The 340B Drug Pricing Program in Michigan

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Key Points

- The 340B Drug Pricing Program allows healthcare organizations that care for low-income patients to purchase outpatient drugs from pharmaceutical manufacturers at reduced prices and to then bill payers (except Medicaid) at non-discounted rates. They are allowed to use these savings to improve their services as they see fit.
- Clinics and hospitals all across Michigan use 340B savings to provide patients with free or discounted prescription drugs, to subsidize the costs of expensive services like inpatient psychiatric care and labor and delivery services, and to hire enough staff to care for their patients.
- Critics of the 340B program are concerned about too little transparency regarding how hospitals and clinics use program savings, the contribution the program makes to rising drug costs, and the role of the program in incentivizing the consolidation of hospitals and physician practices.
- Proponents of the program assert that it is working as intended, allowing Covered Entities (CEs) to maintain high-quality services in a complex healthcare financing environment and serve vulnerable patients, while they adhere to established program transparency and patient benefit requirements.
- In Michigan, recent legislative proposals like SB 94 and SB 95 aim to increase reporting requirements for CEs, including details on how CEs use their savings and what impact the program has on the community.

Program overview

The 340B Drug Pricing Program, authorized in 1992 under Section 340B of the Public Health Service Act, is a federal initiative that requires drug manufacturers whose products are covered by Medicaid, to offer discounts on outpatient drugs to select safety-net providers.[1] [i] The organizations eligible to participate in 340B are known as Covered Entities (CEs) and include certain hospitals and clinics.[ii] The intent of the program is to enable covered entities to "stretch scarce federal resources to reach more eligible patients and provide more comprehensive services".[iii] Since its inception, 340B has evolved to include a broad range of healthcare entities, adapting its structure and scale in response to federal law and regulatory changes. Today, the program has become a significant component of Michigan's healthcare landscape, impacting hospitals, federally qualified health centers, and safety-net clinics.

In essence, 340B safety-net providers purchase outpatient drugs from pharmaceutical manufacturers at reduced prices and then bill payers (except Medicaid) at non-discounted rates.[iv] Providers retain the difference in these rates and use those savings to reinvest in services.[v] Drug manufacturers must sell these outpatient drugs to CEs at no more than the "ceiling price", or calculated maximum price, which is typically 20-50% below average market rates.[vi] The ceiling price is determined by a formula set by the Health Resources and Services Administration (HRSA) that ensures a 340B drug's price is no higher than what state Medicaid programs

[1] Safety-net providers are defined by the Institute of Medicine as "those providers that organize and deliver a significant level of health care and other needed services to uninsured, Medicaid and other vulnerable patients." Agency for Healthcare Research and Quality, "Safety Net," accessed July 30, 2025, https://www.ahrq.gov/topics/safety-net.html.

pay.[vii] For example, a 340B CE can buy a new, brand-name, outpatient drug at a 23.1 percent discount.[viii] If the manufacturer chooses to increase the price of the drug or offers a lower price to other buyers, they must give additional discounts to CEs. In 2023, CEs across the nation purchased $66.3 billion in 340B eligible drugs. [ix]

History and purpose of 340B

The rising cost of drugs has been a challenge for providers and for patients for decades. The 340B program was created in 1992 to address an unintended consequence of an earlier law, the Medicaid Rebate Law (MRL) of 1990.[x] This law mandated that drug manufacturers provide Medicaid with drugs at the lowest price they offer.[xi] Before the MRL was enacted, drug manufacturers voluntarily gave discounts to safety-net providers.[xii] Once the MRL was in place, the lowest price calculation also factored in voluntary discounts, which further decreased the amount that manufacturers could charge Medicaid programs for drugs.[xiii] Consequently, many drug manufacturers stopped voluntarily offering discounts.[xiv] To preserve access to discounted drugs for vulnerable populations, Congress established the 340B program requiring drug manufacturers whose products are covered by Medicaid to offer discounted outpatient drugs to selected safety-net providers. [xv]

The 340B program is overseen by the federal Health Resources and Services Administration (HRSA). The intent of the program, per HRSA and supporting Congressional documents, was to "enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services".[xvi] Importantly, policymakers did not dictate exactly how 340B savings should be used and allowed CEs to choose how to invest the savings to benefit more patients.[xvii]

The first classes of CEs were federal grantee clinics and Disproportionate Share Hospitals (DSH), that care for the uninsured, those covered by Medicaid, and other vulnerable patients. When established in 1992, the program included 13 classes of covered entities (**Table 1**).[xviii] The Patient Protection and Affordable Care Act of 2010 (ACA) expanded eligibility to free-standing cancer hospitals, rural referral centers, and sole community hospitals, resulting in 16 classes of covered entities.[2, xix]

In 2010, HRSA guidance permitted covered entities (CEs) to use 'contract pharmacies', retail pharmacies like CVS or Walgreens, to dispense 340B-eligible drugs.[xx] This allows the CE's patients to pick up their medications at a retail location instead of a CEs on-site pharmacy. The table below classifies hospitals and clinics by their covered entity status and provides examples of CEs across the state.

[2] For-profit hospitals are not eligible to participate in 340B. Participating hospitals must be private nonprofit hospitals under contract with state or local government to provide care to low-income patients not eligible for Medicare or Medicaid, owned or operated by unit of state or local government, and/or are a public or private nonprofit corporation granted governmental powers by a unit of state or local government. Health Resources & Services Administration, "Disproportionate Share Hospitals," 340B Drug Pricing Program, June 2024, https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals.

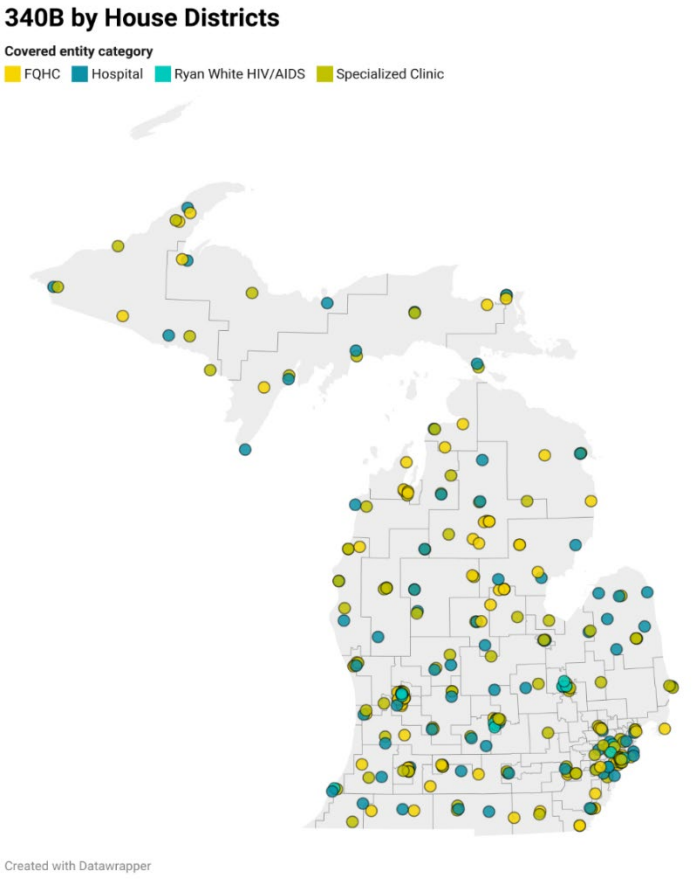
Table 1. 340 B Covered Entity Descriptions and Michigan Examples		
Covered Entity	Description	Michigan Examples
Hospitals		
Disproportionate Share Hospitals (DSH)	Hospitals that meet a specific disproportionate share adjustment percentage based on caring for a high number of Medicare and Medicaid patients. [xxi]	Bronson /Battle Creek Hospital, University of Michigan Hospitals and Health Centers
Children's Hospitals	Hospitals with inpatients predominantly under 18 that meet a specific disproportionate share adjustment or indigent care revenue from state/local governments and Medicaid.[xxii]	No CEs solely categorized as 340B Children's Hospitals
Critical Access Hospitals	Rural hospitals with 25 or fewer acute care inpatient beds, located over 35 miles from another hospital, and maintaining an average length of stay under 96 hours. They also provide 24/7 emergency care. [xxiii]	Mackinac Straits Hospital & Health Center, Trinity Health -Shelby Hospital
Freestanding Cancer Hospitals	Independent hospitals treating cancer patients, meeting a certain disproportionate share adjustment or indigent care calculation. [xxiv]	No CEs solely categorized as 340B Freestanding Cancer Hospitals
Sole Community Hospitals	Typically, rural hospitals that are the only source of inpatient services for a geographic area's Medicare beneficiaries. [xxv]	Spectrum Health System-Big Rapids Hospital, Huron Memorial Hospital
Rural Referral Centers	Acute-care hospitals (rural or urban) that treat a high number of Medicare patients referred from surrounding rural hospitals. [xxvi]	McLaren Central Michigan, Henry Ford Health Wyandotte
Federally Qualified Health Centers		
• Health center program award recipients • Health center program look-alikes • Native Hawaiian health centers • Tribal and urban Indian health centers	Community -based outpatient clinics providing primary care in underserved areas. They meet strict requirements, including sliding scale care and a patient-inclusive board, and qualify for specific Medicare and Medicaid reimbursement. [xxvii]	Sault Ste. Marie Tribal health, Great Lakes Bay Health Centers
Ryan White HIV/AIDS Program Grantees	Entities receiving federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. [xxviii]	Munson Medical Center, Michigan Department of Health and Human services
Specialized Clinics		
• Family Planning Clinics • Comprehensive hemophilia diagnostic treatment centers • Title X family planning clinics	Clinics that receive funding to treat specific diseases or patient populations	Bronson Hemophilia Treatment Center, Washtenaw County Health Department-TB Clinic

• Sexually transmitted disease clinics • Tuberculosis clinics		

Source: Nailah Henry, "The 340B Drug Pricing Program in Michigan", Center for Health and Research Transformation, August 2025

How Providers in Michigan Use 340B Savings

Covered entities in Michigan invest their 340B savings in a variety of ways. According to interviews with expert sources, large urban and metro-area hospital systems may use 340B savings to offer reduced-price medications to low-income patients, provide services to help patients enroll in insurance or communicate with their insurance companies, or to implement mobile clinics to ensure access to needed services. In rural settings, these funds may support high-cost and/or hard-to-staff services such as inpatient psychiatric care or labor and delivery units and be used to open new clinics or pharmacy sites. Smaller and federally supported clinics often rely on 340B savings to sustain core primary care services and maintain staffing levels, expand access to care for uninsured patients, cover high-cost behavioral health programs, expand service hours, and link patients to social supports. The 340B by House District map shows that different types of providers across the state participate in 340B. Covered entities are in nearly every district in Michigan.



Note: This map was created by CHRT using data from the HRSA Office of Pharmacy Affairs July 2025. Entities were included in the map if they were classified as 'participating' and are represented by address of their primary location. Each CE primary location can have multiple sub-entities and every sub-entity is not displayed on the map.

Views on the 340B Program

Debate about the 340B program has largely focused on the program's impacts across three key areas: transparency, drug costs, and market consolidation. Critics of the 340B program, including drug manufacturers, often raise concerns about the lack of transparency around how savings from the program are used, claim the program contributes to pharmaceutical companies increasing the price of drugs, and cite the program as a factor incentivizing hospitals to consolidate with outpatient locations eligible for 340B.

Proponents of 340B, including healthcare organizations that participate in the program, argue that 340B is being used as it was intended by the federal government— to strengthen services for vulnerable patients whose healthcare services cost more than healthcare organizations receive in payment. They also assert that the existence of the 340B program is a necessary response to the high costs and frequency of price increases for drugs and note that it would not be needed if drug manufacturers and wholesalers lowered drug costs.

Transparency

- **Some researchers and critics argue that a lack of clarity exists regarding how 340B savings are used.** They say that there isn't enough transparency.[xxix]

- **Hospitals' spending on free care hasn't always increased.** Several studies in the academic literature show that after Disproportionate Share Hospitals started participating in 340B, their spending on free care for low-income and uninsured patients didn't consistently rise. [xxx]
- **Funds are used for a mix of purposes.** While some studies suggest hospitals use 340B savings to expand access for low-income patients, others indicate the revenue is used to expand their enterprises by acquiring private physician practices. [xxxi]
- **Community benefit information is published.** Hospitals state that they increase transparency through websites and case studies on how 340B savings are used, often published through organizations like the American Hospital Association (AHA). They say this demonstrates alignment with the federal government's intent for the program. [xxxii]
- **Existing program integrity requirements are in place.** Hospitals also assert that the program already requires participants to meet many program integrity requirements through audits and by maintaining auditable records. This is especially important given that there are no federal requirements for covered entities (CEs) to report how 340B savings are spent. [xxxiii]

Drug costs

- **Some researchers and critics argue that 340B increases the overall cost of drugs.** They believe that drug manufacturers raise prices to offset the discounts they're required to give to a growing number of 340B covered entities. [xxxiv]
- **The research on this issue is contradictory.**
  - Some studies suggest that lower list prices for certain drugs, like those for hepatitis C, saved manufacturers money from 340B discounts.[xxxv]
  - Conversely, other studies found that the program contributed to manufacturers increasing the cost of cancer drugs between 1995 and 2013. [xxxvi]
- **Critics also point to the impact on employer-sponsored health plans.** They argue that since these plans do not receive 340B discounts, patients covered by them end up paying more for their drugs. [xxxvii]
- **Proponents of the program counter that manufacturers are responsible for drug prices.** They assert that since manufacturers set the prices, they have the ultimate control over their cost, and therefore, 340B should not be blamed for rising drug prices. [xxxviii]

Market consolidation

- **Critics argue that 340B creates a financial incentive for large health systems to acquire physician practices.** By acquiring new clinics or extending 340B eligibility to them, health systems can purchase discounted outpatient drugs for a wider network, which increases their revenue from the program.[xxxix]
  - **Some evidence supports this concern.** Studies indicate that 340B hospitals are increasingly acquiring certain types of outpatient clinics, such as cancer, psychiatric, and ophthalmology practices. This consolidation can lead to higher overall costs for both payers and patients. [xl]
- **The American Hospital Association (AHA) rejects this assertion.** The AHA argues that 340B is not the primary driver of these acquisitions. They point to other market forces that make it difficult for physician offices to provide care efficiently, which they say drives consolidation. [xli]
- **Consolidation is driven by a variety of factors beyond 340B.**
  - Physician practices are being acquired by a range of entities, including hospitals, healthcare systems, private equity investors, health insurers, and practice management groups.[xlii]
  - Studies report that the reasons for this consolidation include increasing negotiation power with insurers, improving care coordination across different settings, and enhancing administrative support for physicians in a complex healthcare environment. [xliii]

340B legislative and regulatory actions

Since the program's inception, there have not been many changes on the federal level to change or refine 340B. In 2021, states began to pass legislation impacting the program, but states are limited in their abilities to refine the federal program.

Federal activity

Over the past decade, the federal structure of 340B has remained relatively stable, but some notable program changes, litigation outcomes, and regulatory reviews since 2010 include:

- HRSA guidance in 2010 allowing CEs to partner with multiple retail pharmacies to dispense 340B drugs,[xliv]
- the ACA expansion of CEs to include critical access hospitals, sole community hospitals, rural referral centers, free-standing children's hospitals, and free-standing cancer hospitals, [xlv]
- penalties for drug manufacturers that violate program regulations and the establishment of dispute resolution processes established for drug manufacturers and for CEs,[xlvi]
- the Centers for Medicare and Medicaid Services (CMS) final rule that initiated a "clawback" period to recover money from hospitals. This is a budget-neutral measure to offset the lump-sum payments Medicare made to them after a Supreme Court ruling on unlawfully reduced 340B drug payments,[xlvii]
- the introduction of the 340B Rebate Model Pilot Program, that will allow participating drug manufacturers to require CEs to seek a rebate for 340B eligible drugs rather than receive an upfront discount, [xlviii]
- the proposal to move management of 340B from HRSA to CMS,[xlix]
- implementation of a systematic HRSA audit framework to ensure compliance with program rules in a specific number of CEs each year. [l]

Since 2023, several pieces of federal legislation were introduced that may impact 340B: The Equitable Access to 340B Act, The Rural 340B Access Act, The PROTECT 340B Act, The 340B PATIENTS Act, The 340B Transparency Act, The SUSTAIN 340B Act, and The 340B ACCESS Act.[li] These bills aim to establish a variety of reforms to the program to increase transparency around how 340B savings are used, require participating hospitals to provide direct benefits to patients, prevent discrimination against CEs from health plans and pharmacy benefit managers, and expand 340B eligibility to certain types of rural health care providers. [lii]

State activity

States have limited power to change the structure and mechanisms of the federal 340B program but have started to enact laws that require CEs to report data to them, prevent discrimination against 340B entities, and add conditions of how 340B savings are used. The first state to pass legislation directly impacting 340B was Arkansas in 2021. The Arkansas state legislature passed the "340B Drug Pricing Nondiscrimination Act" to prevent payers and Pharmacy Benefit Managers from discriminating against eligible pharmacies and patients in the 340B program. The act also requires patients to have a choice in pharmacy selection and prevents other discriminatory practices.[liii] From 2023 to July 2025, 36 states enacted 340B legislation.[liv] Many focus on preventing Pharmacy Benefit Managers (PBMs) from denying or increasing 340B pricing to CEs or contract pharmacies.[lv] PBMs, as the middleman between pharmacies, patients, insurance companies, and drug manufacturers, can use their negotiating ability to manipulate prices of 340B drugs.[lvi] They might deny claims for 340B drugs or greatly reduce their reimbursement rate.[lvii] Some of the legislation also focuses on increasing reporting requirements for CEs to demonstrate how 340B savings are used.[lviii]

The Michigan state legislature is currently considering 340B bills SB 94 and SB 95.[lix]

Bills like Michigan's SB 94 and SB 95 were enacted in Colorado, Hawaii, Illinois, Maine, Nebraska, New Mexico, North Dakota, Oklahoma, Rhode Island, South Dakota, Tennessee, Utah, and Vermont in 2025.[lx]

Table 2. Federal vs. SB 94 and 95 Covered Entity Reporting Requirements

Requirement	Federal 340B Program	Michigan SB 94 & 95 (Proposed)	Note
Annual Recertification	Required to complete.	Required to submit a copy of.	The state bill requires submitting proof of this federal requirement.
Maintain Records	Required to maintain auditable records.	Required to submit an affidavit affirming compliance with audits. Also, a description of any adverse audits within the past 12 months is required.	The state bill is more specific about how to report on record maintenance and audit outcomes.
Duplicate Discounts	Required to report arrangements with State Medicaid to prevent them.	Required to submit an affidavit affirming compliance with the prohibition.	Both have this requirement, but the state bill requires a formal affidavit.
Non-Compliance	Allowed to self-disclose.	Required to describe any adverse 340B Program audits within the preceding 12 months.	The state bill focuses on formal audits as a source of non-compliance.
Pharmacy Contracts	Required to provide upon request.	No specific mention in the proposed bills.	Federal-only requirement.
Contract Pharmacy Registration	Required to register each contract pharmacy.	No specific mention in the proposed bills.	Federal-only requirement.
Community Impact	Not mentioned.	A description of the impact on patients and the community is required.	State-specific requirement.
Community Health Needs Assessment	Not mentioned.	Required to submit a copy of this assessment if it's required under federal law.	The state bill makes submitting this assessment an explicit requirement if it's already a federal obligation.

Source: Nailah Henry, "The 340B Drug Pricing Program in Michigan", Center for Health and Research Transformation, August 2025

For more information about the 340B Drug Pricing Program in Michigan, please contact Nailah Henry at hnailah@med.umich.edu.

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