-up, referral capture, switches, and per transaction, the latter ranging from \$3 per claim for generics to \$185 per claim or higher for specialty products⁷. PBMs, payers, and plan sponsors may use lower reimbursement to shift 340B revenue to themselves, and may claim manufacturer rebates on 340B prescriptions. Covered entities pay vendors to build out hospital-owned specialty pharmacies (SPs) to increase 340B revenue.

Given the above, it's unclear how much benefit flows past the other stakeholders directly to the patient. Our study sought to answer this question by examining a large national sample of covered entities, contract pharmacies, and patient-administered pharmaceutical products.

340B PRESCRIPTION DISCOUNT CARDS

Two mechanisms that covered entities use to share 340B discounts with patients are 340B prescription discount cards and local cash BIN/PCN/GROUPs. BIN/ PCN/GROUPs are numbers used by pharmacies and payers to exchange claim information. Third-party administrators managing data and patient eligibility for covered entities in contract pharmacy relationships offer 340B discount cards as an option, and the entity selects rules defining how much discount to share. Eligibility tests are performed on the prescriber, the patient, and the product versus the allowed formulary, and ineligible claims may be routed to a backup cash discount card. Some entities report offering 340B cards only to lowincome patients⁴ while others use different strategies to distribute the cards. Not all contract pharmacies accept 340B discount cards. For example, pharmacies that are vertically integrated with a 340B discount card vendor may not accept 340B cards from other vendors.

Figure 1. Flow of revenue to 340B program parties. Example fees or revenue are shown below the name of each party.



To avoid paying fees associated with 340B discount cards, covered entities sometimes use a different mechanism to share 340B discounts with patients at entity-owned pharmacies: a local cash BIN/PCN/GROUP. Such claims may not be routed through a switch, so their capture rate in the IQVIA data assets used for our study is low. For this reason, the current study was limited to discount-sharing at contract pharmacies only.

340B discount cards operate differently from the cash discount cards that most people are more familiar with. For each pharmacy, the cash card collaborates with PBMs that have contracts with the pharmacy and passes on a negotiated rate to the patient. In contrast to 340B discount cards, these cards have few restrictions on usage: they're freely available to any type of patient, and can be used at any pharmacy that accepts them, and most do. While cash discount cards apply to both branded and generic products, 340B discount cards often apply to branded products only, since many covered entities don't convert claims involving generics to a 340B sale because it's unprofitable to do so.

Methods

PHARMACY CLAIMS DATA

Pharmacy claims were sourced from IQVIA's Longitudinal Access and Adjudication Dataset (LAAD) reference data having coordination of benefits data, which we used to calculate the cost of filling prescriptions, and which was available for about half of LAAD claims. Claims spanned all U.S. pharmaceutical products including branded and generic drugs and all disease areas. Because prescriptions can be written for different quantities of medication, script volume was weighted by days of therapy. Thus, a script for 90 days of therapy would have three times the weight of a 30-day script.

CHALLENGES MEASURING DISCOUNT SHARING

A handful of factors make identifying 340B discount sharing challenging. First, 340B policy speaks of patients, but discount sharing has to be quantified using claims data; this is discussed in detail below. Second, there is a lack of data available to researchers that

directly captures the 340B status of pharmacy claims. Finally, once the 340B eligibility of the claim is known, a final "conversion" step determines its 340B status, which adds complexity. Most contract pharmacies use a replenishment model in which claims are filled with neutral inventory, and the covered entity selects the ones to convert to 340B after the claims are filled8. Covered entities use sophisticated conversion strategies to maximize cash flow and/or profitability, such as converting branded products but not generics9.

ESTIMATION OF 340B ELIGIBILITY

We developed a method to classify 340B-eligible pharmacy claims despite unclear federal statute and guidance and inconsistent application of that by stakeholders. The 340B statute points to the Medicaid statute to define the term "covered outpatient drug"¹⁰, and the 340B statute prohibits diversion with this statement: "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity" 10. A 26-year-old federal guidance called the Patient Definition provides high-level suggestions for determining which patients are 340B eligible¹¹, and government enforcement of this guidance is the subject of ongoing litigation¹². However, the concept of determining which prescriptions are 340B eligible is not defined by statute or even by guidance at all. In practice, hospitals and clinics often pay a third-party vendor to apply the general principles of the Patient Definition to a patchwork of available data points from health records, payers, and pharmacy transactions. The hospital or clinic chooses from a menu of variable filter logic offered by the vendor to determine prescription capture. The Office of Inspector General found widespread inconsistency in approaches in the marketplace¹³.

This lack of transparency is further complicated by no public source of data for nearly any aspect of utilization of the program. For example, unlike other federal drug programs there is no accessible data that confirms which claims were actually converted by purchasers, and no public analysis of all 340B sales or associated growth

drivers over time. Additional complexity is introduced when third-party contract pharmacies are involved, and 340B conversion becomes almost invisible due to the multiple parties and non-transparent data exchanges among them.

Absent actual data from entities or vendors, the current study has aimed to replicate the general approach used by hospitals and clinics as they translate government policy on patient eligibility to 340B converted prescriptions. To do this, two conditions were used:

- C1. Was the prescription written at a covered entity?
- C2. Was the script filled at an entity-owned pharmacy or at one of the entity's contract pharmacies?

Conditions C1 and C2 are likely to be conservative. For example, when a patient of a community health center federal grantee is referred to a specialist at a different facility, some community health centers convert the specialist's prescriptions to 340B as if they were their own, regardless of whether the specialist's facility is a covered entity or not (see the discussion in¹⁴ for further details).

Conditions C1 and C2 were used to calculate an eligibility score: the likelihood a pharmacy claim was eligible to be filled with 340B product. A claim with a score of 100% is 340B-eligible, one with a score of zero is non-eligible, and values in-between indicate uncertainty, which arises in condition C1 because there is incomplete knowledge about where claims were written. The facility where the prescription was written was estimated using billing provider information captured on medical claims. For each HCP, a distribution was created for the percentage of effort spent at different facilities, and estimates were calculated separately for each quarter to account for HCPs changing where they practice. Medical claims were extracted from IQVIA data and the CMS Standard Analytical File (SAF). IQVIA medical claims are open (pre-adjudicated), professional, and institutional claims spanning all HCP and facility types and all payers, while Medicare SAF medical claims are closed (adjudicated)

institutional claims submitted by hospital-type providers for Medicare Part A and B. Medicare Part A and B institutional claims for hospital-type providers were removed from IQVIA data to avoid duplicates. Medical claims paid with cash are not captured by either IQVIA data or SAF and were not included in the current study. For a small proportion of providers who may not perform procedures or make diagnoses but who nonetheless write prescriptions, HCP-facility affiliation data from IQVIA's OneKey reference data asset was used to estimate the prescribing facility.

TESTING THE 340B ELIGIBILITY ALGORITHM

We explored ways to test the accuracy of our 340B eligibility scores. NCPDP created a 340B information exchange standard for communication between pharmacies and payers which uses codes to flag claims using 340B product¹⁵. It wasn't possible to use these codes to test claims at contract pharmacies because according to the NCPDP 340B Information Exchange Reference Guide, "It's impossible for a covered entity or contract pharmacy that utilizes a virtual inventory to use 340B identifiers at the point of service in a real-time claim"¹⁵. Almost all contract pharmacies use virtual inventories, and the ones that use physical inventory are likely not representative.

IDENTIFICATION OF 340B PRESCRIPTION DISCOUNT CARDS

There is no published method to identify which pharmacy claims use 340B discount cards, so we created one. Initially, we tried looking for 340B card vendors in the payer names of claims, but out of the more than a dozen vendors that offered 340B cards only one appeared as a payer name with filled scripts. Next, we tried to find a published list of BIN/PCN/ GROUP numbers used by 340B discount card vendors, but multiple sources we consulted confirmed no such published list exists. Instead, we constructed a list of BIN/PCN/GROUP combinations for 340B discount cards algorithmically using a three-stage process. First, we collected known BIN/PCN/GROUP numbers from online sources and from the vendor whose name appeared in paid claims. Second, we confirmed that 340B card claims identified in the first step were being reimbursed to the pharmacy at or close to the 340B discount price. This used invoice price data from IQVIA's DDD subnational sales database for the years 2020 and 2021 and was based on a set of 100 reference products that had high claims volume and high 340B discounts. Third, a score was calculated out of 100 at the claim level measuring how close the amount reimbursed to the pharmacy was to the 340B discount price, scores were averaged for each BIN/PCN/GROUP combination, non-340B entries such as patient savings programs were removed, and the list was ranked. All BIN/PCN/GROUP combinations from the first step had average scores between 75% and 100%, so all combinations at or above a 75% cutoff score were classified as 340B discount cards.

In the current study, claims using 340B discount cards were put in a separate payer type segment. This wasn't necessary to detect discount sharing, but it served three purposes: it established that 340B cards were being captured in the pharmacy claims data used, it quantified the frequency of 340B card usage, and it increased the study's ability to identify the discount sharing mechanism in use, if any.

STUDY DESIGN FOR 340B DISCOUNT SHARING

The study period was July 2020 through June 2021, which at the time of the analysis was the most recent 12 months for which Medicare SAF medical claims were available to estimate eligibility condition C1 above. Only branded products were studied because 340B-eligible claims using generic products are often not converted to 340B sales at contract pharmacies. Products such as vaccines that were not eligible for a 340B discount were removed from claims data, as were products from the five manufacturers that had contract pharmacy restrictions in place during the study period¹⁶ (manufacturers that only changed policies for orphan drugs were not removed since this is a separate issue).

The impact of 340B eligibility on patient out-of-pocket costs at contract pharmacies was estimated using the weighted linear regression

[Avg OPC 340B]i [Avg OPC Non-340B]i

> $=\alpha + \beta_1[340B\text{-eligibility}]_i$ $+\beta_2$ [Avg Days Per Script] $i + \varepsilon_1$

with two independent variables: a binary categorical variable 340B-eligibility with values 0 for non-340Beligible claims and 1 for 340B-eligible claims, and Avg Days Per Script measuring the number of days of therapy per pharmacy claim. The response was the ratio of average out-of-pocket costs for 340B-eligible claims divided by the average out-of-pocket costs for non-340B-eligible claims. The $eta_{ t 1}$ coefficient estimated the 340B discount, with negative values indicating a lower cost for 340B product. Each observation was a separate NDC, weighted by days of therapy and using cluster robust standard errors¹⁷ based on products. A separate regression was performed for each of five payer types: cash, 340B discount cards, cash discount cards, commercial insurance, and Medicare insurance. 340B card claims are 340B-eligible by definition, so non-340B-eligible cash claims were used as the non-340B-eligible sample for 340B card claims.

As an example, suppose cash claims dispensed at contract pharmacies had an average unit price of \$10 for non-340B-eligible claims and \$2 for 340B-eligible claims. The % 340B discount shared with cash patients at contract pharmacies would be 80%.

Patient out-of-pocket costs (OPC) were based on primary patient pay amount, which is the total amount paid to fill the pharmacy claim less the amount paid by the patient's insurance (if any). Primary patient pay measures financial risk to the patient after the cost of the claim has been lowered by the patient's insurance, if any, but before the

possible usage of manufacturer coupons or vouchers, which are irrelevant to 340B patient discount sharing. On claims that used a 340B discount card, primary patient pay was confirmed to capture the discounted price of the product. Manufacturer coupons may result in a lower final patient paid amount, but they do not impact whether or not 340B savings were passed on to the patient.

Non-340B-eligible claims had a 0% likelihood of 340B eligibility, while 340B-eligible claims were those with a likelihood of 340B eligibility of at least 80%, with the 80% cutoff being a compromise between having high confidence that eligible claims were truly 340B-eligible and maximizing sample size. Estimates of discount sharing were combined across products using days of therapy, which is a way of comparing volume across different kinds of products. Findings were similar when raw claim counts were used instead (results not shown). A minimum sample size of 30 claims was required for 340B-eligible and non-340B-eligible claims, respectively, for all unit price calculations. Estimates of discount sharing were not sensitive to the choice of minimum sample size (results not shown).

Pharmacy type was based on HRSA's Office of Pharmacy Affairs Information System (OPAIS) 340B registration and pricing database as a reference and was broken into three types—entity-owned pharmacies, contract pharmacies, and non-340B pharmacies—relative to the pharmacy claim being categorized.

Patient-level income data was unavailable, so low-income, uninsured patients were identified using claims filled using cash, a 340B discount card, or a cash discount card. Patients paying for a claim with cash are frequently uninsured or under-insured, patients using a cash discount card are likely to be under-insured, and 99% of claims in the study using a 340B discount card had the card as the primary and only payer. Studies have shown that uninsured patients are more likely to be low-income¹⁸.

Limitations

Given ongoing litigation debating whether HRSA can enforce a patient definition¹⁹, condition C1 which was used to approximate 340B-eligible claims (prescriptions written at a covered entity) may underestimate the claims covered entities and their vendors convert to 340B sales. While imprecision in the estimate is a limitation, the absence of publicly-available data, combined with the government's lack of clarity on patient eligibility criteria makes no other approach feasible.

The 340B card BIN/PCN/GROUP numbers used for the analysis are an estimate and may have missed 340B cards with low discount sharing or included some BIN/ PCN/GROUP numbers that weren't 340B cards.

It is possible there could be discount sharing mechanisms at contract pharmacies that function outside of the switch, and thus are not fully captured in this study. To the extent such programs exist and organizations would be willing to share claims data on any such models, we would consider including it in future analyses.

The study didn't include generic products. Generics are often not converted to 340B sales, so the usage of 340B cards for such claims should be low.

Claims through the mail channel were under-represented, which decreased capture of specialty products.

Although we considered removing orphan drugs from our sample for rural and free-standing cancer hospitals, there were a few complicating reasons why we did not. First, HRSA's published orphan drug list is not at the NDC level, and wholesalers and TPAs do not share their orphan drug lists with non-customers. Also, given our sample had relatively low capture of specialty mail, many orphan drugs would already have been excluded. Although not accounting for orphan drug status may have caused a slight overestimate of 340B-eligible claims, this would be offset by other factors such as HRSA's lack of enforcement of the diversion prohibition in statue and

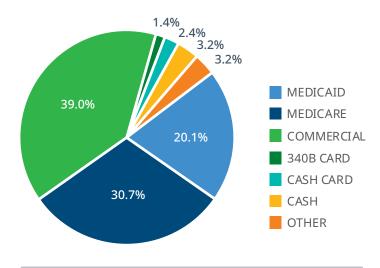
its patient definition guidance, covered entity liberties in interpretation, and the expansion of referral networks which together would cause 340B-eligible claims to be under-estimated by our approach.

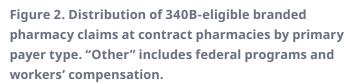
Results

Using the three-step classification algorithm described in Methods, over 500 BIN/PCN/GROUP combinations were classified as 340B discount cards. We tested the accuracy of these classifications with the help of seven third-party administrators who shared BIN/PCN/GROUP information for their 340B discount cards. We created a test sample of 1,526,270 claims confirmed to have used a 340B card, which included branded and generic pharmacy claims filled at contract and entity-owned pharmacies. 45% of pharmacy claims we classified as using a 340B card were in this test data. Of this test sample, 1,339,372 claims (87.8%) were classifiable by our algorithm; the remaining 12.2% had BIN/PCN/GROUP numbers with less than 30 claims during the study period. Of the classifiable claims, 1,172,637 were classified as using a 340B discount card, meaning the algorithm's sensitivity was 87.6%. It was not possible to estimate specificity because we did not know the 340B card status of the remainder of the claims classified by our algorithm.

Around 0.3% of branded pharmacy claims at contract pharmacies and entity-owned pharmacies used a 340B discount card, while at contract pharmacies 1.4% of 340B-eligible, branded claims used one (Figure 2). For comparison, 7% of 340B-eligible, branded claims at contract pharmacies had a payer type of cash, a 340B card, or a cash card, a segment which is comprised of uninsured or under-insured patients.

The percentage of 340B discount cards was calculated relative to all 340B-eligible claims with payer type cash, 340B cards, or cash cards to estimate the penetration of 340B cards among uninsured or under-insured patients. Penetration of 340B cards was highest at independent pharmacies and lower at chain pharmacies (Figure 3). Penetration of 340B cards at entity-owned hospital





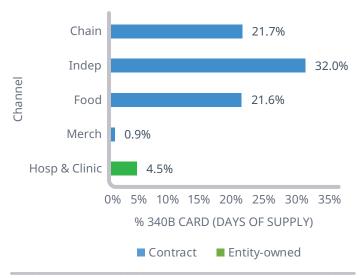


Figure 3. 340B card claims as a percentage of claims paid with cash, 340B cards, or cash cards. Estimates are broken out by distribution channel and measured using days of supply. Contract pharmacy channels (from top to bottom, in blue): chain pharmacies, independent pharmacies, food stores, and mass merchandisers. Entity-owned pharmacy channels (in green): hospitals and clinics.

and clinic pharmacies was relatively low, but as noted above these outlets may use a local BIN/PCN/GROUP mechanism for discount sharing. Claims filled through Mail had low sample size because they normally lack coordination of benefits data required to calculate unit price, and were omitted.

Estimates of discount sharing for contract pharmacies by payer type are summarized in Table 1 on page 11. The average shared discount was 92.9%, 95% CI 90.3% to 95.6% for patients using a 340B discount card, and zero or close to zero for the other payer types. For claims filled using a 340B discount card, the mean reduction in patient out-of-pocket costs was \$661.65, 95% CI \$551.16 to \$812.14 based on 30 days of therapy. There was no evidence of patient discount sharing for cash claims, with the estimate not statistically different to zero. For cash cards, the 340B shared discount was -1.9% which was statistically significant but small, with the negative value indicating slightly higher out-of-pocket costs for

340B-eligible patients. The discount sharing estimate for commercial claims was 2.5%, which could have been due to a small number of 340B card programs that were not captured when BIN/PCN/GROUP data was mined for them. It could also have been caused by commercial payers reimbursing at a lower rate for 340B-eligible claims, assuming patient out-of-pocket costs were based on the reimbursed amount. Medicare claims had a discount sharing estimate of 3.5%, which also could have been due to lower reimbursement for some 340B-eligible claims. Discount sharing was not considered for Medicaid patients because their out-ofpocket costs should be unaffected by 340B eligibilty, and Medicaid FFS is not typically included for contract pharmacies due to federal guidance.

Given the shared discount was 92.9% for the 1.4% of 340B card users and close to zero for other payer types, it raises the question of what the average discount was. Across all payer types for which a shared discount could

Table 1. Estimates of % shared discount for 340B-eligible claims versus non-340B-eligible claims for branded products at contract pharmacies. Payer types "Medicaid" and "Other" were not analyzed (see text). The last row is the percentage of claims for each payer type measured using days of therapy.

STATISTIC	PAYER TYPE				
	CASH	340B CARD	CASH CARD	COMMERCIAL	MEDICARE
% DISCOUNT	0.77%	92.9%	-1.9%	2.5%	3.5%
P VALUE	0.39	p<0.001	p<0.001	0.0026	p<0.001
95% CI	-2.5%, 1.0%	90.3%, 95.6%	-2.69%, -0.92%	0.87%, 4.2%	2.0%, 5.0%
R-SQUARED	0.002	0.96	0.047	0.013	0.0092
% DAYS OF THERAPY	3.2%	1.4%	2.4%	39.0%	30.7%

be estimated (cash, 340B cards, cash cards, commercial, and Medicare) the 340B shared discount was 4.4%. This overall estimate needs to be interpreted with care because the average is an incomplete measure of central tendency for bimodal distributions, such as seen for 340B card claims versus other claims. Although the patient groups that should receive a 340B discount is open to debate, it's clear the majority of low income, uninsured, 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts.

Using a cash discount card may be a better choice for uninsured patients than paying with cash, so the discount sharing estimate for 340B cards was re-estimated using cash discount card claims as the non-340B-eligible sample. The discount sharing estimate decreased only slightly to 90.4%, which suggests the estimate is not sensitive to the choice of non-340B-eligible claims.

The discount sharing estimates in Table 1 were based on 38,000,000 pharmacy claims and 189 to 1,460 product NDCs depending on payer type.

Discussion

The current study has delivered new answers but also new questions about patient discount sharing in the 340B program. We developed new methods for estimating the 340B eligibility of pharmacy claims and for identifying claims using 340B discount counts. We found that the average shared discount was 92.9% when a 340B discount card was used, but only 1.4% of 340B-eligible, branded claims at contract pharmacies used such a card. To put this estimate of 340B card usage into context, the U.S. Census Bureau has reported that 11.4% of the U.S. population lived in poverty in 2020, while 8.6% of the population had no health insurance at any stage of the year²⁰, and there's a high degree of overlap between being low-income and being uninsured¹⁸. If 340B discount cards are capable of directly sharing discounts with vulnerable patients, why are they used so infrequently? A possible answer is hospitals and grantees are using 340B revenue to support additional patient services and uncompensated care, yet several studies have questioned the relationship between uncompensated care and 340B participation^{21,22}. Also, it appears that 340B revenue is benefiting stakeholders other than patients

and hospitals (see Figure 1). Quantifying this revenue waterfall is beyond the scope of the current study, but could be the basis for further research.

A recent study of contract pharmacies found growth was concentrated in affluent and White neighborhoods²³, and the authors noted they couldn't determine whether 340B discounts were passed to patients. The current study helps to answer this question.

The discount sharing estimate of 92.9% is not representative of discounts for the 340B program as a whole because it applies only to branded products dispensed at contract pharmacies, and under-represents claims filled through the specialty mail channel. When findings from the current study are compared to the widespread discount sharing at contract pharmacies reported in the 2018 GAO survey, it suggests either the entities surveyed weren't representative of covered entities overall, entities rarely offer 340B cards to patients, there are other unknown mechanisms for passing discounts to patients, or covered entity behavior has changed in recent years. Whatever the explanation, it may be time for a refresh of government oversight reporting.

Transparency in the 340B program is being compromised at multiple levels by a lack of publicly available data, including but not limited to (1) which claims are 340B-eligible, (2) which 340B-eligible claims are converted to 340B sales, (3) the mechanisms being used by covered entities to share 340B discounts with patients, (4) which types of patients are receiving shared discounts and what factors are influencing these decisions, and (5) which pharmacies accept 340B discount cards, which do not, and what is driving these differences. Although statistical algorithms were created and applied in the current study to compensate for this missing data, more transparent data would without doubt improve estimates of the frequency and magnitude of discount-sharing.

The question of which types of patients are receiving and using 340B discount cards, including their insurance status and income level is being tackled as a follow-on study by our group.

The 340B Drug Discount Program as it exists today is a complex system of arbitrage involving multiple stakeholders, each of which profits from 340B revenue. It's a drug discount program in which most vulnerable patients at contract pharmacies do not get drug discounts. Despite claims that it is impossible to identify and assist 340B-eligible patients at the point of sale in contract pharmacies, the data demonstrates that this can be done, although a possible solution—340B discount cards—is not being widely adopted.

ACKNOWLEDGEMENTS

We thank 340B discount card vendors Capture Rx, Sun Rx, PDMI, 340Basics, Rx Strategies, Wellpartner, Walgreens, Verity, MacroHelix, and PharmaForce for helping us to verify our algorithm identifying 340B discount cards. We thank IQVIA colleagues Shiraz Hasan, BS, MBA, Steve Krikorian, BA, MBA, Chuan Sun, BS, MS, Diane Weisbrod, BS, MSA, Luke Greenwalt, BA, MBA, and external reviewers William B. Feldman, MD, DPHIL, MPH, Ameet Sarpatwari, PhD, JD, and an anonymous reviewer for suggestions on an earlier draft.

FUNDING

This study was partially supported by Bristol Myers Squibb, which reviewed and approved the manuscript but had no role in data collection, analysis, or decision to publish.

References

- Report 102-384 Part I, 102nd Congress, Establishment of limits on prices of drugs procured by the Department of Veterans Affairs, pg. 11. Mr. Montgomery, Committee on Veteran's Affairs. United States House of Representatives. November 25, 1991.
- 2. Slafsky T, Ross S, and Krishnamurthy B. The 340B drug discount program is fulfilling its original purpose. Health Affairs Forefront. March 22, 2018.
- 3. PhRMA. 340B: the unintentional hospital and pharmacy profit stream that was supposed to help patients. Accessed July 2022. https://www.phrma.org/policy-issues/340B
- 4. GAO Report to congressional requesters. Federal oversight of compliance at 340B contract pharmacies needs improvement. June 2018.
- 5. Martin R. 340B program continues to grow while contract pharmacy restrictions take effect. IQVIA Blog. April 2022.
- 6. Fein A. The 2021-22 economic report on pharmaceutical wholesalers and specialty distributors. Drug Channels. October 2021.
- 7. Murray B. 340B third party administrator fee structure. Dinsmore webinar. March 23, 2022. Accessed April 2022. https://www.dinsmore.com/events/watch-340b-tpa-pricing-with-bryan-murray/
- 8. Martin R, Krikorian S. The 340B drug discount program: complexity, challenges, and change. IQVIA White Paper. August 2020.
- 9. Hardman D. Understanding your 340B contract pharmacy agreement: Five areas worth negotiating. AmerisourceBergen Insights. August 30, 2021.
- Social Security Administration. Payment for covered outpatient drugs [296] U.S. https://www.ssa.gov/OP_Home/ssact/title19/1927.htm
- 11. Notice regarding section 602 of the Veterans Health Care Act of 1992 patient and entity eligibility. Federal Register. Vol. 61, No. 20. October 24, 1996.
- 12. Genesis HealthCare, Inc. v. Becerra, No. 20-1701 (4th Cir. 2022), https://law.justia.com/cases/federal/appellate-courts/ca4/20-1701/20-1701-2022-07-01.html
- 13. Office of Inspector General (OIG), HHS. Memorandum report: contract pharmacy arrangements in the 340B program, OEI-05-13-00431. February 4, 2014.
- 14. Which prescriptions are 340B-eligible? National Association of Community Health Centers. March 2018.
- 15. NCPCP. 340B information exchange reference guide version 2. June, 2019. https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf

- 16. 340B Manufacturer Updates. AmerisourceBergen. Accessed April, 2022. https://www.amerisourcebergen.com/provider-solutions/340b-advisory-services/340b-manufacturer-updates
- 17. Cameron C, Miller D. A Practitioner's Guide to Cluster-Robust Inference. J. Human Resources. 50, 2:317—372, 2015.
- 18. Tolbert J, Orgera K. Key facts about the uninsured population. Kaiser Family Foundation. November 6, 2020.
- 19. Cook E, Reinhardt K. HRSA filings in Genesis shed light on definition of "patient" for 340B covered entities. The National Law Review. April 16, 2022. https://www.natlawreview.com/article/hsra-filings-genesis-shed-light-definition-patient-340b-covered-entities
- 20. Shrider E, Kollar M, Chen F, Semega J. Income and Poverty in the United States: 2020. United States Census Bureau. September 14, 2021.
- 21. Conti R, Bach P. The 340B drug discount program: hospitals generate profits by expanding to reach more affluent communities. Health Affairs. October 2014.
- 22. Nikpay SS, Buntin MB, Conti RM. Relationship between initiation of 340B participation and hospital safety-net engagement. Health Services Research. 2020, 55: 157-169.
- 23. Lin JK, Li, P, Doshi J. Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics. JAMA Health Forum. 2022: 3(6).

About the authors



RORY MARTIN, PhD IQVIA Market Access Center of Excellence

Rory uses advanced analytics to create innovative Gross to

Net strategies and solutions to help manufacturers accelerate portfolio growth. He has been an invited speaker at the FDA's Center for Drug Evaluation and Research (CDER) and is the author of several analytics texts.



KEPLER ILLICH UC Davis School of Economics

Kepler is pursuing a PhD in economics focusing on healthcare and industrial organization. He

spent several years focusing on managed market strategy and data analytics, and more recently has shifted his focus towards better understanding the economic forces at play in the U.S. healthcare system.

CONTACT US

iqvia.com



