Washington State Health Care Authority

Report to the Legislature

340B Report to the Legislature

340B annual reporting

Engrossed Substitute Senate Bill 5187; Section 211(32)(b); Chapter 475; Laws of 2023

December 2024

The Health Care Authority (HCA) was directed by the Legislature, pursuant to the requirements in ESSB 5187; Section 211(32)(b), to analyze whether it is providing economical, efficient, and quality prescription drug services through its administrative services model and the quantifiable cost and benefit of this service delivery method. As part of this analysis, HCA is required to provide a fiscal analysis to the Governor and Legislature that contains the cost and benefits of reimbursing for prescription drugs through a carved-in managed care benefit, a carved-out fee-for-service benefit, and an administrative services model. The analysis must include the community benefit attributable to 340B providers as a result of the model and the federal financial participation provided to the state under each model.

In addition, HCA must establish an annual reporting requirement for all covered entities participating in the 340B drug pricing program that receive Medicaid funds.

Acknowledgements

Milliman was retained to provide an analysis of 340B utilizationand reimbursement in the Managed Care program. The survey was creatd using a template provided by the National Academy for State Health Policy (NASHP).

Financial Services Division

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Drug Rebate Program and 340B

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) is a program that includes the Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers. The MDRP helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid clients. Approximately 780 drug manufacturers currently participate in this program. All fifty states and the District of Columbia cover prescription drugs under the MDRP, which is authorized by Section 1927 of the Social Security Act.

The MDRP requires a drug manufacturer to enter into a National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. When a manufacturer markets a new covered outpatient drug (COD), it must also submit product and pricing data to CMS via the Medicaid Drug Programs (MDP) system. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid quarterly by drug manufacturers and shared among the states and the federal government to offset the overall cost of prescription drugs under the Medicaid program.

Background of 340B Program

The 340B Drug Pricing Program is a federal program created in 1992 for section 340B(a)(4) of the Public Health Service Act (PHSA). The program requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at reduced prices similar to the MDRP.

Provider participation in the 340B Program is voluntary. To purchase drugs at the 340B price, the eligible organization must register with the Health Resources and Services Administration (HRSA) and meet and maintain certain requirements with HRSA and the 340B Office of Pharmacy Affairs Information System (OPAIS).

When an eligible organization enrolls in the 340B Program they must decide whether they will "carve-in" and use 340B purchased drugs for Washington Apple Health (Medicaid) clients, or "carve-out" and purchase drugs outside the 340B Program. If the organization chooses to carve-in, they do so for both fee-for-service (FFS) and managed care organizations (MCO).

340B Program requirements

Covered entities should always ensure they are adhering to all federal, state, and local laws.

Federal requirements

- Upon enrollment in the 340B Program, covered entities must determine if they will participate and use 340B purchased drugs for Apple Health clients. This practice of participation is commonly referred to as "carving-in." When a provider chooses to "carve-out," they will need to purchase drugs outside of the 340B Program.

- Covered entities are responsible for maintaining the accuracy of their information on the Medicaid Exclusion File (MEF).
- Eligible covered entities must recertify their eligibility with HRSA every year and notify the Office of Pharmacy Affairs whenever there is a change in their eligibility. Changes in eligibility status could require the covered entity to stop purchasing drugs through the 340B Program.
- Manufacturers are permitted to audit covered entities' records if they suspect product diversion or that multiple discounts are taking place. Covered entities must have procedures in place to prevent duplicate discounts.

State requirements

- All claims from Medicaid provider numbers and National Provider Identifiers listed as participating with Medicaid are excluded from drug rebate invoicing. Utilization from billing IDs which are not properly identified on the Medicaid Exclusion File (MEF) are included in rebate invoicing. This is true for both MCO and FFS.
- Covered entities which choose to participate and carve-in with Apple Health should bill the state at actual acquisition cost (AAC) for FFS. MCO claims should be submitted per the plans 340B billing guidelines.
- Washington does not support 340B contract pharmacies and has administrative code making clear that drugs purchased under section 340B of the Public Health Service Act (PHS) can be billed to the agency only by the 340B-qualified entities themselves. This also applies to both MCO and FFS claims.
- Providers electing to participate with Apple Health must submit a completed 340B attestation form annually.

Prescription Drug Program

The purpose of the Prescription Drug Program is to pay providers for outpatient drugs, devices, and drug-related supplies. The program is governed by federal and state regulations.

HCA reimburses for medically necessary drugs, devices, and supplies according to rules in Washington Administrative Code (WAC) and the Reimbursement section of the Prescription Drug billing guide. HCA covers outpatient drugs, including over-the-counter drugs listed in HCA's Apple Health Preferred Drug List, when the manufacturer has a signed drug rebate agreement with the federal Secretary of the Department of Health and Human Services (HHS).

Pharmacy Point-of-Sale (POS) reimbursement

The AAC is adjudicated by the payment system based upon the available prices in the drug file. Depending on the status of the drug, POS reimburses at the lowest of the available rates using the following price points:

- National average drug acquisition cost (NADAC)
- Maximum allowable cost (MAC)
- Federal upper limit (FUL)
- Wholesale acquisition cost
- Provider's usual and customary charge to the non-Medicaid population
- Submitted ingredient cost
- 340B MAC for covered outpatient drugs purchased, dispensed, or administered under section 340B of the Public Health Services Act (PHSA) and dispensed to Apple Health clients.
- Actual acquisition cost. HCA uses the following sources to determine AAC including, but not limited to:
    - National average drug acquisition cost (NADAC) published by CMS
    - Acquisition cost data made available to HCA by audits from state or federal agencies, other state health care purchasing organizations, pharmacy benefit managers, individual pharmacy providers, other third-party payers, drug file databases, actuaries, and other consultants.

Outpatient prospective payment system (OPPS)

HCA pays for outpatient hospital services using several payment methods including, but not limited to, the following:

- Enhanced ambulatory patient group (EAPG) or maximum allowable fee schedule
    - OPPS uses an EAPG-based reimbursement method as its primary reimbursement method. HCA uses the EAPG software provided by Solventum Health Information Systems to group OPPS claims based on services performed and resource intensity.
    - The total OPPS claim payment is the sum of the EAPG payments plus the sum of the allowed amounts for each non-EAPG service.
- Only hospitals paid by HCA using the Critical Access Hospital payment methodology are exempt from OPPS. These hospitals are paid using the weighted costs-to-charges (WCC) payment method.

Actual acquisition cost and 340B reimbursement

All claims submitted to Washington Apple Health through fee-for-service (FFS) or managed care for outpatient drugs purchased, dispensed, or administered by PHSA-qualified covered entities participating in the 340B Program:

- May be billed only by the PHSA-qualified covered entity participating in the 340B Program under their participating Medicaid provider number or NPI listed in the quarterly Medicaid exclusion file; and
- Are excluded from Medicaid drug rebate invoicing.
- Except for the claim types below, all drugs purchased, dispensed, or administered by a PHS-qualified covered entity participating in the 340B Program must be billed at the AAC when submitted through FFS to the agency. Exceptions to the AAC billing requirement are only made for:
    - Outpatient hospital claims paid under the enhanced ambulatory payment group (EAPG) methodology; and
    - Ambulatory surgery claims paid under payment group methodology.

Survey methodology

Utilizing a template provided by the National Academy for State Health Policy (NASHP), a survey was sent to all 340B providers that are listed as participating with Washington state. This survey included providers from applicable border areas in Oregon and Idaho.

500 participating providers were surveyed.

- 30 Family Planning/STD clinics
- 347 Federally Qualified Health Centers/Community Health Centers
- 108 Hospitals- Disproportionate Share, Critical Access and Rural Referral Centers

Table 1: Provider survey distribution and responses

Entity Type	Surveys Sent	Responses Received	Percent
Family Planning/STD clinics	30	15	50.00%
Federally Qualified Health Centers/Community Health Centers	347	43	12.40%
Hospitals- Disproportionate Share, Critical Access and Rural Referral Centers	108	51	47.20%
Other	15	0	0.00%
Total	**500**	**109**	**22.50%**

Providers received a questionnaire and form to provide information about utilization for the 2021-2022 calendar years (see Appendix A). The questions focused on the amount of prescriptions processed, aggregate non-340B cost compared to 340B across both on-site clinic/hospital administered drugs and covered entity owned pharmacy dispensing. The survey also requested the AAC of 50 of the most prescribed branded drugs. Additionally, we requested a narrative reporting of how providers utilize the savings generated from 340b.

Survey results

As part of the survey providers were encouraged to provide a narrative with any examples of how savings generated through the 340B program are utilized by the covered entity. This was to include what services, staffing, or benefits are paid for by the generated spread and cost-variance and how this aligns with the covered entity's community benefit plan. Providers were also encouraged to illustrate any instances where the covered entity passes on any savings or cost-variance generated from acquiring a drug under the 340B program directly to the uninsured or low-income patients receiving prescriptions or other services from the covered entity.

Some examples of how savings are utilized given by providers were:

- Specialty services and outreach in rural communities
- Pharmacy services in pharmacy deserts
- Behavioral health services integrated ins Primary Care
- Tele-Behavioral Health

- Case Management to Medicare Patients
- Prescription compassionate care programs
- Administrative costs associated with administering the 340B program including, staff and payments to third party administrators necessary for ensuring program compliance and prevention of diversion and duplicate discounts
- Uninsured patient services, reducing unnecessary emergency room visits.
- Pharmacy sliding scale discounts
- Uninsured and underinsured health care navigation services.
- Expanding access to care in rural communities
- Dental care, including adult dental, which is not covered by Medicaid.
- Health equity teams focusing on social determinants of health
- On call triage teams to evaluate urgent care needs
- Remote monitoring of clinical indicators for patients that live outside of a reasonable distance to a clinic or hospital.
- Training programs not otherwise reimbursed through graduate medical education funding, including dental assistants, nurse practitioners, dentists and pediatricians.
- Funding a sliding scale model to ensure that 100% of services are provided on a sliding fee scale based on income.
- Maintain an in-house stock of reproductive medications, allowing the patient to receive their prescription immediately.
- Administrative costs of running the health center

In the columns below, the data represents a roll-up of the information supplied by providers on the survey.

- Non-340B Estimated Cost- *the aggregate estimated cost of drugs when purchased outside of the 340B Program,*
- Provider Reported 340B Cost- *the provider supplied aggregate actual acquisition cost for drugs purchased through the 340B Program,*
- Payments for 340B Drugs Dispensed- *reimbursement received for 340B drugs dispensed or administered*

109 surveys (21.8%) were returned:

- 15 Family Planning/STD clinics
- 43 Federally Qualified Health Centers/Community Health Centers
- 51 Hospitals- Disproportionate Share, Critical Access and Rural Referral Centers

Table 2: Family Planning/STD clinic responses

Entity Type	CY	# 340B Scripts Processed	Coverage Type	Non-340B Estimated Cost	Provider Reported 340B Cost	Payments for 340B Drugs Dispensed
Family Planning- Physician administered	2021	18,391.00	Apple Health	$24,876.38	$1,095.01	$39,142.03
Family Planning- Physician administered	2022	19,418.00	Apple Health	$58,985.00	$79.29	$181,239.00

Table 3: Federally Qualified Health Center/Community Health Center responses

Entity Type	CY	# 340B Scripts Processed	Coverage Type	Non-340B Estimated Cost	Provider Reported 340B Cost	Payments for 340B Drugs Dispensed
FQHC- Physician administered	2021	137,734	Apple Health	$26,331,127.00	$3,600,043.00	$13,983,312.00
FQHC- Physician administered	2022	159,938	Apple Health	$30,106,610.00	$4,511,183.00	$17,213,633.00
FQHC-Entity Owned Pharmacy	2021	1,238,901	Apple Health	$117,905,514.00	$52,489,625.00	$112,833,537.00
FQHC-Entity Owned Pharmacy	2022	1,352,101	Apple Health	$140,770,139.00	$40,216,269.00	$139,054,614.00

Table 4: Hospital – Disproportionate Share, Critical Access and Rural Referral Center responses

Entity Type	CY	# 340B Scripts Processed	Coverage Type	Non-340B Estimated Cost	Provider Reported 340B Cost	Payments for 340B Drugs Dispensed
Hospital- Physician administered	2021	699,591	Apple Health	$54,292,496.00	$26,705,169.00	$19,442,452.00
Hospital- Physician administered	2022	738,499	Apple Health	$61,138,351.00	$35,646,174.00	$21,161,380.00
Hospital-Entity Owned Pharmacy	2021	83,822	Apple Health	$14,977,904.00	$5,865,832.00	$11,129,561.00
Hospital-Entity Owned Pharmacy	2022	98,973	Apple Health	$17,667,499.00	$8,602,925.00	$15,948,968.00

Limitations of the survey

Some factors must be considered regarding the mechanism of survey and comparison of these disparate provider types.

The survey results may not be reflective of all reimbursement received by providers for drug related costs. Family planning clinics may receive additional reimbursement for ancillary services provided when they serve clients in relation to these visits for the drugs and related services. Family planning clinics responding to the survey do not operate pharmacies. Reimbursement may vary between provider types.

One of the family planning clinic survey respondents only provided information relating to one product. HCA attempted to reach out and obtain more information about the full breadth of their dispensed drugs and did not receive a response.

FQHC's are paid under an encounter rate methodology that provides for full cost reimbursement. Some FQHCs do not include pharmacy services in their cost determination. Many hospitals are reimbursed for inpatient and outpatient services using a grouping methodology, which does not reimburse for drugs individually. These providers may still be able to purchase drugs at a 340B price. These outliers were excluded from reporting.

All information received from the surveys was self-reported and has not been audited by HCA.

Conclusion

Based on the information provided, some providers are being reimbursed above their self-reported costs for prescriptions of 340B covered drugs in the Medicaid program. Since the data is self-reported from providers, it is difficult to conclude how much of this is based on the way that the providers answered the questions or what percentage of the overage is because of the intrinsic differences between the FFS and MCO reimbursement methodologies.

HCA was directed to establish this 340B provider reporting as an annual requirement. Other measures may be necessary, including memorializing the requirement in statute with consequences related to non-compliance.

Milliman report

Milliman was retained to perform an analysis of the Apple Health Managed Care program and the reimbursement to participating 340B providers (see Appendix B). This analysis was done by comparing data for calendar year 2022 and creating estimated costs for the following three scenarios:

- Carved-out fee-for-service
- Carved-in managed care
- The administrative services model

Fee-for-service scenario

- There are two repricing scenarios for FFS which form an estimated range of results.
- The lower cost scenario represents the hypothetical cost if all 340B experience for MC clients were reimbursed at FFS levels on a CY 2022 basis.
    - FFS reimbursement levels are much lower than MC in the historical CY 2022 data.
    - However, there are several factors that may bring FFS and MC reimbursement levels closer together in future periods. We have outlined several of these considerations outside the scope of this analysis in Section IV; Limitations
- The higher cost scenario has the same repricing methodology as the lower cost scenario but removes contributions from two large therapeutic classes that are expected to have substantial pricing or drug mix changes after the experience period.
    - The intent of this scenario is to illustrate sensitivity of results to one of the key limitations of this analysis
    - The two therapeutic classes removed for this scenario were “Antidiabetics” and “Cytokine and Cam Antagonists”

Managed care scenario

- This scenario is intended to illustrate the hypothetical cost if all 340B experience was reimbursed through managed care.
- It illustrates the result of repricing FFS claims in the historical scenario to MC reimbursement levels.
- There is a small amount of FFS experience that gets repriced to managed care rates, therefore the change from the historical scenario is minimal.

Administrative services only scenario

- This scenario is identical to the managed care scenario except the cost associated with risk margin and premium taxes was removed because under this arrangement, MCOs do not carry the benefit cost risk for these services.

Table 5: Pharmacy expense

CY 2022 POINT-OF-SALE PHARMACY EXPENSE AT 340B COVERED ENTITIES IN $ MILLIONS

SCENARIO	BENEFIT EXPENSE	NON-BENEFIT EXPENSE	TOTAL	% CHG FROM HISTORICAL
Historical Experience	$ 177.6	$ 10.3	$ 187.9	
Repricing Scenarios				
Managed Care	180.1	10.5	190.6	1.4%
Admin. Services Only	180.1	4.6	184.7	(1.7%)
Fee-for-Service: Higher Cost[1]	134.2	0.0	134.2	(28.6%)
Fee-for-Service: Lower Cost	81.3	0.0	81.3	(56.8%)

Key observations

HCA notes that the most significant finding comes from the FFS analysis. While this is an estimate, the scenario results in the greater reduction of cost, and potentially more savings overall because of the state regulatory requirement that 340B covered entities bill Medicaid FFS at their AAC. The cost reduction should not be viewed as direct savings. Due to various factors, changes to the pharmacy landscape, and possible provider responses, this cost reduction estimate for would likely not be fully realized as savings for several quarters. It also more closely aligns with the reimbursement levels shown by the net of rebate under MDRP for non-340B pharmacies.

Appendix A: Survey questionnaire

View the survey questionnaire template.

Appendix B: Milliman report

View the Milliman report.