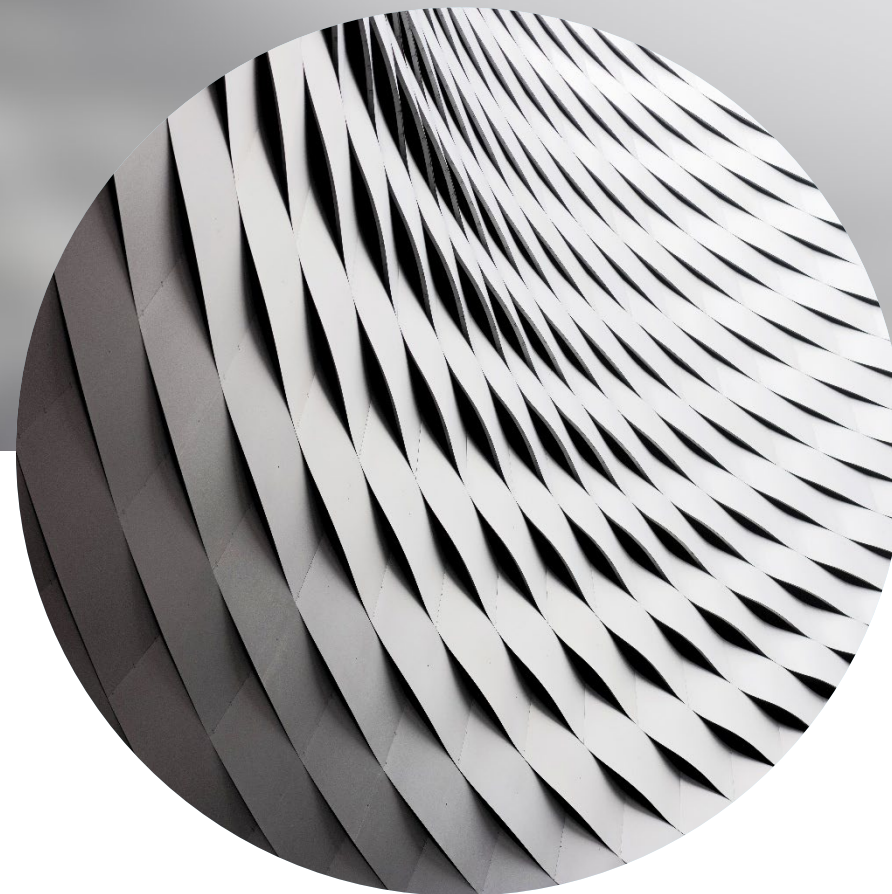


MARCH 2025

Analysis of 340B STD Clinic Enrollment Trends and Prescribing Activity

Prepared for the HIV + Hepatitis Policy Institute



Agenda

1. Background & Research Questions
2. Enrollment Trends: Methodology and Caveats
3. Enrollment Trends: Results
4. Prescribing Activity: Methodology and Caveats
5. Prescribing Activity: Results

SECTION ONE

1 Background & Research Questions

Background/Research Questions

- Sexually Transmitted Disease (STD) clinics comprise one of the 22 types of facilities eligible to purchase discounted drugs under the 340B Drug Discount Program.
- STD clinics are one of the fastest growing covered entity types in terms of purchases at the discounted 340B price: between 2021 and 2023, 340B purchases by STD clinics increased 90 percent from \$871 million to \$1.7 billion.*
- Of the top ten drugs in terms of 2023 340B purchases across all covered entity types, two relate to the treatment/prevention of HIV.*
- Given the size and growth of STD clinic purchases, these analyses seek to inform the following questions:
 - How much are 340B STD clinics contributing to ending HIV, Hepatitis B/C, and STDs?
 - What types of clinics have enrolled as 340B STD clinics and how did they qualify for the program?
 - How many prescriptions for Pre-Exposure Prophylaxis (PrEP) or treatments for HIV, Hepatitis B/C, or other STDs were written by these clinics?

*<https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases>

SECTION TWO

2 Enrollment Trends: Methodology and Caveats

Enrollment Trends: Methodology and Caveats

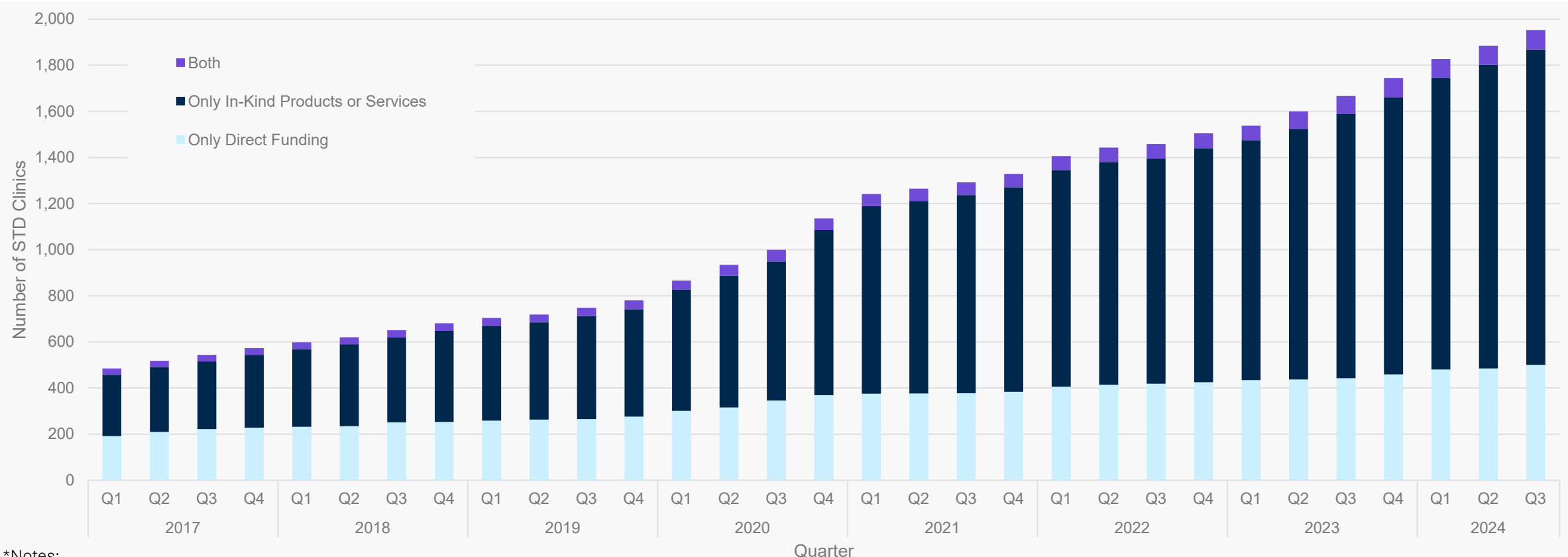
- Reference HRSA Office of Pharmacy Affairs Information System (OPAIS) covered entity database to identify all sites currently or historically registered as STD clinics between 2017 and 2024.
- Exclude locations also registered under a different 340B covered entity type (e.g., DSH hospital, Ryan White clinic) based on analysis of covered entity site addresses.
 - Caveat: variation in appearance of an address e.g., inclusion or exclusion of suite number, can complicate address-based matching.
- Reference the “Nature of Support” field within HRSA OPAIS to determine if covered entity reports eligibility based on receipt of “in-kind products or services,” “direct funding,” or both.
- Use wildcard string searches on covered entity name to classify STD clinics into the following categories.
 - Caveat: covered entity name may not capture the services offered by, or mission of, a particular clinic.

Category	Illustrative Search Terms
Correctional Institutions	Correction, Prison, Jail, Penitentiary, Women’s Facility, Sheriff, Detention, Colony
Family Planning	Planned Parenthood, Reproductive, Pregnancy, Obstetric, Gynecology, OBGYN
Hepatitis Clinics	Hepatitis, Liver
HIV/AIDS	HIV, AIDS, PrEP
LGBTQ+	Pride, LGBT, Gay, Lesbian, Rainbow
Public Health Agencies	Department of Health, Government, Health Unit, Health and Human, Bureau of Health, Health District, Board of Health, Agency, City of, Public Health, State Service Center, County, Health Authority
STD Clinics	STD, STI, Sexual
Other	N/A – not otherwise classified

SECTION THREE

3 Enrollment Trends: Results

340B-Enrolled STD Clinics Over Time by “Nature of Support”*



*Notes:
 [1] Each distinct 340B ID is counted as one clinic and this analysis is limited to entities who are ONLY registered as STD clinics and no other entity type.
 [2] Clinics that only receive direct funding from the CDC or an intermediate organization are included under the "Only Direct Funding" category.
 [3] Clinics that receive only in-kind products or services are included under the "Only In-Kind Products or Services" category.
 [4] Clinics that received both direct funding and in-kind products or services are included under the "Both" category

340B-Enrolled STD Clinics by “Nature of Support” (Q1 2017 – Q3 2024)*

Count of Clinics Enrolled in 340B Program			
Funding Type	Q1 2017	Q3 2024	Growth Rate
Only Direct	191	501	162%
Only In-Kind	266	1,367	414%
Both	28	85	204%
Total	485	1,953	303%

*Notes:

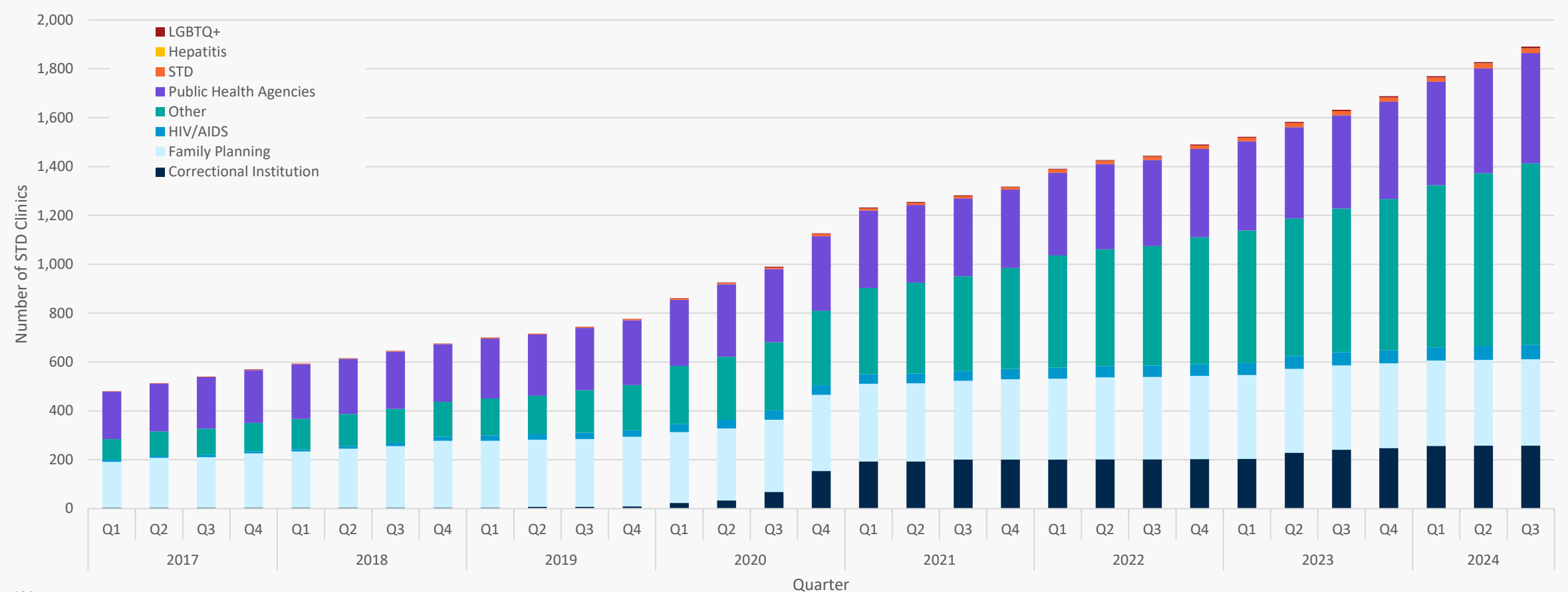
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340B-Enrolled STD Clinics Over Time by Clinic Category*



*Notes:
 [1] Each distinct 340B ID is counted as one clinic and this analysis is limited to entities who are ONLY registered as STD clinics and no other entity type.
 [2] Categories were determined using wildcard searches for key terms in entity names and as a result may not be comprehensive in identifying all entities for each category.

340B-Enrolled STD Clinics by Clinic Category Q1 2017 – Q3 2024*

Count of Clinics Enrolled in 340B Program				
Clinic Type	Q1 2017	Q3 2024	Growth Rate	
Correctional Institution	1	81	8000%	
Family Planning	195	363	86%	
Hepatitis	0	1	--	
HIV/AIDS	9	59	556%	
LGBTQ+	1	7	600%	
Other	84	794	845%	
Public Health Agencies	193	630	226%	
STD	2	18	800%	
Total	485	1,953	303%	

*Notes:

[1] Each distinct 340B ID is counted as one clinic and this analysis is limited to entities who are ONLY registered as STD clinics and no other entity type.

[2] Categories were determined using wildcard searches for key terms in entity names and as a result may not be comprehensive in identifying all entities for each category.

SECTION FOUR

4 Prescribing Activity: Methodology and Caveats

Prescribing Activity: Methodology and Caveats

- Identify sites enrolled in the 340B program as STD clinics (with no registration(s) under any other covered entity type) in 2022 per HRSA OPAIS.
- Identify healthcare providers registered with an address matching to a 340B STD clinic active in 2022 per the CMS National Plan and Provider Enumeration System (NPPES) National Provider Identifier (NPI) Registry.
 - Caveat: NPI Registry may not be maintained up-to-date or properly account for providers who practice in multiple facilities; variation in appearance of an address e.g., inclusion or exclusion of suite number, can complicate address-based matching.
- Reference 2022 Medicare Part D Prescription Drug Event (PDE) records and Medicaid pharmacy records for certain states (CA, GA, IL, NY, TX), available through the CMS Chronic Conditions Warehouse (CCW).
- Limit Medicare PDE and Medicaid pharmacy records to dispenses having a prescriber linked by address to a 2022 340B STD clinic.
 - Caveat: Analysis excludes patients without insurance or who are covered by commercial insurance or another payer type; not all prescriptions written by providers at 340B STD clinics are necessarily filled using 340B-priced inventory.
- Reference Elsevier Gold Standard Drug Database to categorize dispenses by the therapeutic class of the drug dispensed; identify dispenses of Pre-exposure Prophylaxis (PrEP) and treatments for HIV, Hepatitis B/C, or other STDs.

SECTION FIVE

5 Prescribing Activity: Results

Therapeutic Class Breakdown of 2022 Medicare (National)/Medicaid (5 States) Dispenses Prescribed by Potential STD Clinic Providers*

Therapeutic Class	National Part D Cost	Percent of Part D Cost	National Medicare Dispenses	Medicaid Dispenses (CA, GA, IL, NY, TX)	Total Dispenses
General Anti-infectives Systemic	\$500,346,432	24.3%	635,763	144,143	779,906
Alimentary Tract and Metabolism	\$391,281,704	19.0%	1,279,589	177,095	1,456,684
Antineoplastic and Immunomodulating Agents	\$300,185,133	14.6%	59,241	4,620	63,861
Central and Peripheral Nervous System	\$176,753,385	8.6%	2,037,210	311,325	2,348,535
Blood and Blood Forming Organs	\$149,511,396	7.3%	282,124	7,450	289,574
Respiratory System	\$146,194,209	7.1%	484,495	200,759	685,254
Cardiovascular System	\$140,618,673	6.8%	2,726,986	215,106	2,942,092
Musculo-Skeletal System	\$98,862,902	4.8%	456,814	84,355	541,169
Dermatologicals	\$38,540,521	1.9%	188,664	37,339	226,003
Systemic Hormonal Agents (excluding Sex Hormones)	\$38,272,486	1.9%	466,396	48,861	515,257
Genito-urinary System and Sex Hormones	\$33,908,897	1.6%	363,492	88,300	451,792
Sensory Organs	\$22,305,723	1.1%	142,453	9,318	151,771
Vitamins, Minerals, and Dietary or Nutritional Supplements	\$13,676,646	0.7%	110,131	74,041	184,172
Medical Devices and Supplies	\$4,885,908	0.2%	51,799	51,122	102,921
Detoxifying Agents	\$3,358,731	0.2%	4,885	133	5,018
Hospital Solutions	\$156,332	0.0%	1,098	136	1,234
Compounding Agents and Supplies	\$0	0.0%	0	520	520
Total	\$2,058,859,078	100.0%	9,291,140	1,454,623	10,745,763

*Notes:

[1] This analysis is limited to prescribers that are affiliated with entities registered as ONLY STD clinics and no other entity type.

[2] Part D Cost is defined as total reimbursement paid to pharmacies by the Part D plan and the patient. Medicaid costs are excluded from this analysis because cost is not consistently available in claims data.

[3] Medicaid dispenses are limited to California, Georgia, Illinois, New York, and Texas.

Therapeutic Sub-Class for 2022 Medicare (National)/Medicaid (5 States) Dispenses Prescribed by Potential STD Clinic Providers (General Anti-Infective Systemic Drugs)*

Therapeutic Class	National Part D Cost	National Medicare Dispenses	Medicaid Dispenses (CA, GA, IL, NY, TX)	Total Dispenses
HIV Antivirals	\$454,510,367	157,823	23,721	181,544
Hepatitis Antivirals	\$20,785,261	3,512	465	3,977
Systemic Antibiotics	\$15,723,575	358,440	75,754	434,194
Other	\$6,425,528	70,350	28,314	98,664
Herpes Virus, incl. Cytomegalovirus (CMV), Antivirals	\$2,901,702	45,638	15,889	61,527
Total	\$500,346,432	635,763	144,143	779,906

*Notes:

[1] This analysis is limited to prescribers that are affiliated with entities registered as ONLY STD clinics and no other entity type.

[2] Part D Cost is defined as total reimbursement paid to pharmacies by the Part D plan and the patient. Medicaid costs are excluded from this analysis because cost is not consistently available in claims data.

[3] Medicaid dispenses are limited to California, Georgia, Illinois, New York, and Texas.

Summary of 2022 Medicare (National)/Medicaid (5 States) Dispenses Prescribed by Potential STD Clinic Providers*

		All Dispenses										
		STD Related Drugs		PrEP		HIV Treatment Drugs		Hepatitis B/C Treatment Drugs		PrEP & STD, HIV/Hep B/C Treatment Drugs		
		Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total
Medicare Part D (National)		10,957,046	186,054	1.7%	25,795	0.2%	171,258	1.6%	3,668	0.0%	359,702	3.3%
Medicaid (5 States)												
	CA	613,090	35,043	5.7%	5,101	0.8%	8,017	1.3%	131	0.0%	43,179	7.0%
	GA	12,950	749	5.8%	65	0.5%	1,094	8.4%	0	0.0%	1,843	14.2%
	IL	183,648	6,533	3.6%	3,150	1.7%	10,374	5.6%	88	0.0%	16,968	9.2%
	NY	472,229	13,947	3.0%	2,877	0.6%	4,756	1.0%	128	0.0%	18,819	4.0%
	TX	231,492	6,444	2.8%	263	0.1%	1,662	0.7%	143	0.1%	8,228	3.6%
Total		12,470,455	248,770	2.0%	37,251	0.3%	197,161	1.6%	4,158	0.0%	448,739	3.6%
		Brand Dispenses										
		STD Related Drugs		PrEP		HIV Treatment Drugs		Hepatitis B/C Treatment Drugs		PrEP & STD, HIV/Hep B/C Treatment Drugs		
		Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total
Medicare Part D (National)		1,335,726	0	0.0%	22,789	1.7%	155,723	11.7%	1,970	0.1%	157,693	11.8%
Medicaid (5 States)												
	CA	61,672	0	0.0%	3,516	5.7%	6,421	10.4%	89	0.1%	6,510	10.6%
	GA	1,606	0	0.0%	47	2.9%	952	59.3%	0	0.0%	952	59.3%
	IL	27,426	0	0.0%	1,748	6.4%	8,522	31.1%	37	0.1%	8,559	31.2%
	NY	44,811	0	0.0%	1,435	3.2%	3,218	7.2%	53	0.1%	3,271	7.3%
	TX	37,327	0	0.0%	263	0.7%	1,619	4.3%	122	0.3%	1,741	4.7%
Total		1,508,568	0	0.0%	29,798	2.0%	176,455	11.7%	2,271	0.2%	178,726	11.8%

*Notes:

[1] This analysis is limited to prescribers that are affiliated with entities registered as ONLY STD clinics and no other entity type.

[2] STD Related Drugs include antibiotics that are also used to treat other conditions.

[3] Certain drugs are included in multiple categories. For example, the PrEP category includes drugs that can be used as part of an HIV treatment regimen or taken on their own as PrEP.

Top 10 Brands by Medicare (National) Spending Prescribed by Potential STD Clinic Providers in 2022*

Drug Name	Total Part D Cost	Total Part D Claims (National)	Total Medicaid Claims (CA, GA, IL, NY, TX)	Total Claims
BIKTARVY	\$170,069,225	44,283	6,327	50,610
ELIQUIS	\$108,021,173	133,708	2,470	136,178
REVLIMID	\$56,176,125	2,997	38	3,035
TRULICITY	\$52,160,200	38,491	5,499	43,990
DESCOVY	\$48,749,320	22,426	6,263	28,689
JARDIANCE	\$42,562,890	40,310	3,217	43,527
XARELTO	\$42,439,664	46,702	1,139	47,841
OZEMPIC	\$39,219,396	29,035	3,558	32,593
TIVICAY	\$38,340,330	16,783	1,243	18,026
GENVOYA	\$36,785,617	9,521	1,759	11,280

*Notes:

[1] This analysis is limited to prescribers that are affiliated with entities registered as ONLY STD clinics and no other entity type.

[2] Highlighted brands are used to treat STDs, Hepatitis B/C, or HIV.

[3] This analysis excludes generic drugs.

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