

# The 340B Drug Pricing Program Needs a New Prescription

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*Christina Smith  
Thomas Schatz*



## Introduction

Federal healthcare programs are often well-intended but end up costing more than expected and become subject to waste, fraud, abuse, and mismanagement. One of the best (or worst) examples of such a result is the 340B Drug Pricing Program, which is administered by the Health Resources and Services Administration (HRSA).<sup>1</sup> Citizens Against Government Waste (CAGW) and its lobbying arm, the Council for Citizens Against Government Waste (CCAGW) have long been concerned about the misuse and abuse of the 340B program.<sup>2</sup>

The 340B program was created in 1992 after the Medicaid Drug Rebate Program, which was established in 1990, set price controls on the cost of drugs that led to higher rather than lower prices. 340B requires manufacturers participating in Medicaid to sell drugs at a discount of between 20 to 50 percent to “covered entities,” including federally funded facilities like community health centers, black lung clinics, tuberculosis clinics, and hemophilia treatment centers.<sup>3</sup> The program includes disproportionate share hospitals (DSH), which receive supplemental federal funds related to the number of low-income Medicare and Medicaid patients and uninsured indigent patients served.

In 1992, the House of Representatives passed a bill to clarify that the savings from the discounted drugs would allow the covered “entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>4</sup> However, the bill was not enacted by the Senate, so there was no mandate for covered entities to pass along drug savings to their patients, and the definition of a 340B patient has been broadly interpreted, allowing the program to be used to inflate the profits of hospitals and pharmacies.<sup>5</sup> There have been several reports issued by Congress, the Government Accountability Office (GAO), the media, and the private sector about the abuses of 340B and the need for programmatic reforms.

Since 340B was created by a federal statute, CAGW has argued it can only be modified or reformed by Congress. But the lack of action on Capitol Hill has enabled and encouraged states to pass legislation with varying provisions that will not only fail to prevent the abuses of 340B but also raise constitutional and jurisdictional issues that are being challenged in court.

This issue brief reviews the problems arising from the 340B drug discount program and offers reforms that Congress should consider implementing to restore the program to its original intent to help patients rather than enrich hospitals and pharmacies.

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<sup>1</sup> Health Resources & Services Administration, “340B Drug Pricing Program,” December 2023, <https://www.hrsa.gov/opa>.

<sup>2</sup> Council for Citizens Against Government Waste (CCAGW), “340B Drug Discount Program,” <https://www.ccagw.org/340B>.

<sup>3</sup> Elizabeth L. Wright, “Pharmaceutical Price Controls: A Prescription for Disaster,” Citizens Against Government Waste (CAGW), October 2016, <https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Controls%20-%20A%20Prescription%20for%20Disaster.pdf>.

<sup>4</sup> Medicaid and Department of Veterans Affairs Drug Rebate Amendments of 1992, H.R. 2890, <https://www.congress.gov/bill/102nd-congress/house-bill/2890>.

<sup>5</sup> Stephen T. Parente and Michael Ramlet, “Unprecedented Growth, Questionable Policy: The 340B Drug Program,” Carlson School of Management, University of Minnesota, <https://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/inline-files/340BMinnesotaWhitePaper.pdf>.

## Exploding Entities and Expenditures

The costs associated with the 340B program have increased substantially over the past 10 years. In 2014, 340B discounted purchases were \$9 billion, but by 2020, they reached \$38 billion, or 322 percent more than in 2014, and a 27 percent increase from the \$29.9 billion spent in 2019.<sup>6</sup> On April 14, 2023, the healthcare data analytics firm IQVIA released its study, “The 340B Drug Discount Program Exceeds \$100B in 2022,” which described the massive increase in spending, noting how the misuse of the funds by hospitals and contract pharmacies is ongoing, and patients are still not getting the benefits Congress intended them to receive.<sup>7</sup>

The number of unique covered entities grew from 3,600 in 2010 to more than 5,000 in 2020, while the number of sites, including provider locations related to those entities, grew by 700 percent.<sup>8</sup> Contract pharmacies had the largest impact on the growth of 340B. There were fewer than 1,300 contract pharmacies in the 340B program in 2010, but by 2021, there were 29,971, an increase of 2,205 percent.<sup>9</sup>

A September 24, 2022, *New York Times* article about Richmond Community Hospital in Virginia, owned by Bon Secours, found that instead of reinvesting profits from 340B drug sales into its DSH facility and improving patient care, the money was being used instead to invest in facilities in the city’s wealthier neighborhoods. Dr. Lucas English, who worked in the hospital’s emergency department until 2018, said, “Bon Secours was basically laundering money through this poor hospital to its wealthy outposts ... It was all about profits.” Dr. Peter B. Bach, who has written about the use of 340B profits to open more clinics in wealthier areas, said the hospitals are “nakedly capitalizing on programs that are intended to help poor people.”<sup>10</sup>

## Reports of Abuses Abound

Government reports and third-party studies provide ample evidence that the 340B program is misused and program benefits are not being allocated to the intended patients. A November 2021 Xcenda study, “340B and Health Equity: A Missed Opportunity in Medically Underserved Areas,” showed how the program is not being implemented as intended to help low-income and vulnerable individuals gain access to low-cost prescription drugs.<sup>11</sup> Instead, it is boosting hospitals’ coffers and their contract pharmacies’ profits that are largely located in areas that do not serve low-income people.

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<sup>6</sup> Drug Channels, “The 340B Program Soared to \$38 Billion in 2020-Up 27% vs. 2019 (rerun),” September 22, 2021, <https://www.drugchannels.net/2021/09/exclusive-340b-program-soared-to-38.html>.

<sup>7</sup> IQVIA, “The 340B Drug Discount Program Exceeds \$100B in 2022,” April 14, 2023, <https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-exceeds-uds100b-in-2022>.

<sup>8</sup> IQVIA, “340B Drug Discount Program Growth Drivers,” April 16, 2021, <https://www.iqvia.com/locations/united-states/blogs/2021/04/340b-drug-discount-program-growth-drivers>.

<sup>9</sup> Drug Channels, “340B Continues Its Unbridled Takeover of Pharmacies and PBMs,” June 15, 2021, <https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html>.

<sup>10</sup> Katie Thomas and Jessica Silver-Greenberg, “How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits,” *The New York Times*, September 24, 2022, <https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poorneighborhood.html>.

<sup>11</sup> Amerisource Bergen, Xcenda, “340B and health equity: a missed opportunity in medically underserved areas,” 2021, [https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studiespdf/xcenda\\_issue\\_brief\\_340b\\_muas\\_nov2021.pdf?la=en&hash=43F8AA8291C2A71A014B1B10BB1E4F4616882938](https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studiespdf/xcenda_issue_brief_340b_muas_nov2021.pdf?la=en&hash=43F8AA8291C2A71A014B1B10BB1E4F4616882938).

An October 28, 2020, coalition letter led by CCAGW signed by 18 organizations to then-Senate Health, Education, Labor, and Pensions Committee Chairman Lamar Alexander (R-Tenn.) and House Education and Labor Committee Ranking Member Greg Walden (R-Ore.) cited findings from the April 2016 Community Oncology Alliance report, “Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014.” The report found that the movement from lower-cost physician offices to higher-cost hospital outpatient settings led to increased costs in the 340B program. The coalition letter summarized the report’s findings by stating, “When a 340B hospital purchases a physician’s office, it can administer their heavily discounted drugs to its newly acquired patients that have insurance, charging the insurers the full reimbursable price and pocketing the difference.”<sup>12</sup>

The coalition letter also cited a December 2017 Berkeley Research Group (BRG) report, “The Oncology Drug Marketplace: Trends in Discounting and Site of Care,” which echoed the Community Oncology Alliance’s findings. The BRG report noted that the “shift in site of oncology care from the physician office to the hospital outpatient setting has continued unabated since 2008, and almost 50 percent of 2016 Medicare Part B chemotherapy drug administration claims occurred in the hospital outpatient setting – up from just 23 percent in 2008” and “average profit margins on Part B-reimbursed physician-administered oncology drugs purchased at a 340B price increased from 40 percent in 2010 to 49 percent in 2015 and have created substantial financial incentives for 340B hospitals to expand oncology services, despite overall healthcare costs increasing as a result of this shift in site of care.”<sup>13</sup>

The letter included a comment from the January 10, 2018, House Energy and Commerce Committee report, “Review of the 340B Drug Pricing Program,” that while HRSA prohibits diversion and resale of 340B drugs to ineligible patients, “a large percentage of HRSA’s audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016.”<sup>14</sup>

A May 14, 2014, CAGW blog post noted, “Because of a poorly written law and unclear regulations that allow a broad interpretation of the term ‘patient,’ permit too many organizations to qualify for the program and provide little control over how the drug savings can be spent, consumers and taxpayers ultimately end up paying for a program that has become nothing more than an ATM for nonprofit hospitals and pharmacies.”<sup>15</sup>

Subsequent CAGW commentary, including a July 17, 2015 blog post that summarized a June 2015 GAO report on 340B, cited both a September 2011 GAO report and a February 2014 HHS Office of the Inspector General (OIG) report that found “many troubling issues within the program, such as 45 percent of covered entities had profited from the 340B program, that the savings from the discounted drugs were often not passed along to low-income patients, that drugs were being diverted to people that were not patients of the covered entities, and that drug

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<sup>12</sup> CCAGW, “CCAGW Leads Coalition in Letter to Senate and House Offering Reforms for 340B Pricing Program, October 28, 2020, <https://www.ccagw.org/sites/default/files/Coalition%20Letter%20340B%20Alexander-Walden%2010-28-2020.pdf>.

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> Elizabeth Wright, “What is the 340B Program and Why You Need to Care,” *The WasteWatcher*, CAGW, May 14, 2014, <https://www.cagw.org/thewastewatcher/what-340b-program-and-why-you-need-care>.

manufacturers were providing duplicate rebates to covered entities and states via the 340B program and Medicaid respectively, both practices which are proscribed by law.”<sup>16</sup>

Beyond the impact of the 340B program on pharmaceutical sales, biopharmaceutical drug companies are facing further market challenges due to government price controls. The April 23, 2023, IQVIA study noted that the Inflation Reduction Act’s (IRA) price controls will impose additional pressure on future research and development. CAGW submitted comments in response to the Center for Medicare and Medicaid Services (CMS), “initial guidance for implementation of the Negotiation Program for initial price applicability year 2026.” The price controls in the IRA will further distort the medical marketplace. The IRA also expanded the 340B drug discount program despite its flaws.<sup>17</sup>

### States Step into the Void Left by Congress

In the absence of congressional action, states are increasingly stepping in to consider and adopt legislation to reform the 340B program. In 2021, CCAGW sent a letter opposing 340B legislation to the Arkansas state legislature.<sup>18</sup> In 2022, CCAGW sent letters in opposition to Connecticut’s SB355,<sup>19</sup> Louisiana’s HB548,<sup>20</sup> Maine’s LD 1938,<sup>21</sup> Mississippi’s HB 733,<sup>22</sup> and Utah’s HB 308.<sup>23</sup> In 2023, CCAGW sent a letter in opposition to Mississippi’s SB 2484.<sup>24</sup> Through March 14, 2024, letters on 340B were sent in opposition to Kentucky’s SB27,<sup>25</sup> West Virginia’s SB325,<sup>26</sup> Oklahoma’s SB1628,<sup>27</sup> Virginia’s SB119,<sup>28</sup> Nebraska’s LB984,<sup>29</sup> and

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<sup>16</sup> Elizabeth Wright, “More Proof the 340B Program Needs Reform,” *The WasteWatcher*, CAGW, July 17, 2015, <https://www.ccagw.org/thewastewatcher/more-proof-340b-program-needs-reform>.

<sup>17</sup> Drug Channels, “The Inflation Reduction Act: Three Unintended Consequences for Biosimilars, Health Plans, Providers, and Pharmacies,” September 13, 2022, <https://www.drugchannels.net/2022/09/the-inflation-reduction-act-three.html>.

<sup>18</sup> Council for Citizens Against Government Waste (CCAGW), “CCAGW Urges Arkansas Senate Insurance and Commerce Committee to Oppose HB 1881,” April 22, 2021, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-arkansas-senate-insurance-and-commerce-committee-oppose>.

<sup>19</sup> CCAGW, “CCAGW Urges Connecticut Committee on Insurance and Real Estate to Oppose SB 355,” March 24, 2022, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-connecticut-committee-insurance-and-real-estate-oppose>.

<sup>20</sup> CCAGW, “CCAGW Urges Louisiana Senate Health and Welfare Committee to Oppose HB548,” May 2, 2022, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-louisiana-senate-health-and-welfare-committee-oppose>.

<sup>21</sup> CCAGW, “CCAGW Urges Maine Joint Committee on Health Coverage, Insurance, and Financial Services to Oppose LD 1938,” February 14, 2022, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-maine-joint-committee-health-coverage-insurance-and-0>.

<sup>22</sup> CCAGW, “CCAGW Urges Mississippi House of Representatives to Oppose HB 733,” February 7, 2022, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-mississippi-house-representatives-oppose-hb-733-0>.

<sup>23</sup> CCAGW, “CCAGW Urges Utah House Labor and Commerce Committee to Oppose HB 308,” March 24, 2022, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-utah-house-labor-and-commerce-committee-oppose-hb-308>.

<sup>24</sup> CCAGW, “CCAGW Urges Mississippi Senate to Oppose SB 2484,” January 24, 2023, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-mississippi-senate-oppose-sb-2484>.

<sup>25</sup> CCAGW, “CCAGW Urges Kentucky Legislators to Oppose Senate Bill 27,” January 30, 2024, <https://www.ccagw.org/legislative-affairs/letters-officials/ccagw-urges-kentucky-legislators-oppose-senate-bill-27>.

<sup>26</sup> CCAGW, “CCAGW Urges West Virginia Legislators to Oppose Senate Bill 325,” January 31, 2024, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-west-virginia-legislators-oppose-senate-bill-325>.

<sup>27</sup> CCAGW, “CCAGW Urges Oklahoma Senators to Oppose SB 1628,” February 16, 2024, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-oklahoma-senators-oppose-sb-1628-0>.

<sup>28</sup> CCAGW, “CCAGW Urges Virginia Legislators to Oppose Senate Bill 119,” February 26, 2024, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-virginia-legislators-oppose-senate-bill-119>.

<sup>29</sup> CCAGW, “CCAGW Urges Nebraska Legislators to Oppose LB984,” February 27, 2024, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-nebraska-legislators-oppose-lb-984>.

Mississippi's HB 728.<sup>30</sup> The manufacturer mandates and price controls found in state legislation will further distort the medical marketplace and not solve the underlying problems in the 340B drug discount program.

The bills enacted in Arkansas and Louisiana are currently being challenged in court on the grounds that they violate the Commerce Clause and the federal 340B statute. The issue is whether provisions in the state laws that require 340B drugs to be sold to unlimited number of contract pharmacies and attempt to regulate commercial transactions outside of the states violate federal law and the Constitution. CCAGW has argued that changes to 340B must only be made by Congress, and instead of enacting legislation, state legislators should encourage their congressional delegation to reform the 340B program.

### Required Reforms

To improve and reform the 340B drug discount program, Congress should clearly define a patient as an uninsured, low-income individual that does not qualify for Medicare or Medicaid. This would tighten the loose interpretation of eligibility that has gone on for far too long and help to ensure that the program operates closer to the way it was originally intended. Duplicate discounting for 340B is another ongoing problem that could be addressed with increased oversight from CMS. Improving reporting requirements will help to ensure that the patients benefit from the program as intended.

There have been sufficient reports by Congress, the media, and outside organizations about the corruption, costs, failure, and abuse of the 340B program. All that remains is the will to get the job done, which will both save the taxpayers money and give low-income patients the discounts on drugs that they have long deserved.

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<sup>30</sup> CCAGW, "CCAGW Urges Mississippi Legislators to Oppose House Bill 728," February 20, 2024, <https://www.ccagw.org/legislative-affairs/state-action/ccagw-urges-mississippi-legislators-oppose-house-bill-728>.