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Agency of Human Services

Act 165, Sec. 5
340B Drug Reimbursement; Report

Report to:
House Committees on Health Care
and
Senate Committees on Finance and on Health and Welfare
Pursuant to Act 165, Sec. 5

Al Gobeille, Secretary
Vermont Agency of Human Services

Cory Gustafson, Commissioner
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Department of Vermont Health Access

April 28, 2017

Purpose of this Report:

This report is intended to provide a brief overview of the 340B Drug Discount Program administered by the Health Resources and Services Administration (HRSA). In addition, it will provide an overview of Vermont Medicaid's specific 340B policies and experience with the program, and recommendations for future discussion regarding potential changes to the Medicaid 340B program for Vermont. Is it not intended to be an exhaustive review of the 340B program nationally, however there are some excellent sources for anyone requiring more detailed information on the program. In addition to many of the references included at the end of this report, the HRSA 340B website https://www.hrsa.gov/opa/ , and the Medicare Payment Advisory Commission (MEDPAC) Report http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 are both very helpful.

Background and Program Description:

The Medicaid Drug Rebate Program was created in 1990 by Congress, which created a "ceiling price" for medications provided to Medicaid patients. The amount of the rebates paid to states were based on a "best-price" calculation, which did not consider the discounted prices that manufacturers were offering directly to federally funded clinics and public hospitals serving large numbers of low-income and uninsured patients.

Continuing to offer these discounts would have required the manufacturer to pass along that "best price" calculation to Medicaid. In 1992, Congressional hearings found that failing to exempt these voluntary discounts under the Medicaid Drug Rebate Program caused prices to rise significantly for these facilities. The Public Health Service (PHS) Act created the 340B program to help combat these unintended consequences.

The 340B program sets a statutory ceiling price for what drug manufacturers can charge 340B eligible health care providers, known as Covered Entities (CEs), for drugs provided to qualified patients. However, covered entities that participate in HRSA's Prime Vendor Program (PVP) often pay less than the ceiling price. HRSA calculates a 340B ceiling price for each

covered outpatient drug as the difference between the drug's average manufacturer price (AMP) and its unit rebate amount (URA). HRSA calculates URAs using a statutory formula that is based on the same formula used to calculate Medicaid drug rebates. The statutory formula for the URA varies based on whether the drug is a single-source or innovator, multiple-source drug (e.g., a brand-name drug); a non-innovator multiple-source drug (e.g., a generic drug); or a clotting factor or exclusively pediatric drug. According to statute, HRSA is allowed to disclose ceiling prices to covered entities but not to the general public. (Medicare Payment Advisory Commission, 2015). Another aspect of 340B is the Prime Vendor Program, which is a consolidated contracting and distributing entity that can negotiate discounts that are even lower that what can be provided through the 340B program (LaCouture, 2014).

Some examples of CEs are critical access hospitals, disproportionate share (DSH) hospitals, sole community hospitals, rural referral centers, children's hospitals, freestanding cancer hospitals, Federally Qualified Health Centers, and others (Medicare Payment Advisory Commission, 2015).

Covered entities can dispense the discounted medications to uninsured patients and patients covered by Medicare or private insurance. In cases where the covered entity treats an insured patient with discounted medication, the Federal Government or the patient's private insurance routinely reimburses the entity for the full price of the medication, and the entity can retain the difference between the reduced price it pays for the drug and the full amount for which it is reimbursed.

The original intention of this program was "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. No. 102-384(II), at 12 (1992)) The DVHA interprets this as a mandate to benefit individual low-income, uninsured and under-insured patients by passing along the lower cost of the 340B-eligible medications. However, the current 340B legislation does not control how covered entities utilize the extra funds generated by the program. Covered entities can purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, and generate revenue if the reimbursements for the drugs from payers exceed the discounted prices they pay for the drugs. Because the 340B statute does not restrict how covered entities can use this revenue, entities can use these funds to expand the number of patients served, increase the scope

of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose. HRSA does not have statutory authority to track how covered entities use this revenue. (Medicare Payment Advisory Commission, 2015)

Critics of the 340B program believe that since the program was designed to help patients who cannot afford their medications, it should not allow covered entities to receive the revenue that is received through this program. However, covered entities believe that this revenue helps the facility cover the cost of providing services to the uninsured or underinsured patients. In a 2014 report, the Office of Inspector General found that 22 of thirty covered entities offered the 340B price to uninsured patients while eight reported that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements. (Wright, 2014).

Scope and Impact of the 340B Program:

In 2015, Apexus, the 340B Prime Vendor, disclosed that $12 billion dollars was spent on medications through the 340B program (Fein A. , New OIG report Shows Hospitals' Huge 340B Profits from Medicare-Paid Cancer Drugs, 2015). Not including direct sales, Apexus stated that 340B drugs are now more than 44% of purchases made by hospitals included in the 340B program (Fein A. , New OIG report Shows Hospitals' Huge 340B Profits from Medicare-Paid Cancer Drugs, 2015).

Also in 2015, IMS Institute for Healthcare Informatics stated that the “net price spending,” or the amount spent after discounts on pharmaceuticals was $309.5 billion. Based on this information, the amount of 340B purchases made in 2015 was estimated by the author to be 3.9% of the pharmaceutical market, not 2% stated by other stakeholders in the 340B business. This amount was underestimated because the $12 billion dollars spent on medications did not include direct sales from manufacturers to the covered entities (Fein, Reality Check: 340B is 4% (not 2%) of the U.S. Drug Market - And Growing Quickly, 2016).

Medicare Part B pays the same amount to 340B hospitals as non-340B hospitals for drugs used to treat cancer and rheumatoid arthritis even though the 340B hospitals can purchase the drugs at a large discount.

In 2011 the RAND Corporation published a study of policy options for addressing Medicare payment differentials across ambulatory settings. Sponsored by the Assistant Secretary of Planning and Evaluation in the U.S. Department of Health and Human Services that analyzed potential options for modifying Medicare payment policies to improve the value of services provided in ambulatory settings by addressing the differential in the amount that Medicare pays for similar facility services in various ambulatory settings. In their summary, the authors verify that "The findings confirm that payments tend to be highest for services provided in hospitals, but they also indicate that payment differentials generally exceed cost differentials and vary by procedure." (Wynn, Hussey, & Ruder, 2011)

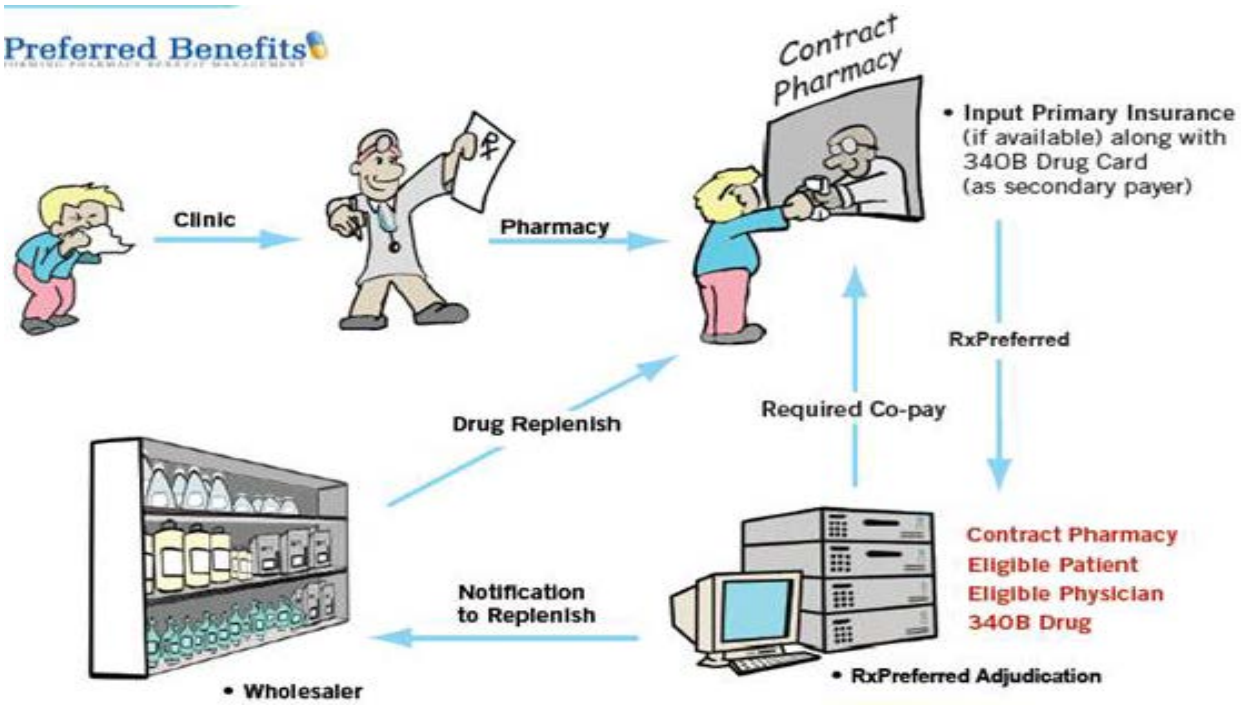
Page 55 of the RAND Study states: "There has been a substantial increase in hospital purchases of provider practices in recent years, largely to expand the hospital's referral base and to position the hospital system as an accountable care organization. However, the consequences are increased Medicare payments and beneficiary coinsurance, as well as additional competition for community-based practices...For oncology practices, one reason cited for the growth is the opportunity to expand the patient base for drugs purchased under the 340B discount drug purchase plan. The program allows facilities to purchase outpatient drugs at prices below market.

Because the [Outpatient Prospective Payment System] payment rates for drugs furnished to hospital outpatients are the same for all hospitals without regard to whether the drugs were purchased through the 340B program, hospitals have an incentive to increase margins by expanding their patient base for chemotherapy administration. At the same time, changes in Medicare payments for chemotherapy drugs furnished in [physician offices] have limited the ability of oncologists to profit on these drugs and have increased the attractiveness of affiliating with a hospital." (Wynn, Hussey, & Ruder, 2011)

<u>Figures 1 and 2 below visually demonstrate the flow of 340B medications:</u>

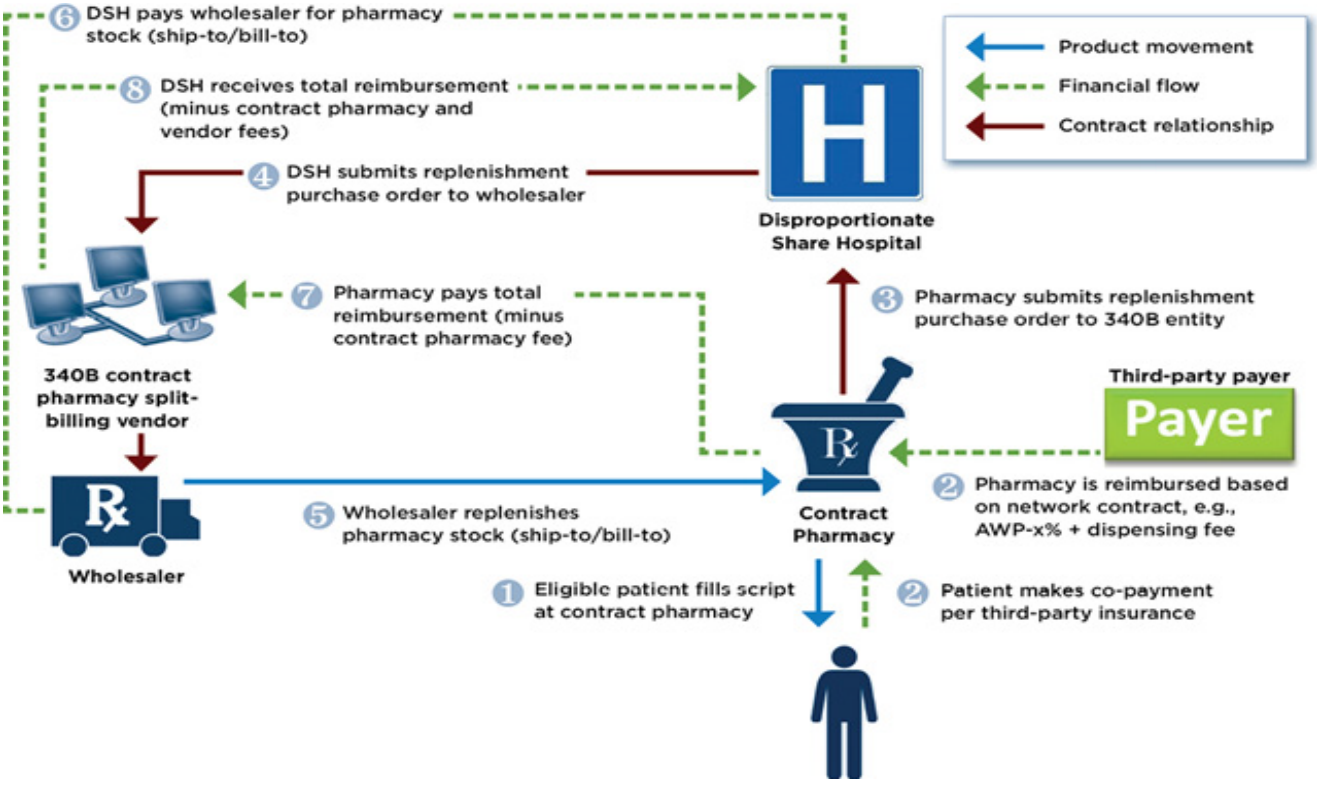
Basic Flow of 340B Program

Figure 1: Diagram of 340B Flow (Rx Preferred Benefits, 2015)



340 B Product Movement, Financial Flow, and Contract Relationships

Figure 2**:** Diagram of product movement, financial flow, and contract relationship of the 340B program. (Fein A. , 2013)



<u>Medicaid Rules and Guidance:</u>

CMS requires states to develop specific 340B policies so that CEs are clear on how to participate with the state Medicaid program. CE's must assure that manufacturers are not charged a duplicate discount. This occurs when a 340B purchased drug already purchased at a discount, is also submitted for a manufacturer rebate, thus the manufacturer is actually paying a "double discount" on that drug. This is prohibited by law, and all CEs must have procedures in place to prevent this from occurring.

Some states require all CEs to "carve-out" Medicaid, meaning that CEs cannot use any 340B inventory for Medicaid patients. This assures that no duplicate discounts occur, and it is the easiest option for the Medicaid program to administer. Most states allow entities to "carve-in", that is, to use 340B inventory for eligible patients, but CEs must pass along their acquisition

cost to states. This is because states should not pay more for 340B drugs, than they do for non-340B rebated drugs. This keeps the cost down to the Medicaid program and assures Medicaid is not overpaying for drugs.

Vermont's 340B Program:

Vermont allows CEs to "carve-in" Medicaid through a special enrollment process. Although the burden of the "duplicate discount" provision resides with the CE, the DVHA also has processes in place to avoid this occurrence. This is done through a retrospective (back-end) and manual process by which DVHA asks the CE to validate which claims are 340B eligible. These claims are withheld from any rebate processing.

Pharmacy Claims: On the front-end, the DVHA processes 340B and non-340B pharmacy claims at the point of service (POS) exactly the same as regular pharmacy claims. Then monthly, claims from those 340B enrolled pharmacies are sent to the entity for confirmation that each claim is 340B eligible, and the entity provides the correct 340B acquisition cost. DVHA pays the entity the 340B acquisition cost plus a dispensing fee. DVHA then calculates the difference in net cost by comparing the 340B net cost to the DVHA net cost and refunds 10% of any savings up to a maximum of $3 per claim back to the entity. Dispensing Fees (DF) vary depending on the entity. FQHC pharmacies receive a DF of $15 per claim, all other pharmacies receive $11.13 effective 4/1/17. Prior to April 1st, the DF for all other pharmacies was $4.75.

Physician Administered Drugs: The DVHA processes both 340B and non-340B professional and institutional outpatient claims the same. Then monthly, claims attributed to those 340B enrolled entities are sent to the entity for confirmation that each claim is 340B eligible, and the entity provides the correct 340B acquisition cost. DVHA pays the entity the 340B acquisition cost plus an administrative fee. DVHA then calculates the difference in net cost by comparing the 340B net cost to the DVHA net cost and refunds 10% of any savings up to a maximum of $3 per claim back to the entity. Administrative Fees are currently $4.75 per claim for all hospital entities.

Vermont's Medicaid-Enrolled Covered Entities as of March 31, 2017

Provider Name	Affiliated Pharmacy	Provider #
Central Vermont Medical Center		0470001
Community Health Center of Burlington INC	CHP (Community Health Pharmacy)	1015558
Copley Professional Services Group DBA Community Health Services of Lamoille Valley	CHP (Community Health Pharmacy)	1015558
Northern Counties Health Care	CHP (Community Health Pharmacy)	1015558
Richford Health Center, INC.	CHP (Community Health Pharmacy)	1015558
The Health Center	CHP (Community Health Pharmacy)	1015558
Northern Tiers Health Ctr for Health	Notch Pharmacy	1011139
Southwestern Vermont Medical Center		0470012
University of Vermont Medical Center	UVMMC Outpatient Pharmacies (see below)	0470003, 0VN0997
Springfield Hospital		0471306 0470018
Indian Stream Health Center		1021803
Berkshire Medical Center		0220046
Brattleboro Memorial Hospital.		0470011
University of Vermont Medical Center Pharmacy	University of VT Med RX (3 locations)	0472300, 0473500 0473501,0473502 0473503,0473504 1012209,1012210
Planned Parenthood*		0006041
UMass Memorial Medical Center		0220163

**Planned Parenthood is not addressed in this document.*

Advantages and Disadvantages of the 340B Program:

Advantages:

Patients:

- Many uninsured and underinsured patients receive a discount on drugs through the 340B program. However, there is no reporting requirement to determine to what extent that occurs.

Providers (Covered Entities)

- Increases revenue substantially for hospitals and other covered entities
- Encourages safety-net providers to offer additional services

Payers:

- Only Medicaid receives a discount, other payers do not benefit

Disadvantages:

Patients:

- The funds generated by the program are not required to be used toward "qualified patients"
- Underinsured patients may pay full cost for the medication even though the covered entity received the medication at a discounted cost.

Providers (CEs):

- Places pressures on physician practices, particularly oncologists to sell their practices to hospitals to create outpatient departments due to the extensive increase in profit through the 340B drug pricing for oncology medications. (Fein A. , 340B Purchases Hit $12 Billion in 2015 - And Almost Half of the Hospital Market, 2016)

Payers:

- Medicare is significantly disadvantaged since 340B discounts are not passed along to the Medicare program
- Commercial/Private payers also do not receive the discounts
- Medicaid receives the discount, and Vermont achieves modest savings from the program

Savings Impact of 340B on State Medicaid Programs:

Due to the "duplicate discount" prohibition, state Medicaid programs can receive either a rebate, or a discount, but not both. Drugs eligible for 340B discounts may not be also rebated. Therefore, the 340B acquisition cost for the medications should be at least as low as the Medicaid net cost (net of rebate), otherwise it would be more expensive for Medicaid to pay for 340B drugs compared to non-340B medications.

The DVHA conducted a recent analysis on pharmacy and medical claims. This analysis compared the 340B net cost to what that same drug would have cost DVHA through a non-340B pharmacy or provider. Below is a chart summarizing the results of the analysis. The rows labeled "DRUG" represent non-FQHC pharmacies, the rows labeled "FQHC" represent FQHC pharmacies, and the rows labeled "HOSP" represent physician-administered drugs given in outpatient hospital settings. The claims analysis was done on all claims paid between April 1st, 2016 and September 30, 2016. The DVHA compared the 340B net cost (calculated as the 340B acquisition cost plus the 340B dispensing fee) to the DVHA net cost (calculated as the pharmacy payment minus all rebates received for that drug claim) to arrive at any savings attributable to the program.

Among the pharmacies, the results show an overall savings of 8.8% with all the savings coming from the non-FQHC pharmacies. The FQHC pharmacies represented a loss to DVHA of 11.89% in the second quarter of 2016, and a loss of 8.91% in the third quarter of 2016. It is important to note that in the second quarter of 2016, the dispensing fee for both was $15. On July 1st, 2016, the dispensing fee for the non-FQHC pharmacies was decreased to $4.75 per a statutory requirement. This contributed to an increased **quarterly** savings of $22,988, although many other factors affect savings, as outlined below.

The hospital analysis represented a 25% loss to DVHA in the second quarter 2016, and a 5.3% loss in the third quarter of 2016. Again, the administrative (dispensing) fee changed from $15 in second quarter to $4.75 in the third quarter which contributed to a reduction of the loss to DVHA.

There is a great deal of variability in the individual drug saving calculations that impacted this analysis. These include a) the mix of drugs used during the quarter b) variability in acquisition costs reported from different entities for the same drug in the same quarter b) variability in claims payments due to the structure of the OPPS payment system c) the mix of high and low cost claims in a quarter. A higher percentage of low cost claims results in higher 340B costs vs. DVHA net costs due to the 340B dispensing fees d) DVHA does not require a National Drug Code (NDC) on 340B claims, therefore it is difficult to validate 340B acquisition cost in situations where one drug code maps to multiple NDC's. NDC's indicate the labeler, drug, strength, dosage form, and package size of each medication. This level of detail is required to ascertain correct rebate information. e) DVHA does not validate that the reported acquisition cost from entities is not greater than the "340B ceiling price" which is equal to Average Manufacturer Price (AMP) minus the Unit Rebate Amount (URA) e.g. AMP-URA. It was noted that in some cases, the reported 340B acquisition cost exceeded the ceiling price. All of these factors combined caused significant variability in net costs to occur.

Covered Entity	# Claims	Total Amt Paid	340B NET COST	DVHA NET COST	SAVINGS/(LOSS)	% SAVINGS/(LOSS)
HOSP Q-3	1,526	$ 1,434,747.35	$ 775,124.10	$ 735,894.25	$ (39,229.85)	-5.33%
HOSP Q-2	1,594	$ 1,231,729.99	$ 815,303.53	$ 651,985.39	$ (163,318.13)	-25.05%
HOSP SUBTOTAL	3,120	$ 2,666,477.34	$ 1,590,427.63	$ 1,387,879.64	$ (202,547.98)	-14.59%
DRUG Q-3	3,548	$ 769,633.56	$ 268,412.74	$ 333,073.38	$ 64,660.64	19.41%
DRUG Q-2	3,397	$ 634,126.11	$ 246,772.65	$ 288,445.79	$ 41,673.14	14.45%
FQHC Q-3	4,352	$ 377,238.52	$ 143,893.75	$ 132,119.14	$ (11,774.60)	-8.91%
FQHC Q-2	4,505	$ 376,593.48	$ 154,390.61	$ 137,984.03	$ (16,406.58)	-11.89%
PHARM SUBTOT/	15,802	$ 2,157,591.67	$ 813,469.74	$ 891,622.34	$ 78,152.60	8.77%
TOTALS	**18,922**	**$ 4,824,069.01**	**$ 2,403,897.37**	**$ 2,279,501.98**	**$ (124,395.39)**	**-5.46%**

In addition to the payments above, each Covered Entity receives back 10% of the total savings or a maximum (cap) of $3 per claim, except Planned Parenthood who receives 40% of the savings without a cap. The chart below lists the incentive payments made to all entities for the second and third quarter 2016. Annualized data would approximate $350,000 per year.

Covered Entity	***6-month Incentives Paid***
HOSPITAL Q-2	*$2,310*
HOSPITAL Q-3	*$2,808*
HOSP SubTotals	***$5,118***
PHARM Q-2	*$24,276*
PHARM Q-3	*$18,801*
PHARM SubTotals	***$43,077***
Planned Parenthood(PPNNE)	
PPNNE Q-2	*$63,770*
PPNNE Q-3	*$64,816*
PPNNE SubTotals	***$128,586***
TOTALS	***$176,781***

Other State Medicaid Programs:

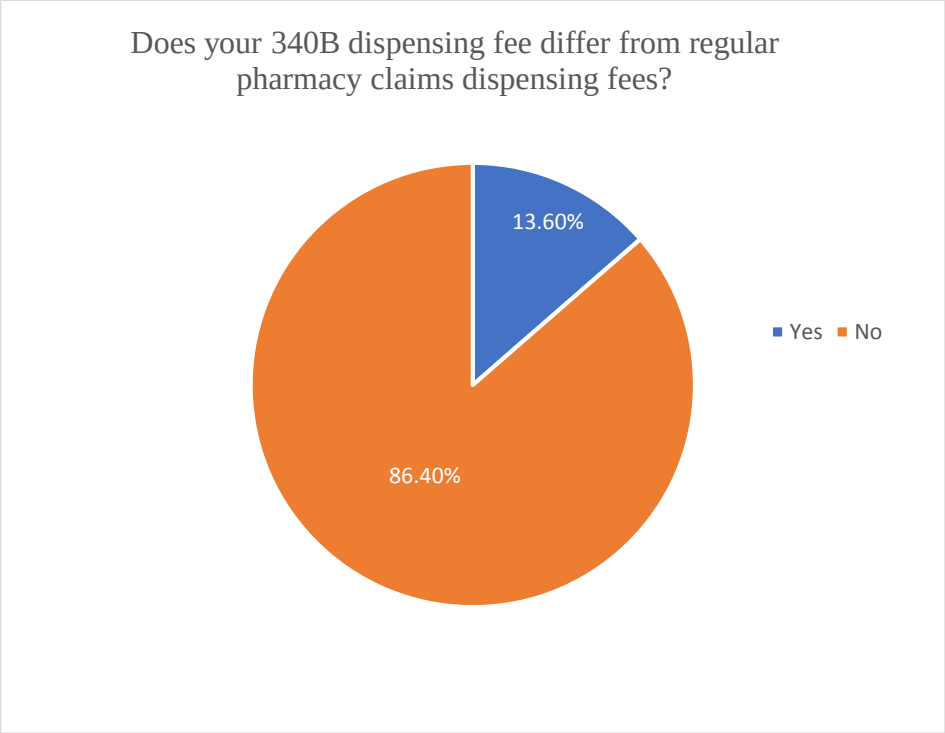
The DVHA conducted a nationwide 340B survey of other state Medicaid programs. The states were asked about their reimbursement structures on both pharmacy and physician-administered drugs. Of fifty (50) states surveyed, twenty-two (22) states responded. Below is a summary of the questions and responses to the survey.

1) How do you price POS pharmacy claims from 340B entities that have carved in Medicaid?

   Almost all states price 340B pharmacy claims using 340B Acquisition cost plus a Dispensing Fee, the same as Vermont. One state pays the regular pharmacy rate, then invoices the entity the AMP-URA to recoup 340B “ceiling price” net cost.

2) What is your 340B pharmacy dispensing fee?

340B Dispensing fees varied by state from a low of $7.25 in California to a high of $15 in Montana and Vermont. More than 85% of all states responding applied the same dispensing fee to 340B claims and non-340B claims.

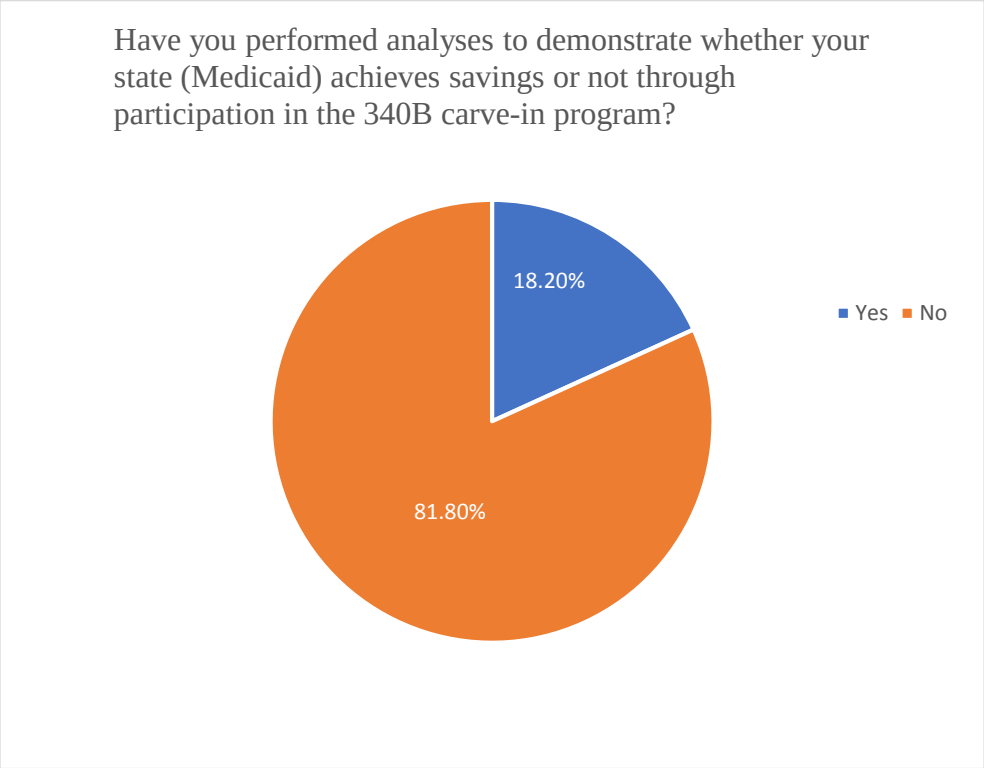


3) How do you price Physician administered (PA) claims from 340B entities that have carved in Medicaid?

Responses were quite variable for this question. Thirteen states (60%) price PA claims at 340B Acquisition Cost, six states pay the same for 340B claims and non-340B claims, one pays off Wholesale Acquisition Cost, and one pays off Invoice Price. Notably, no states paid an additional administrative or dispensing fee like Vermont, and no state had a "shared savings arrangement like Vermont's.

4) Have you performed analyses to demonstrate whether your state Medicaid program achieves savings or not through participation in the 340B program?

More than 80% of respondents had not done any analyses on savings in their state. One state noted significant administrative burden from administering the 340B program, one state noted savings on hemophilia products, one state that does not require 340B acquisition cost (340B AAC) noted that they could achieve significant savings if they could require 340B AAC.



Recommendations for Future Discussion Regarding Potentially Restructuring Vermont's Medicaid 340B Program:

The DVHA sets forth the following recommendations for additional discussion. The DVHA intends to meet with interested stakeholders about these recommendations after publication and consideration of the report.

1. Align dispensing fees between FQHC and non-FQHC pharmacies to the regular Medicaid dispensing fee of $11.13 that became effective on 4/1/17.

    a. Current dispensing fees for 340B Medicaid enrolled pharmacies are varied. We now pay FQHC pharmacies a $15 DF, and non-FQHC pharmacies $11.13 (since 4/1/17).
    b. DVHA pays more for 340B drugs from FQHC pharmacies than it does for non-340B drugs subject to rebates. Reducing the dispensing fee would increase savings or reduce loss to DVHA.
2. Currently DVHA pays a $4.75 fee to entities for Physician-administered drugs. Since the hospital analysis demonstrated a loss to DVHA for both quarters, we recommend eliminating the administrative/dispensing fees for physician administered drugs. In addition, CMS does not recognize dispensing fees for non-pharmacy providers.
3. Compare all reported 340B prices against the ceiling price (AMP-URA) for that quarter. This would assure that the DVHA is not being charged more than the "ceiling price" for 340B drugs and would reduce variability in submitted drug prices.
4. Eliminate the retrospective settlement process.
    a. Adjudicate pharmacy claims against AMP-URA at point of sale
    b. Require CE's to submit their 340B prices on submitted physician-administered drug claims
    c. Administrative burden is high to operate the program retrospectively, and is prone to errors in calculations, and variability in pricing of 340B pharmacy claims. DVHA currently allocates 0.5-0.75 FTEs to operate this program retrospectively. Covered entities also experience burden in this retrospective settlement process. Adjudicating at the point of service would eliminate most of this effort.
5. Eliminate the shared savings program as CMS does not allow this in State Plan. The DVHA is not aware of any other shared savings arrangements by other states. This would increase annual savings to Medicaid by approximately $96,000 based on incentive payments paid in 2016.
6. Require entities to report the NDC on all physician-administered drug claims. Lack of an NDC makes it difficult for DVHA to validate the reported 340B cost.
7. Calculate savings based on the difference between DVHA net cost and 340B net cost. Today, savings calculations are done based on DVHA **gross costs** compared to 340B net costs. This results in a falsely elevated "savings" calculation. For example, if DVHA's

gross is $2000 dollars and 340B net is $1200 dollars, the savings would be calculated at $800 dollars and the entity would receive $80 dollars back in an incentive payment. But if DVHA's net is $1250 dollars and the 340B net is $1200 dollars, the savings is only $50 dollars, not $800 dollars. In addition, the 340B provider agreements specify a net to net calculation.

One of the potential impacts associated with making these changes could be that pharmacies, hospitals, and other entities may "carve out" 340B drugs from the Medicaid program if reimbursement is not high enough. If all entities carved out of Medicaid today, it would result in a net gain to DVHA of $124,395 per year. However, with the recommended changes, DVHA is likely to see savings from the 340B program.

These recommendations for future discussion, if implemented, would have an impact on providers, particularly health centers and hospitals. The DVHA will engage in a stakeholder process prior to any decision to implement these recommendations for discussion, expecting this stakeholder process to provide more insight into potential financial impacts, beneficiary impacts, necessary administrative changes, and the appropriate lead time for these potential changes.

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