LHE
Legacy Health Endowment

340B PROGRAM

HISTORY | OVERVIEW | FUTURE

Legacy Health Endowment
Jeffrey Lewis, President & CEO
Date: 07/01/2025

WHY THIS WHITE PAPER?

Over the years, the federal 340B Drug Pricing Program ("340B Program") has faced scrutiny from various stakeholders, each arguing that it is too broad, not broad enough, allows too many contract pharmacies, lacks transparency, maintains an outdated sliding-fee scale that only applies to certain entity types, or continues to struggle with issues like duplicate discounts.

REVITALIZING THE 340B DEBATE: URGENT CALL FOR SUBSTANTIAL REFORMS

Covered entities, pharmaceutical manufacturers, trade associations, and lobbyists at both the federal and state levels must recall the foundational goal of the 340B Program—addressing specific healthcare needs while achieving remarkable outcomes. Yet, the path forward is not about expansion but about strategic evaluation. Viewing the program through a "2025 lens" allows for a much-needed reassessment of its direction and goals, guided by legislative action.

This reflection should prompt governors and state legislators to consider why California removed the 340B Program from its Medi-Cal discussions, effectively resolving the issue of duplicate discounts.

Furthermore, why has the federally qualified health center sliding-fee scale not evolved beyond catering to those at or below 200% of the Federal Poverty Level (FPL) for nearly five decades? Why do other covered entities not have sliding fee scale obligations? Why is there still a significant gap in transparency that prevents stakeholders from fully understanding who benefits, whether patients, Pharmacy Benefit Managers, chain drug stores, wholesalers, insurers, employers, or the covered entities themselves?

The necessity for greater transparency cannot be overstressed. It is the cornerstone of accountability and fairness within the 340B Program, and it is crucial for all stakeholders to feel this.

This White Paper has been crafted with contributions from numerous experts, whose insights have been invaluable in outlining the complexities and the path forward.

Sincerely,

Jeffrey Lewis
President and Chief Executive Officer
Legacy Health Endowment

I. UNDERSTANDING THE 340B PROGRAM'S PAST: A NECESSITY FOR GRASPING ITS PRESENT STATE

The 340B Program's genesis can be traced back to 1990 when Congress created the Medicaid Drug Rebate Program to lower the cost of outpatient pharmaceuticals reimbursed by state Medicaid agencies. The 340B Program was enacted specifically to mitigate the adverse effects of the Medicaid Drug Rebate Program on other non-Medicaid healthcare services by allowing discounts to certain eligible healthcare entities. The rebate program requires drug companies to enter into a rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) as a precondition for Medicaid coverage of their drugs.[1] The agreement specifies that the manufacturer of each outpatient drug covered by Medicaid must pay a rebate to Medicaid based on the lower of a calculated benchmark or the manufacturer's "best price" for that drug. As a result of the Medicaid rebate law and the "best price" requirement, many pharmaceutical companies discontinued offering deep discounts on their drugs to non-Medicaid purchasers because the deep discounts required the companies to pay significant rebates to Medicaid. When manufacturers began raising their prices, the Medicaid savings achieved through the rebate program were offset by increased government spending on drugs bought by non-Medicaid purchasers, such as various federal agencies (*e.g.*, the U.S. Department of Veterans Affairs, and the U.S. Department of Defense), state and local governments, and providers receiving federal and/or state support.

[1] Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143-161 (codified as amended at 42 U.S.C. § 1396r-8).

Congress enacted Section 340B of the Public Health Service Act in 1992[2] and Section 1927(a)(5) of the Social Security Act to address these unintended effects.[3] These statutes required pharmaceutical manufacturers participating in the Medicaid program to sign a Pharmaceutical Pricing Agreement (PPA), obligating them to provide discounts on covered outpatient drugs to specified government-supported facilities, referred to as "covered entities," serving the nation's most medically vulnerable populations. The duty to participate in the 340B Program was extended to manufacturers of drugs covered under Medicare Part B with the Medicare Modernization Act of 2003.[4]

Initially, covered entities included:

- Disproportionate share hospitals (DSH) with a large Medicaid patient base (large urban, small urban, and certain rural hospitals)
- Federally Qualified Health Centers (FQHCs) and FQHC look-alikes
- State-operated AIDS drug assistance programs and other Ryan White CARE Act programs
- Clinics treating tuberculosis, black lung, family planning, and sexually transmitted diseases
- Hemophilia treatment centers, public housing primary care clinics, and homeless clinics
- Urban Indian clinics and Native Hawaiian health centers

In 2010, in addition to formally recognizing children's hospitals as covered entities under the 340B Program, the Patient Protection and Affordable Care Act (ACA) expanded 340B access to four new categories of covered entities:

- Cancer hospitals
- Critical-access hospitals
- Sole community hospitals
- Rural referral centers[5]

[2] Codified at 42 U.S.C. § 256(b).
[3] Codified at 42 U.S.C. § 1396r-8(a)(5).
[4] *See* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, codified at 42 U.S.C. § 1396r-8(a).
[5] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101, 124 Stat. 119 (2010).

The 340B Program is administered by the Health Resources and Services Administration (HRSA) through its Office of Pharmacy Affairs (OPA).[6] Both HRSA and OPA are components of HHS. Congress intended for the 340B Program to allow covered entities serving vulnerable populations to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive care."[7] The 340B statute imposes general compliance responsibilities on all covered entities and more specific requirements unique to certain categories of covered entities. The general compliance obligations include the following:

- Prohibition against reselling or transferring 340B drugs to anyone other than the covered entity's patients, a practice commonly known as "diversion."[8]
- Obligation of the covered entity to protect a manufacturer from "duplicate discounts" occurs when the manufacturer gives both a 340B discount and a Medicaid rebate on the same drug.[9]
- Requirement that the covered entity maintains auditable records of its 340B Program activities, demonstrating eligibility and compliance with the diversion and duplicate discount prohibitions.[10]

The diversion and duplicate discount prohibitions limit covered entities' ability to use the discounted drugs they are entitled to purchase, while the auditable record requirement generates documentation that HRSA and participating drug manufacturers can use to confirm eligibility and compliance.

Covered entities are also responsible for complying with OPA registration requirements, which include ensuring the accuracy and completeness of information submitted to, and contained in, the OPA Information System (OPAIS), and certifying the accuracy of the information on OPAIS annually.[11] Compliance obligations specific to certain types of covered entities include (1) the prohibition against purchasing drugs through a

[6] *See* HRSA Statement of Organization, Functions and Delegations of Authority, 69 Fed. Reg. 56,433, 56443 (Sep. 21, 2004).
[7] H.R. Rep. No. 102–384, 102d Cong., 2d Sess., pt. 2, at 12 (1992).
[8] 42 U.S.C. § 256b(a)(5)(B).
[9] *Id.* § 256b(a)(5)(A).
[10] *Id.* § 256b(a)(5)(C).
[11] *Id.* § 256b(a)(7).

group purchasing organization (GPO), which only applies to DSHs and children's and cancer hospitals,[12] and (2) the unavailability of 340B Program pricing on orphan drugs, which only applies to sole community hospitals (SCHs), critical access hospital (CAHs), rural referral center (RRCs), and cancer hospitals.[13]

The 340B statute gives HRSA and drug manufacturers authority to audit covered entities.[14] Surprisingly, during the first two decades of the program, the government exercised its audit authority on only one occasion, and manufacturers never performed an audit.[15] Circumstances changed dramatically when, in 2011, the Government Accountability Office (GAO) published a report on the 340B Program that found HRSA's oversight and enforcement of the 340B Program to be inadequate due in part to HRSA's over reliance on self-policing by covered entities.[16] The GAO report was mandated by Congress under the ACA and championed by Senators Orrin Hatch (R-UT) and Mike Enzi (R-WY), who had tried unsuccessfully to restrict or sunset the program by direct amendment to the 340B statute.[17] Publication of the GAO report and political pressure from Congress convinced HRSA to launch a major initiative to audit 340B-covered entities.[18] Within a month of the report's publication, HRSA administrator Mary Wakefield announced that HRSA would begin auditing covered entities.[19] The audits commenced in January of 2012 and have continued ever since.

[12] *Id.* § 256b(a)(4)(L)(iii).
[13] *Id.* § 256b(e).
[14] *Id.* § 256b(a)(5)(c); 42 U.S.C. § 256b(e).
[15] We are aware of only one audit occurring prior to 2012. In 2005, Aliquippa Community Hospital was accused of reselling drugs purchased through the 340B Program to ineligible providers. *See* Letter from Mary Wakefield, Administrator, HRSA, to Sen. Charles Grassley at 6 (Oct. 21, 2011); *Jury Indicts Director of Program Utilizing 340B Discounts*, DRUG DISCOUNT MONITOR (Jan. 2006).
[16] U.S. Government Accountability Office, Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight is Needed, GAO-11-836, WWW.GAO.GOV (Sept. 2011), http://www.gao.gov/new.items/d11836.pdf.
[17] *340B: To Be or Not to Be,* DRUG DISCOUNT MONITOR (Aug. 7, 2009).
[18] U.S. Government Accountability Office, Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight is Needed, GAO-11-836, September 2011, *available at* http://www.gao.gov/new.items/d11836.pdf.
[19] *See also* Letter from Mary Wakefield, Administrator, HRSA, to Sen. Charles Grassley at 6 (Oct. 21, 2011), https://www.340bhealth.org/files/HRSA_letter_to_Grassley_10_21_2011.pdf.

Both OPA and HRSA rely extensively on a government contractor called Apexus to assist with administering the 340B Program. Apexus staffs the 340B call center and provides technical assistance to 340B-covered entities and other stakeholders. It also administers the 340B prime vendor program (PVP), which negotiates discounts below 340B ceiling prices for covered entities and provides distribution and other value-added services to prime vendor participants.[20]

Notably, the 340B statute did not include an explicit grant of regulatory authority to HHS or its subordinate divisions, including HRSA, regarding much of the implementation of the 340B statute. HRSA's ability to administer the program by issuing legally binding policies was the subject of extensive litigation by the pharmaceutical trade association, Pharmaceutical Research and Manufacturers of America (PhRMA), in response to HRSA's effort to implement the orphan drug exclusion applicable to CAHs, RRCs, SCHs, and cancer hospitals.[21] The litigation targeted the agency's orphan drug regulation, which sought to narrow the orphan drug exclusion to only those instances in which orphan drugs were used for the purpose for which orphan drug status was approved by the U.S. Food and Drug Administration (FDA). Under the regulation, the hospitals were permitted to buy orphan drugs at 340B prices if they were used for purposes other than to treat a rare disease or condition — for example, if they were used for an off-label indication or to treat a common condition.[22] The rule was struck down and vacated in May 2014 by the U.S. District Court for the District of Columbia, which concluded that HRSA lacked the statutory authority to promulgate such a rule.[23] However, the District Court raised the possibility that HHS could issue the rule as an interpretive, rather than a

[20] Apexus, *340B Prime Vendor Solutions*, WWW.340BPVP.COM, https://www.340bpvp.com/about/ (last visited May 10, 2020).
[21] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014).
[22] 78 Fed. Reg. 44,016, 44,027 (Jul. 23, 2013).
[23] 42 U.S.C. § 256b(d); *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014).

legislative, rule. Immediately thereafter, HHS issued an interpretive rule identical in substance to the vacated final rule.[24] In 2015, the same District Court judge struck down the interpretive rule as contrary to the plain language of the 340B statute.[25]

The orphan drug litigation clarified that HRSA only has regulatory authority to implement the 340B Program in three areas. According to the District Court, Congress specifically authorized rulemaking in three places:

1. Establishing an administrative dispute-resolution process to address pricing disputes between manufacturers and covered entities.
2. The "regulatory issuance" of precisely defined standards of methodology for the calculation of ceiling prices and
3. The imposition of monetary civil sanctions against manufacturers for overcharging for 340B drugs.[26]

In the absence of explicit regulatory authority, HRSA has no practical choice but to issue sub-regulatory guidance in an attempt to administer the 340B Program, including its 1996 patient definition.[27] HRSA's attempt to police the 340B Program through the issuance of sub-regulatory guidance has frequently been attacked, most notably when it failed to defend its guidance regarding the 340B orphan drug rules in litigation brought by PhRMA.[28] HRSA has often acknowledged its lack of regulatory authority over many aspects of the 340B Program[29] and has repeatedly asked Congress for a more explicit grant of authority. HRSA's requests

[24] *See Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, Health Resources & Services Administration*, http://www.hrsa.gov/opa/programrequirements/interpretiverule/interpretiverule.pdf (last visited Apr. 13, 2020).
[25] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31 (D.D.C. 2015) (holding that HRSA's interpretive rule was inconsistent with the orphan drug exclusion of the 340B statute.)
[26] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014).
[27] *See, e.g.,* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 47,884 (Sept. 19, 1994); Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 47,884 (Sept. 19, 1994); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996); Final Notice Regarding 340B Drug Pricing Program: Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[28] *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014) (HRSA has cited this case as a holding that clarified its limited regulatory authority).
[29] *See id*; *See, e.g.,* U.S. Gov't Accountability Off., *GAO-20-212*, *340B Drug Discount Program: Oversight of the Intersection with the*

have received a chilly reception in Congress, mainly because bipartisan congressional leadership has faulted HRSA for failing to implement mandatory regulations under the rule that Congress had granted HRSA.[30]

Against that backdrop, the 340B Program has been the subject of considerable debate among program stakeholders, including covered entities, drug manufacturers, payers, state Medicaid agencies, and pharmacies. The discussion intensified dramatically following the expansion of the 340B Program in the ACA in 2010 and the recognition by HRSA in 2010 that covered entities may contract with multiple third-party pharmacies to dispense the covered entities' 340B drugs to their eligible patients.[31]

Drug manufacturers have been critical of HRSA's oversight of the 340B Program, particularly since the ACA was passed. They have suggested reforms, including changing the definition of a "patient" eligible to receive a covered entity's 340B drugs, limiting the program to uninsured patients, reducing or eliminating the recognition of contract pharmacies, and requiring reporting on the quantity and use of 340B Program resources. Some of these efforts have manifested in direct efforts from PhRMA, efforts by individual manufacturers, and manufacturer-led coalitions calling for the reform of the 340B Program, including the Alliance for Integrity and Reform of 340B (AIR-340B) and the Alliance to Save America's 340B Program (ASAP 340B).

Covered entities are also represented by groups that seek to preserve covered entities' access to the 340B Program and the resources it generates. Hospitals are represented by 340B Health and the American

Medicaid Drug Rebate Program Needs Improvement, 46 (2020);
Contract Pharmacies Needs Improvements 59 (2018), https://www.gao.gov/assets/700/692697.pdf.

[30] In 2018, a bicameral, bipartisan Congressional leadership letter *rejected* HRSA's request for additional regulatory because, the letter stated, HRSA still had failed to regulate in areas Congress had specifically mandated for it to do so. *See* Letter to Krista Pedley from Sens. Lamar Alexander and Patty Murray and Reps. Greg Walden and Frank Pallone, August 27, 2018, *available at* https://republicans-energycommerce.house.gov/wp-content/uploads/2018/08/20180827HRSA.pdf (since that letter, Congress has not acted to provide HRSA with additional rulemaking authority).

[31] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("2010 Contract Pharmacy Guidelines").

Hospital Association, with America's Essential Hospitals representing the interests of certain public hospitals and the Children's Hospital Association representing the interests of children's hospitals. FQHCs are represented by the National Association of Community Health Centers (NACHC) and the Alliance for Community Health (ACH). Ryan White Clinics represent Ryan White HIV/AIDS Program clinics for 340B Access (RWC-340B). Family-planning grantees are represented by the Planned Parenthood Federation of America (PPFA). This list is not exhaustive, as other groups may be involved depending on the issues (e.g., ADAP Advocacy Association, Community Access National Network, and the National Association of State and Territorial AIDS Directors).

This section will discuss four areas of potential reform:

1. Who should be eligible to receive a drug purchased by a 340B Program "covered entity" as a "patient" of the covered entity;
2. How the 340B Program contract pharmacy program was established, the intent behind it, how covered entities may and should use the savings, and how supporting vendors should be compensated;
3. How 340B Program covered entities should account for and invest savings generated through the program; and
4. Whether drug manufacturers are serious about efforts to reform the 340B Program to make it sustainable for covered entities. Who should be a "patient" eligible to receive a 340B drug from a covered entity?

When Congress established the 340B Program in 1992, it made clear in the statute that a covered entity could only use 340B drugs for its "patients."[32] However, Congress provided no guidance on who qualified as a patient. HRSA stepped in to fill this gap by publishing in 1996 a three-part definition of a patient that still governs today. During the first 20 years of the program, covered entities enjoyed a fair amount of

[32] 42 U.S.C. § 256b(a)(5)(B).

discretion in how they applied HRSA's 1996 definition to their patients. Many hospitals routinely qualified outside prescriptions for 340B when the prescription was written as part of follow-up care at the hospital. However, when political scrutiny of the 340B Program intensified, and HRSA began auditing covered entities in 2012, HRSA tightened its application of the 1996 definition by limiting prescription eligibility to only those originating from a registered covered entity site. The only exception was when a covered entity could document that an outside prescription was written as part of a referral for consultation. In 2007, and again in 2015, HRSA tried to narrow its interpretation of "patient" further by proposing changes to the 1996 definition that would have eliminated eligibility of all outside prescriptions and even some prescriptions that met the location test.[33] Those changes were never adopted, and prescriptions written pursuant to documented referrals are still eligible. In 2023, a federal court in South Carolina ruled that HRSA applies its patient guidelines too narrowly in audits, but to date HRSA has not adopted changes based on that litigation.[34] A more detailed discussion of HRSA's increasingly strict application of the 1996 patient definition guidelines is addressed below.

A. 1996 Patient Definition Guidelines

Section 340B(a)(5)(B) of the Public Health Service Act explicitly prohibits a covered entity from reselling or transferring 340B discounted drugs to a person who is not "a patient of the entity."[35] However, the statute lacks a definition of "patient." To address this omission, HRSA issued a notice on Oct. 24, 1996, defining the

[33] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of Patient, 72 Fed. Reg. 1543 (Jan. 12, 2007); 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).
[34] *Genesis Health Care, Inc. v. Becerra*, 701 F.Supp.3d 312 (D.S.C. 2023).
[35] 42 U.S.C. § 256b(a)(5)(B).

term "patient" for purposes of the 340B Program.[36] According to that notice, an individual must satisfy three requirements to be eligible to receive the discounted drugs:

- First, the covered entity must maintain records of the individual's healthcare. This requirement is sometimes called the "maintenance-of-record" or "record maintenance" test.
- Second, the individual must be under the care of a physician or other healthcare professional employed by, under contract with, or in a referral relationship with the covered entity, such that responsibility for the individual's care remains with the covered entity. This requirement is sometimes called the "professional care test."
- Third, in the case of health centers and grantees, the individual must receive a range of healthcare services consistent with the services for which grant funding or FQHC look-alike status has been provided to the covered entity. This requirement does not apply to 340B hospitals.

HRSA first suggested that a prescription's eligibility might depend on the location in which it originates in a Sept. 15, 1998, letter responding to numerous 340B-related questions, including questions about the definition of patient.[37] The letter was issued to 340B Health, previously known as Safety Net Hospitals for Pharmaceutical Access (SNHPA), and before that, the Public Hospital Pharmacy Coalition (PHPC).[38] 340B Health is an organization of more than 1,400 public and private non-profit hospitals participating in the 340B Program and serves as the lead advocate for hospitals on 340B legislative and regulatory issues.[39] HRSA's 1998 letter asserted that to meet the 340B patient definition for hospitals, an individual must receive services at a facility reimbursable on the hospital's Medicare cost report. The 1998 letter does not explicitly state that a prescription must be written during that encounter, but the 340B hospital community was concerned that HRSA might take that position. Notwithstanding the ambiguity of the 1998 letter and the absence of a location

[36] *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996).
[37] *See* Letter from Jimmy Mitchell, Director, OPA, to William von Oehsen, General Counsel, 340B Health (Sept. 15, 1998).
[38] *Id*.
[39] References to 340B Health are also intended to refer to SNHPA and/or PHPC for simplicity and clarity.

requirement in the 340B statute, 340B Health responded to the letter by engaging in several years of advocacy culminating in the agency's 2001 written acknowledgment of a hospital's right to use 340B drugs to fill prescriptions originating from non-cost report sites in certain circumstances. HRSA was persuaded that patient relationships often encompass the delivery of care outside the walls of a hospital or any of its off-site locations.

B. The Morford Letter

After receiving the 1998 letter, 340B Health made several appeals to HRSA to clarify that the Medicare cost report test described in the letter was not intended to limit 340B eligibility to only those patient prescriptions written in cost report sites.[40] The hospitals felt strongly that the Medicare cost report test should only be used to identify hospital facilities eligible to purchase and use 340B drugs, not to determine where 340B-eligible prescriptions may be written. The cost report test, according to hospitals, was appropriate for qualifying non-retail drugs used by and within hospitals but inappropriate for qualifying retail drugs dispensed by hospital in-house and contract pharmacies. Among 340B Health's concerns was those patients receiving hospital services outside of a hospital facility, many of whom could be uninsured or otherwise vulnerable or high-risk, would be prohibited from filling their prescriptions with 340B drugs. OPA advised 340B Health that it would study the patient definition issue further as part of its strategic planning initiative.[41] Finally, the deputy administrator of HRSA, Thomas Morford, sent 340B Health a letter dated Jan. 26, 2001, clarifying the 340B patient definition further concerning outside prescriptions.[42] The Morford Letter clarified that a prescription

[40] *See* Memorandum from 340B Health to OPA (Nov. 23, 1998).
[41] *See* Letter from Jimmy Mitchell, Director, OPA, to William von Oehsen, General Counsel, 340B Health, and Ted Slafsky, Director, 340B Health (May 28, 1999) (communicating OPA's decision to address the patient definition issue as part of its strategic planning initiative).
[42] *See* Letter from Thomas Morford, Deputy Administrator, HRSA, to William von Oehsen, General Counsel, 340B Health (Jan. 26, 2001) [copy available from Powers Law].

filled with 340B drugs does not necessarily have to be written within a facility that is reimbursable on the hospital's Medicare cost report to qualify for 340B status.

The Morford Letter incorporated recommendations from a 1999 report prepared by outside researchers and commissioned by OPA as part of the agency's strategic planning process.[43] The report's authors recommended that OPA provide a more precise patient definition, noting a consensus "that the Medicare cost report test is unreasonable and will prevent [340B hospitals] from being able to meet patient needs adequately."[44] The Morford Letter was sent to 340B Health, expecting to be broadly disseminated and relied upon by hospitals participating in the 340B Program. After it was sent in 2001, it was discussed at dozens of industry conferences and became a relied-upon standard. HRSA attended and presented at many of those conferences, and Apexus co-hosted several of them. Over time, the interpretations of the patient definition reflected in the Morford Letter became an industry standard for the 340B hospital community, as well as for vendors and other parties serving 340B hospitals.

The Morford Letter acknowledged that "there are circumstances where it would be permissible" for a 340B-eligible pharmacy to provide the 340B discount even if the entity does not give the physician service that resulted in the prescription. Specifically, the Morford Letter stated that:

> HRSA would not object to program participation where a patient initiates their care at an eligible covered entity hospital and pursues additional care through its non-cost report clinics, so long as the continuing non-cost-report care bears a proximate relationship to the care that was initially cost-reported at the covered-entity hospital and the patient fills his or her prescription at the covered entity's Medicare cost report pharmacy. A patient's subsequent, non-cost report care should bear a proximate relationship to the initial covered-entity hospital care with respect to both type and time of care.

[43] Barbara F. Brandt, PhD, and Karen Blumenschein, PharmD, for the Office of Drug Pricing, *Focus Group Study Report #1* (Aug. 4, 1999).
[44] *Id.* at 9.

HRSA then applied its "proximate relationship" test to a hypothetical diabetic patient who receives initial care at a hospital emergency room, receives follow-up care at a facility that does not appear on the hospital's cost report, and then gets a prescription for insulin as a result of this follow-up care, with the prescription written by a prescriber from the non-hospital facility. HRSA asserted that this hypothetical patient's insulin prescription would qualify as 340B eligible, even though the site of his follow-up care is not included on the cost report. If this patient were to return to the same non-cost report clinic two years later for an unrelated orthopedic condition, however, HRSA determined under the test that they would not be eligible to receive 340B drugs at that time.

Hospitals viewed the Morford Letter's proximate relationship test for qualifying outside prescriptions as a practice that HRSA endorsed. The Morford Letter's perspective on patient definition became part of the very fabric of the 340B Program.[45] However, when HRSA launched its audit program in 2012, it began to retreat from the guidance it provided in the Morford Letter. The agency has at no point rescinded the Morford Letter, but it began to clearly reject it about 10 years ago. For example, in audit reports issued in the mid-2010s, HRSA consistently stated the position that the Morford Letter concerns a specific set of facts and "would not apply to current situations because the specific situation that was addressed in that letter involved prescriptions issued by pharmacies on a hospital's Medicare cost report and was addressed to situations involving follow-up care received at outpatient clinics affiliated with the hospital, not care received at private physicians' offices." Hospital reliance on the Morford Letter effectively ended by 2017.

[45] *See* 340B Health Principles to Help 340B Hospitals Comply with Prohibition Against Diversion at III.

C. "Referral for Consultation"

As stated above, under HRSA's 1996 patient definition guidance, the relationship between an individual and hospital may meet the professional-care test of the patient definition guidance if the individual receives healthcare services from a healthcare professional who "provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity."[46] In 2014, HRSA posted a 340B Hot Topics newsletter that included a response to a question regarding patient eligibility when a prescription results from a referral by the hospital to a non-hospital clinic. The HRSA newsletter states:

> If we refer patients to an outside clinic, can we fill their prescriptions from our 340B clinic?
>
> A covered entity may send a patient to an outside clinic not registered with 340B and consider that patient 340B-eligible only if the 340B patient receives healthcare from a healthcare professional who is either employed by the covered entity or provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity (61 Fed. Reg. 55156 (October 24, 1996)). If the covered entity can document that it retained responsibility for the healthcare services provided to the patient, then that individual may be eligible. [47]

HRSA confirms, therefore, that outside prescriptions may be considered 340B-eligible in certain circumstances. According to the newsletter, the key to determining whether an outside prescription is 340B-eligible is that the covered entity has documentation to show that it retained responsibility for the healthcare services provided to the patient. HRSA did not elaborate on the type of documentation the covered entity should maintain to show that it retained responsibility for the care provided. Apexus has substantially the same question and answer posted as an FAQ on its website.[48]

---

[46] 61 Fed. Reg. at 55,157.
[47] Health Resources and Services Administration, *340B Hot Topics*, WWW.HRSA.GOV (Apr. 2017), http://www.hrsa.gov/opa/updates/august2014.html.
[48] Apexus, Frequently Asked Questions, *FAQ ID: 1493*, WWW.340BPVP.COM (Sep. 30, 2020), https://www.340bpvp.com/resourceCenter/faqSearch.html?category=content&Ntt=1493.

In 2015, Apexus's website provided guidance indicating that covered entities could meet the professional care test using a referral agreement.[49] The guidance focused on what constitutes an acceptable referral-for-consultation arrangement, as that term is used in the professional care test. It included a template referral agreement presenting Apexus' view of a compliant agreement.[50] Apexus emphasized that the guidance did not represent the only compliant approach and the "endorsement of the content of This Guide by the Office of Pharmacy Affairs is not stated or implied."[51] Apexus subsequently deleted both the guidance and template agreement from its website, which could indicate that It is no longer confident that the guidance is consistent with HRSA policy. It could also mean that Apexus viewed the guidance as legal advice falling outside the scope of its technical assistance responsibilities.

Before its removal, the guidance stated that some covered entities do not have adequate systems to document referrals consistently. To address this issue, Apexus stated that some covered entities enter into agreements with physicians that explain the responsibilities of the covered entity and the physician when the covered entity refers a patient for follow-up healthcare. The accompanying template agreement stated that the covered entity may refer patients to a physician for consultation and medical care. It also said that, in accepting the referrals, the physician must agree that the covered entity would continue to have responsibility for the patient's care and the use of 340B drugs transferred to the patient.

The agreement included provisions requiring the prescribing professional to furnish the covered entity with a list of NPIs for all applicable professionals and to document medical encounters consistent with professional standards and applicable law. The latter requirement could be satisfied either by entering "notes

[49] See Apexus 340B University Policy to Practice Guide; Patient Definition: Referral Relationships.
[50] *Id.* at Appendix A.
[51] *Id.* at 1.

on patient care and treatment" into the covered entity's electronic health record (EHR) system, "where available so that it can be accessed electronically, real-time by the covered entity for purposes of patient follow-up"; or by forwarding the covered entity "copies of all medical encounter notes" if EHR documentation is not possible.[52]

D. Proposed Changes Under 2015 Mega Guidance

In August 2015, HRSA proposed sweeping changes to the 340B Program by publishing an omnibus guidance, commonly called the 340B Mega Guidance, that addressed nearly every aspect of the program, including patient definition.[53] Adoption of the proposed patient definition changes would have doubled the number of tests necessary for qualifying a prescription for the 340B Program, which, in turn, would have significantly circumscribed the types of relationships that covered entities could have with their patients. Putting aside the increased costs of demonstrating compliance with the new six-part definition, covered entities would have encountered a sharp drop in program savings based on the simple reality that fewer prescriptions would pass all six tests. HRSA also proposed that the new patient definition standard be applied "on a prescription-by-prescription or order-by-order basis."[54] Fortunately for the covered entity community, the Mega Guidance was never finalized. On Sept. 1, 2016, it was sent to the Office of Management and Budget (OMB), where it stalled.[55] Five months later, following President Donald J. Trump's inauguration, HRSA withdrew the Mega Guidance from OMB review in its entirety.[56]

[52] *Id.*
[53] 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (Aug. 28, 2015).
[54] *See* 80 Fed. Reg. 52,300, 52,306 – 52,308, 52,319.
[55] Office of Management and Budget, Office of Information and Regulatory Affairs, Rulemaking Identification Number 0906-AB08, at https://www.reginfo.gov/public/do/eoDetails?rrid=126712.
[56] *Id.*

The Mega Guidance would have established the following six tests for an individual to qualify as a 340B eligible patient:

1. the individual would have to receive a healthcare service at a covered entity site that is registered for the 340B Program and listed in the OPAIS database;

2. the individual would have to receive a healthcare service provided by a covered entity provider who is either employed by the covered entity or an independent contractor such that the covered entity could bill for services on behalf of the provider;

3. the individual would have to receive a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2);

4. the individual's healthcare would have to be consistent with the scope of the covered entity's federal grant, project, designation, or contract;

5. the individual's drug would have to be ordered or prescribed pursuant to a healthcare service that is classified as an outpatient and

6. the individual would have to have a relationship with the covered entity such that the covered entity maintained access to auditable records demonstrating a provider-to-patient relationship and the entity's responsibility for the patient's care and satisfaction of each element of the patient definition for each 340B drug.[57]

The fourth criterion would not have applied to hospitals.

The first three tests, read together, would have required all 340B prescriptions to originate from a site registered in the OPAIS database. In short, they would have to meet today's location test. This point was reinforced in the preamble of the Mega Guidance:

> An individual who sees a physician in their private practice who is not listed on the public 340B database or any other non-340B site of a covered entity, even as a follow-up to care at a registered site, would not be eligible to receive 340B drugs for the services provided at these non-340B sites.[58]

[57] 80 Fed. Reg. 52,300, 52,319 (Aug. 28, 2015).
[58] *Id*.

Prescriptions written at unregistered physician clinics or academic practice plans would not be eligible for 340B even if the covered entity had access to the affiliated covered entity's records and was responsible for the care provided. HRSA went further by disqualifying prescriptions written by physicians who had contract-referral arrangements with the covered entity. Even prescriptions satisfying the location test under the first prong of the proposed patient definition might not meet the second or third tests. Also disqualified would be discharge prescriptions.

One of the bright spots in the Mega Guidance was its telemedicine discussion. In explaining the importance of a prescription originating from a registered location, HRSA made the following comment:

> The use of telemedicine to issue a prescription by a covered-entity provider is permitted as long as the practice is authorized under state or federal law and the drug purchase otherwise complies with the 340B Program.[59]

This comment strongly suggests that HRSA considers telemedicine a healthcare service for the 340B patient definition. Because it was included in a broader discussion about how a healthcare service must be furnished in a registered 340B facility for the service to satisfy patient definition standards, it also suggests that the location of the telehealth services is key to determining whether the services establish a patient relationship.

E. Evolution of the Location Test

HRSA's audits of covered entities often hinge on the determination of whether outside prescriptions are eligible under the 340B Program. Initially, HRSA's judgments about such prescriptions were primarily based on whether a patient returned to the covered entity for follow-up care. For instance, HRSA reversed a preliminary audit finding of diversion when a covered entity had classified an outside prescription for allergy medication as 340B-eligible. This decision was because the patient had been seen in the entity's emergency

[59] *Id*. at 52,307.

room for an allergic reaction a few months prior to and again more than a year after the prescription was written. HRSA stated, "Upon review of the provided records, particularly the documentation of a return visit to [the covered entity's] emergency department after the audit, we have determined this as sufficient evidence of continued care for the referred individual."

In another instance, HRSA reversed a diversion finding where the patient had initially only received laboratory tests at the hospital. The outside prescription was written before the patient returned for an unrelated medical procedure. These decisions indicate an initial flexibility in HRSA's approach to defining patient care continuity.

In other audit reports, HRSA indicated that a covered entity must have additional documentation to demonstrate that it maintained responsibility for patient care after being referred outside the covered entity for follow-up services. In one of these audit reports, HRSA reviewed an outside prescription filled with 340B drugs and written by a professional who had entered into an agreement with a hospital using the Apexus referral arrangement template described above. The agreement stated that the hospital would refer patients to the outside prescriber as needed for consultation and medical care. The agreement required that the physician enter the medical treatment notes for any of the hospital’s patients in the hospital’s EHR or forward a copy of the notes to the hospital. The agreement also stated that the hospital would continue to be responsible for the care provided to the patient. The agreement, however, was not enough to convince HRSA that prescriptions written by the physician's group could be considered 340B-eligible. HRSA disqualified the prescriptions because the referral arrangement entered into between the hospital physicians was optional, the hospital did not document a written referral for consultation, and the hospital did not have a summary of the referral visit.

From 2012-2019, and again since 2024, HRSA applies a more stringent test to determine if outside prescriptions meet the 1996 patient definition, focusing on whether the covered entity can document that the prescriptions were part of a formal referral arrangement. The necessary documentation must include:

1. A referral from the covered entity.
2. A medical record or a summary of the visit that resulted in the prescription.

Covered entities that provide documentation showing coordination between the covered entity and the outside prescriber in managing the patient's care are more likely to establish 340B eligibility.

An illustrative case occurred during a 2016 audit of a large health system in Tennessee. The 340B hospital utilized both in-house and contract pharmacies to process outside prescriptions from sites integrated with the hospital but not eligible under the hospital's Medicare cost report. The hospital contended that these prescriptions met the 1996 patient definition due to the organizational, operational, and clinical integration with the prescribers. However, HRSA employed a strict interpretation, rejecting these claims due to the absence of documented referrals proving the hospital retained care responsibility. In HRSA's audit report, each ineligible prescription was detailed alongside the location where it was prescribed or dispensed, highlighting the importance of clear, documented referral pathways in maintaining 340B compliance.

F. 2019-2024: Erosion of HRSA Location Standards

Likely in response to a lawsuit brought by a South Carolina FQHC called Genesis Health Care, Inc. (Genesis), HRSA began to signal its willingness to recognize exceptions to the test based on its apparent realization that it may lack the requisite authority to enforce the location test. Agency concerns about the scope of its enforcement authority surfaced in late September 2019 when former OPA Director Rear Admiral Krista Pedley remarked during a national Medicaid drug rebate conference that HRSA was reevaluating its

enforcement of specific 340B Program policies not explicitly authorized under the 340B statute. Shortly thereafter, HRSA began including new language in its audit report cover letters informing covered entities that the findings reflected in the audit reports are "based on HRSA's interpretation of the statute" and that covered entities dissatisfied with their findings are invited to share their "alternative" interpretation of the statute in support of their appeals. This new language seemed to be a concession by HRSA that its sub-regulatory interpretations of the 340B statute, including its interpretation that 340B prescriptions must originate from 340B-registered sites, are subject to challenge. In addition to the Genesis lawsuit, HRSA's willingness to accept the 340B eligibility of outside prescriptions on a case-by-case basis appeared to have been caused, at least in part, by a 2019 White House executive order that required agencies to reevaluate their reliance on interpretive guidance, discussed below.

HRSA's diminished confidence in its legal authority to enforce the location test and other 340B sub-regulatory policies is likely attributable to a White House executive order issued on Oct. 9, 2019, aimed at prohibiting federal administrative agencies from issuing binding rules through guidance documents.[60] The executive order, entitled "Transparency and Fairness in Civil Proceedings," states:

> Guidance documents may not be used to impose new standards of conduct on persons outside the executive branch except as expressly authorized by law or expressly incorporated into a contract. When an agency takes an administrative enforcement action, engages in adjudication, or otherwise decides that has legal consequence for a person, it must establish a violation of law by applying statutes or regulations. The agency may not treat noncompliance with a standard of conduct announced solely in a guidance document as itself a violation of applicable statutes or regulations. When an agency uses a guidance document to state the legal applicability of a statute or regulation,

[60] *See* Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, Exec. Order No. 13892, 84 Fed. Reg. 55,239 (2019); Promoting the Rule of Law Through Improved Agency Guidance Documents, Exec. Order No. 13891, 84 Fed. Reg. 55,235 (2019) (this second executive order requires agency guidance documents to be searchable and maintained on a single repository page on an agency's website).

> that document can do no more, with respect to prohibition of conduct, than articulate the agency's understanding of how a statute or regulation applies to particular circumstances.[61]

The executive order had dramatic implications for the 340B Program because HRSA oversees the program and is primarily regulated through sub-regulatory guidance. As previously mentioned, HRSA only has regulatory authority to address three subject areas in the 340B Program: the administrative dispute process, the methodology for calculating ceiling prices, and the imposition of monetary civil sanctions.[62] Among the subject areas for which HRSA does not have regulatory authority is the definition of patient. Suppose a covered entity disregards HRSA's patient definition. In that case, it appears that, according to this executive order, the agency may not enforce its patient definition in an audit or other proceeding because HRSA's patient definition is sub-regulatory guidance and would instead have to justify any action under the statute alone. That would appear to hold even though HRSA published its definition of a patient in the Federal Register and responded to public comments on the definition. HRSA has acknowledged that it lacks regulatory authority to administer the 340B Program except in the three previously described areas unrelated to patient definition.[63] As such, diversion findings based on HRSA's narrow interpretation of the statutory term "patient" may be challenged because, contrary to the executive order, they reflect an effort to enforce a sub-regulatory standard.

G. The *Genesis* Decision

Genesis went to court to challenge a diversion finding it received during an HRSA audit for filling outside prescriptions with 340B drugs. Genesis filed the lawsuit in the wake of an onsite HRSA audit in June

[61] *Id.*
[62] *See Pharm. Research v. Dept. of Health and Human Serv.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014); *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31 (D.D.C. 2015) (holding that HRSA's interpretive rule was inconsistent with the orphan drug exclusion of the 340B statute).
[63] Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations, 115 Cong. 12 (2017) (Statements of Director Krista Pedley, Director Debra Draper, and Assistant Inspector General Erin Bliss).

2017 that resulted in Genesis receiving several adverse audit findings. In particular, HRSA found that Genesis had diverted 340B drugs to ineligible individuals.[64] HRSA also found that Genesis had failed to maintain auditable records, which stemmed mainly from HRSA's observation that 340B medications were being dispensed from unmarked bottles, and threatened to remove Genesis from the 340B Program on that basis. Regarding the diversion finding, HRSA identified 18 prescriptions within the audit sample written at private physician offices rather than within a Genesis facility. Ten of these prescriptions were filled at Genesis' in-house pharmacy, and eight were filled at pharmacies that were contracted with Genesis. The prescriptions were written for low-income individuals previously receiving care from Genesis. According to the HRSA audit report, Genesis could not provide records directly linking the 18 sampled prescriptions to a Genesis service. In support of the diversion finding, HRSA noted the absence of (1) records of referrals from Genesis to the prescribers; (2) records of referral arrangements between the private providers and Genesis; and (3) records demonstrating that the responsibility for care resulting in the prescriptions remained with Genesis. HRSA later seemed to establish an additional patient eligibility requirement when, in a March 2019 letter, it expressed an expectation that Genesis "have initiated the healthcare service resulting in the prescription . . . ."[65]

Genesis challenged the audit report because it believed it had provided adequate records, primarily in the form of electronic medical records and dictations, demonstrating responsibility for the care of each patient who received a prescription within the audit sample.[66] In its disagreement with HRSA's findings, Genesis argued that the 18 prescriptions satisfied the 1996 three-part patient definition and the withdrawn

[64] Exhibit 1 of Petitioner's Verified Petition for Judicial Review and Emergency Motion to Stay, *Genesis Health Care v. Azar*, No. 4:18-mc-235-RBH, 2-4 (D.S.C. Jun 28, 2018).
[65] Petitioner's Amended Verified Petition for Judicial Review, Emergency Motion to Stay, and Petition for Declaratory Relief, *Genesis Health Care v. Azar*, No. 4:18-mc-235-RBH, 8-9, 16-17 (D.S.C. May 24, 2019).
[66] Exhibit 2 of Petitioner's Verified Petition for Judicial Review and Emergency Motion to Stay, *Genesis Health Care v. Azar*, No. 4:18-mc-235-RBH, 11-14 (D.S.C. Jun. 28, 2018) (Genesis' disagreement letter to HRSA's Final Report was included as Exhibit 2).

six-part Mega Guidance definition because neither policy required a specific link between the prescription at issue and a patient encounter.[67] Instead, they required auditable records demonstrating an ongoing patient-provider relationship once the patient relationship had been established.[68] Genesis provided more than 1,300 records in support of its position that, for each prescription identified in the audit report, there was an ongoing patient-provider relationship between Genesis and the patient. [69] Genesis contended that the 1996 patient definition did not give specific guidance regarding the documentation requirements for referral prescriptions, timelines regarding patient eligibility, or further clarification on the definition of "responsibility of care provided remains with the covered entity."[70] Its position was that as long as documented healthcare services were furnished to the relevant individuals by a Genesis-employed or contracted provider within the scope of Genesis' qualifying grant, and as long as Genesis could document an ongoing responsibility for the individuals, all prescriptions written for such individuals were 340B-eligible, irrespective of the prescriber's status or prescription's location. HRSA vacated all findings against Genesis in response to the lawsuit. HRSA also removed any reference to the Genesis audit from its audit summary page on the HRSA website.[71] In December 2019, the court dismissed the case as moot due to HRSA withdrawing its audit findings.[72] Genesis appealed that decision.

[67] *Id*.
[68] *Id.*
[69] *Id.* (Genesis noted that it had departments specifically tasked with "ensuring that [it] . . . take continuing responsibility for patients, advises patients of preventive healthcare measures available to them, and makes every effort to collect and synthesize medical records from all providers from which a [Genesis] patient is receiving care to provide continuity of care, and to coordinate medical findings as well as medication therapies among multiple providers and multiple specialties caring for the same patient").
[70] *Id.*
[71] Health Resources and Services Administration, *Program Integrity: FY17 Audit Results*, WWW.HRSA.GOV (September 10, 2019), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-17-results.html.
[72] *Genesis Health Care, Inc. v. Azar*, No. 4:19-cv-1531 2019 WL 6909572 (D.S.C. Dec. 19, 2019).

On July 1, 2022, the Fourth Circuit Court issued a decision holding that the *Genesis* case was not moot and remanded the case to the District Court for a final decision.[73] The Fourth Circuit noted that HRSA could audit Genesis in the future and that the FQHC must comply with HRSA's requirements.[74] Therefore, the court held an "ongoing disagreement over how 'patient' is to be defined in the context of the 340B Program" that must be resolved by the District Court.[75] At the District Court, Genesis had requested a declaratory judgment that: (1) the only statutory requirement for 340B eligibility is that an individual be a patient of the covered entity; (2) the plain wording of the 340B statute requires that any prescription from any source for a patient of a covered entity may be filled with 340B drugs; and (3) any HRSA interpretations or guidance in contradiction of the 340B statute are unlawful and unenforceable.[76]

The District Court issued its decision on Nov. 3, 2023. The court was sharply critical of HRSA's interpretation of the word "patient," significantly where it departed from its most carefully considered interpretation of the term – the 1996 patient definition guidelines. The court determined that the plain meaning of the word "patient" is "an individual awaiting or under medical care," using the definition from Merriam-Webster.[77] Though the court did not definitively determine the duration of a patient relationship, it implied that the two-year look-back period used by Genesis or the three-year standard used by the American Medical Association might be acceptable.[78] In contrast to HRSA's focus on the location in which a prescription is written, whether the prescription flows directly from a covered entity service, and whether the prescription was written after the establishment of a patient relationship, the court explicitly declared that "the only

[73] *Genesis Health Care, Inc. v. Becerra*, No. 20-1701, 2022 WL 2375178 (4th Cir. July 1, 2022).
[74] *Id*. at 5.
[75] *Id*. at 13.
[76] *Id*. at 8.
[77] *Genesis Health Care, Inc. v. Becerra,* 701 F.Supp.3d 312, 324 (D.S.C. Nov. 3, 2023).
[78] *Id.* at 20.

statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity."[79] In addition, the court declared that "the plain wording of the 340B statute does not require the 'covered entity' to have initiated the healthcare service resulting in the prescription."[80] The court stated that "the statute does require an ongoing patient relationship" but disagreed with HRSA's position that "the 340B drug prescription must originate from the ongoing relationship."[81] The court appeared to accept the 1996 patient definition guidelines as a persuasive interpretation of the term "patient." Still, it rejected the location and timing elements that HRSA had applied since, including in its audit of Genesis.

The court also very clearly endorsed that the 340B Program was created to benefit covered entities. The court stated:

> Bearing in mind that the purpose of the 340B statute was, in part, to make "covered entities" profitable so they could stretch federal resources as far as possible, reach more eligible patients, and provide more comprehensive services, a broad definition of the term "patient" complies with congressional intent in that the more patients a "covered entity" can sell discounted 340B drugs to, the greater the "covered entity's" profit margin, and the greater the ability of the "covered entity" to provide services to the indigent and achieve the purpose of the 340B statute.[82]

Though the decision only directly applies to the dispute between HRSA and Genesis, the opinion represents the first time in 27 years that a judge was asked to consider HRSA's interpretation of the word "patient" in the 340B statute. Thus, 340B stakeholders initially believed that its outcome would be highly influential on HRSA and on covered entities seeking to comply with the 340B statute while meeting the program's original intent to enable covered entities to "reach[] more eligible patients and provid[e] more comprehensive services."[83]

[79] *Id.* at 29 (emphasis original).
[80] *Id.*
[81] *Id.* at 21.
[82] *Genesis Health Care, Inc. v. Becerra,* No. 4:19-CV-01531 at 23 (D.S.C. Nov. 3, 2023).
[83] *Id.* at 3 (quoting H.R. REP. 102-384(II) at 12).

H. Life After the *Genesis* Decision – What Comes Next?

In the aftermath of the *Genesis* decision, it remained unknown whether and how HRSA would adjust its approach to auditing covered entities for compliance with the diversion prohibition. The covered entity community was hopeful that HRSA would adopt the standards outlined in *Genesis*. FQHCs, in particular, moved quickly to adopt the *Genesis* standards. Prior to Genesis, many health centers had long believed that they should be able to fill all their patients' prescriptions using 340B drugs. Some pointed out that "pharmaceutical services as may be appropriate for particular centers" is a "required primary health service" under the statute authorizing the health center program.[84] Others noted that health centers provide comprehensive healthcare to underserved individuals, often serving as the patient's primary medical home or sole healthcare access point. Notably, Genesis is an FQHC, and the court reviewed HRSA's interpretation of "patient" through that lens. It is unclear whether the court would have reached the same conclusions if the plaintiff had been a hospital or other covered entity type.

Drug manufacturers have, and undoubtedly will continue, to downplay the significance of *Genesis* or otherwise advocate to limit the outcome of *Genesis* to the particular facts of that case. Manufacturers have long tried to narrow the definition of "patient," sometimes suggesting that only uninsured patients should be eligible to obtain 340B drugs. Manufacturers are particularly critical of 340B Program practices that expand access to 340B drugs, including telemedicine programs, contract pharmacy arrangements, and infusion centers that fulfill outside orders with 340B medications.

HRSA seemed to agree with manufacturers, adding a statement to its webpage stating that the *Genesis* decision applied only to Genesis Health Care.[85] In 2024, HRSA finally released several audit findings that it had

[84] 42 U.S.C. § 254b(b)(1)(A)(i)(V).
[85] Specifically, HRSA added this statement: "HRSA notes that the decision in *Genesis Health Care, Inc. v. Becerra,* Civ. 4:19-cv-01531-

previously withheld pending the *Genesis* outcome. Many of the audit reports reviewed facts that were very similar to the facts presented in the *Genesis* case or were even more favorable to the covered entity than the facts in the *Genesis* case. Unfortunately for the covered entity community, HRSA issued diversion findings for these covered entities, demonstrating that it has reverted to its prior location test.

I. So, What Should Be Done?

The court's *Genesis* decision highlights a pressing need for Congress to intervene and clearly define who qualifies as a patient eligible for the 340B Program by focusing on who wrote the prescription and who is receiving it – both a prescription and patient test. Congress should interpret "patient" of a 340B covered entity that meets the following criteria:

1) The prescriber is:

a) Employed by the covered entity; or

b) Provides healthcare services to patients whose responsibility for care still rests with the covered entity (for example, a professional serving the entity's patients by referral, medical case management, medication therapy management, telehealth, etc.);

2) The covered entity maintains the medical records of the care provided to the individual;

3) The individual received services from the covered entity that were consistent with its range of services for which grant funding has been provided (not applicable to hospitals); and

4) The covered entity must have seen the individual and provided substantive primary care to them within the 12 months preceding the prescription.

Medical providers not contracted with or employed by the covered entity are not qualified as providers of a covered entity for purposes of writing prescriptions eligible to be filled with the covered entity's 340B drugs. If the prescriber had been contracted with or employed by the covered entity when the prescription was written, but is not contracted with or employed by the covered entity when the prescription is presented to be filled, the patient must have been seen by a medical provider currently employed by or contracted by the covered entity before their medication can be filled or refilled using

RBH (D.S.C. November 3, 2023), is applicable solely to Genesis Health Care." *Id*.

340B drugs.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only healthcare service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a state-operated or funded AIDS Drug Assistance Program (ADAP) receiving financial assistance under Title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so, registered as eligible by the state program.

At no time should a prescription from a provider not affiliated with the covered entity be eligible for 340B. Additionally, the covered entity must have seen the patient in person or via telehealth within the past two years, along with the appropriate lab tests when needed, to qualify the prescription for the 340B Program.

It is imperative that the 340B Program only benefits people who are currently patients of a covered entity – those who have had a meaningful medical encounter in the preceding 12 months. The *Genesis* decision poses risks by potentially allowing for a broader interpretation of who qualifies as a "patient" under the 340B Program. The court's decision to reject HRSA's restrictive definition, without providing additional clarity, could lead covered entities to classify prescriptions written by unaffiliated prescribers as eligible for 340B discounts. This interpretation, while legally permissible, removes the direct link between the patient's encounter and the prescription, which could lead to administrative challenges.

It is common for pharmacies to serve multiple covered entities as a 340B contract pharmacy. In situations where individuals are patients of more than one entity, the absence of a clear link between a covered entity encounter and the prescription can complicate the process for third-party administrators and contract pharmacies in determining the correct covered entity for a prescription. Covered entities must therefore carefully consider how this expanded definition of "patient" impacts their ability to maintain

auditable records that demonstrate compliance with all 340B Program requirements and ensure that only one covered entity is "claiming" a prescription.

Moreover, the *Genesis* decision could provoke drug manufacturers, some of whom supported HRSA's interpretation through amicus briefs, to impose further restrictions on 340B drug access. The decision also highlights HRSA's enforcement limitations, potentially prompting legislative action to increase HRSA's rulemaking authority and clarify the definition of "patient" and other 340B Program aspects. Since the Affordable Care Act's passage in 2010, there have been several bills proposed to amend the 340B statute. The *Genesis* decision highlights the ongoing tension between the original intent of Congress, the expansive interpretation by the courts intended to increase covered entity profits, and recent legislative attempts to scrutinize the use of 340B savings by covered entities.

II. HISTORY AND INTENT OF CONTRACT PHARMACY ARRANGEMENTS

The 340B Program is an outpatient drug program intended to benefit covered entities. The statute, though, is silent about how covered entities deliver those outpatient drugs to their patients. Outpatient drugs are typically either dispensed by a pharmacy or administered by a provider in a clinical setting. To access the program's benefits, a covered entity must have a way to deliver its discounted drugs to eligible patients and be paid for them (or not paid, as the case may be with uninsured or indigent patients).

Many 340B covered entities do not operate their own pharmacies, commonly referred to as in-house pharmacies (regardless of whether they are literally located within a covered entity site). Because the requirements to obtain a pharmacy license are complex and establishing and operating a pharmacy can be expensive, HRSA has acknowledged that many covered entities do not "expend precious resources to develop their own in-house pharmacies."[86] Consequently, many covered entities participate in the 340B Program by relying on independent retail pharmacies that are accessible where the covered entity's patients reside. These arrangements are established by contract between covered entities and pharmacies, so they are often called "contract pharmacy arrangements," and the pharmacies are generally referred to as "contract pharmacies."

The contract pharmacy distribution model is the only viable way in which many covered entities can participate and obtain the benefits of the 340B Program. Drugs dispensed by contract pharmacies are purchased by the covered entity using a "bill to/ship to" process in which the drugs are purchased by, and billed to, the covered entity but shipped to the contract pharmacy. Contract pharmacies are not permitted to purchase 340B drugs.[87] After receiving the covered entity's 340B drugs, the contract pharmacy dispenses the

[86] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("1996 Contract Pharmacy Notice").
[87] This is a fundamental program tenet often misrepresented by opponents, including drug manufacturers.

drugs to the covered entity's patients, collects reimbursement for the drugs from both the patient and the patient's third-party payer (if any), and remits the collected reimbursement to the covered entity. The covered entity, in turn, pays the pharmacy a fee for its dispensing and billing services.

Contract pharmacy arrangements are built on the well-established commercial practice of one party purchasing and taking title to a product and a second party taking possession of the product on the first party's behalf. Contract pharmacy distribution arrangements are used elsewhere within the U.S. drug distribution system and are not unique to the 340B Program.[88]

Contract pharmacies help fulfill the 340B Program's purpose of enabling covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[89] Covered entities that lack in-house pharmacies can only participate in the 340B Program by contracting with outside pharmacies. Some covered entities, particularly in rural areas, serve patients living hundreds of miles away.[90] Covered entities, therefore, contract with pharmacies that are not located nearby to meet the needs of these patients. In other instances, drugs may only be available from specialty pharmacies designated by the drug company, which may be located on the opposite side of the country from the covered entity.[91]

[88] *See, e.g.*, Fed. Trade Comm'n, Univ. of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010); 134 Cong. Rec. H6971-02 (1988) (statement of Rep. Charlie Rose) ("[H]ealth centers often include onsite pharmacies, or agreements with community pharmacists to ensure that the medicines needed to treat or control these chronic conditions are available."); *Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and Means*, 91st Cong. 2129 (1969) (statement of Jacob W. Miller, Chairman, Comm. Pub. Affs., Am. Pharm. Ass'n) ("As I am sure you are aware, many health care facilities do not maintain their own onsite pharmaceutical services … [r]ather, they look to the community pharmacies to provide such service on a contract basis.").
[89] H.R. Rep. No. 102-384(II), at 12 (1992).
[90] Caitlin Ostroff, *Millions of Americans Live Nowhere Near a Hospital, Jeopardizing Their Lives*, CNN (Aug. 3, 2017), https://www.cnn.com/2017/08/03/health/hospital-deserts/index.html.
[91] *See Limited Distribution Drugs 101*, Clarivate (Sept. 27, 2019), https://clarivate.com/blog/limited-distribution-drugs-101.

A. History

From the beginning of the 340B Program, the HHS recognized that the program could only function if certain covered entities were permitted to use contract pharmacy arrangements:

> During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B Program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B Program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.[92]

In 1995, HRSA published proposed guidelines for contract pharmacy services under the 340B Program in the Federal Register.[93] In 1996, after considering comments submitted in response to its Nov. 1, 1995, notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute.[94] Under contract pharmacy arrangements, the covered entities purchase 340B drugs from manufacturers and direct the manufacturers to ship the 340B drugs to the contract pharmacy. In the Aug. 23, 1996, guidance, HRSA noted that "many covered entities … do not operate their own licensed pharmacies."[95] The secretary explained why the 340B Program is essential for these covered entities:

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the federal poverty level and subsidize prescription drugs for many

[92] 1996 Contract Pharmacy Notice, 61 Fed. Reg. 43,549.
[93] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (Nov. 1, 1995).
[94] 1996 Contract Pharmacy Notice, 61 Fed. Reg. 43,549.
[95] *Id.*

> of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower-income patients, increase the number of patients whom they can subsidize, and expand services and formularies.[96]

The agency's guidance "encourage[d]" covered entities that did not operate their own licensed pharmacies to utilize contract pharmacy services.[97] HRSA's Aug. 23, 1996, guidance was clear that the 340B statute requires pharmaceutical manufacturers to sell 340B discounted drugs to covered entities through contract pharmacy arrangements.[98] HRSA was also clear that covered entity arrangements with contract pharmacies are agency relationships.[99] Finally, HRSA observed that the use of contract pharmacies does not constitute "an unauthorized expansion of the [340B] program" because "[t]he statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself."[100] HRSA emphasized that contract pharmacy distribution arrangements did not "create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under state law."[101]

In 2010, HRSA published a notice clarifying that covered entities may contract with multiple pharmacies.[102] The covered entity must have a separate contract pharmacy agreement with each contract pharmacy. However, a covered entity may contract with multiple sites of a chain pharmacy under one agreement. The contract pharmacy guidelines include "essential covered entity compliance elements" that must be addressed in contract pharmacy agreements.[103] Significantly, throughout the preamble to the

[96] *Id.*
[97] *Id.* at 43,555.
[98] *Id.* at 43,549-50.
[99] *Id*. "ODP" is the Office of Drug Pricing within HRSA.
[100] *Id.*
[101] *Id.* at 43,550
[102] 2010 Contract Pharmacy Guidelines, 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[103] *Id.* at 10,277.

guidelines, HRSA emphasized that covered entities retain the responsibility to comply with all 340B Program requirements when entering into a contract pharmacy arrangement and that HRSA will hold the covered entity accountable for any violations of these requirements by the contract pharmacy.[104]

In addition, the contract pharmacy guidelines require the 340B covered entity to maintain auditable records to demonstrate 340B compliance and verify that the contract pharmacy has a tracking system to ensure that the covered entity's 340B drugs are not diverted to non-eligible patients.[105] Similarly, the 340B covered entity is responsible for developing a system to verify patient eligibility.[106] The agreement must also acknowledge that HRSA and participating drug manufacturers may audit records pertaining to covered entity compliance with program requirements.[107] Though not an essential compliance element, HRSA expects covered entities to have policies and procedures describing their oversight of any contract pharmacies with which they contract, and to conduct annual independent audits of their contract pharmacies to ensure their compliance with 340B Program requirements.[108] Due to the complexity of 340B contract pharmacy arrangements, many covered entities and contract pharmacies use third-party administrators to verify patient eligibility and manage inventory, among other tasks. Regardless of how the arrangement is managed, the covered entity remains solely responsible to the government for its 340B compliance.

Manufacturers complained that HRSA lacked the authority to allow covered entities to use an unlimited number of contract pharmacy arrangements. HRSA defended its action as follows:

> Comment: The proposed revisions are substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for

[104] *Id*. at 10,273-74.
[105] *Id*. at 10,275.
[106] *Id*. at 10,278.
[107] *Id*.
[108] *Contract Pharmacy Oversight*, Office of Pharmacy Affairs Update (Feb. 6, 2014), http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html.

covered entities under the law.

Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. HRSA has considered contract pharmacy service guidelines to be ''interpretative rules and statements of policy'' exempt from notice and comment rulemaking under the APA.[109]

Since 2010, the number of 340B contract pharmacies has grown considerably. Every administration, Republican and Democrat, has consistently interpreted the 340B statute as allowing contract pharmacy arrangements. Contract pharmacy arrangements must be registered with OPA and appear on the 340B database before implementation. OPA requires contract pharmacies to be registered during the first 15 days of each calendar quarter (*i.e.*, Jan. 1 to 15) for a start date on the first day of the next calendar quarter (*i.e.*, April 1).[110]

B. Importance of 340B Contract Pharmacy Savings

In many communities, especially those in low-income rural and urban areas, safety net providers along with the contract pharmacies they collaborate with often represent the sole access point to affordable healthcare for underserved populations. The 340B Program plays a critical role by enabling covered entities to offer discounted drugs to financially needy patients. This arrangement allows uninsured and under-insured patients of these entities to obtain their prescriptions at convenient locations, frequently at significantly reduced costs or even free of charge.

Without the availability of discounted medications through contract pharmacies, numerous patients from these covered entities would face the real risk of losing access to essential, life-saving medications. This

[109] 2010 Contract Pharmacy Guidelines, 75 Fed. Reg. at 10,273.
[110] Notice Regarding Section 340B of the Public Health Service Act – Registration Period, 77 Fed. Reg. 43,342 (July 24, 2012).

is particularly vital for those serving in remote or rural communities, where contract pharmacies effectively reduce the geographic and logistical barriers that typically hinder access to affordable medications.

Furthermore, covered entities use 340B Program savings to subsidize the cost of important, life-saving healthcare services. For insured patients, covered entities benefit from the difference between the 340B price and the insurer's payment for the drug. Covered entities use these funds to supplement their federal grants and other program income, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended.[111] Many of the programs and services that covered entities support with 340B savings are critical to treating the whole patient but are not reimbursed by public or private insurance and are often most needed by patients who lack insurance. Congress designed the 340B Program to provide funding for just these sorts of programs and services.

Contract pharmacies are also clinically beneficial. When a patient fulfills a prescription at a contracted pharmacy, the covered entity receives information regarding the dispense. In that way, it knows that the patient has actually filled the prescription. If the patient experiences difficulty paying for the prescription, or obtaining insurance coverage for it, the contract pharmacy can notify the covered entity and the covered entity can determine whether the patient qualifies for financial assistance, or if there is a way that the covered entity can obtain coverage for the prescription. The contract pharmacy fills in information that the covered entity lacking an in-house pharmacy would otherwise never see.

Contract pharmacies are also highly beneficial for hospital covered entities as well as grantees. Hospitals use contract pharmacies in many of the same ways that grantees use them. They can contract with pharmacies in locations near where their patients live or obtain care or use contract pharmacies to extend

[111] H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

discounts to qualifying patients. Many hospitals have provider-based locations strewn across an area – whether urban or rural – and it is not feasible to expect a patient to come to the hospital's in-house pharmacy (if it has one) to fill prescriptions. Contracted pharmacies allow the hospital to meet the patient where the patient is – an especially valuable service for patients who lack reliable transportation.

Contract pharmacies can also greatly help reduce costs for hospitals that provide healthcare for their own employees. Because DSHs, freestanding cancer hospitals, and children's hospitals are subject to the GPO prohibition, any drugs that an in-house pharmacy would carry for non-340B patients would have to be purchased at the full sticker price – often called the "WAC" price or wholesale acquisition cost. By locating a contracted pharmacy in or near the hospital, the hospital can provide pharmacy services to its non-patient employees without suffering unmanageable drug costs.

C. Current Regulatory Landscape and Potential Changes

As noted above, HRSA issued guidance in 1996 to allow covered entities to contract with one third-party pharmacy to dispense 340B drugs on the covered entity's behalf and revised that guidance in 2010 to allow covered entities to enter into multiple contract pharmacy arrangements.[112] The contract pharmacy program has grown since 2010, and many covered entities, particularly large hospital systems, realize millions of dollars of revenue from their contract pharmacy arrangements.

In 2020, after more than 20 years of providing 340B drugs through contract pharmacies, manufacturers began announcing policies that they would no longer offer 340B drugs through contract pharmacies or would place conditions on contract pharmacy access to 340B pricing. Manufacturers argue that neither the 340B statute nor the Pharmaceutical Pricing Agreement (PPA)—an agreement with HHS under which the

[112] 2010 Contract Pharmacy Guidelines, 75 Fed. Reg. 10,272; 1996 Contract Pharmacy Notice, 61 Fed. Reg. 43,549.

manufacturer agrees to sell covered outpatient drugs to covered entities at or below the 340B ceiling price as a condition of Medicaid and Medicare Part B coverage of those drugs—requires them to offer 340B discounted drugs if those drugs are distributed through a contract pharmacy.

The first manufacturer to limit its participation in contract pharmacy arrangements was Eli Lilly. On July 1, 2020, HRSA published a "limited distribution plan" on its official manufacturer notices website for several formulations of Lilly's drug Cialis.[113] The limited distribution plan stated that, effective July 1, 2020, Lilly would not offer 340B pricing for these drugs if a covered entity sought to purchase the drugs through a contract pharmacy arrangement. Lilly later expanded its policy to all its retail drug products, with a qualified exception for its insulin products and for covered entities without in-house pharmacies, effective Sept. 1, 2020.[114] Soon after, Sanofi, AstraZeneca, and Novartis announced contract pharmacy polices similar to Lilly's, effective Oct. 1, 2020. To date, more than 37 manufacturers have announced restrictive contract pharmacy policies.[115] Several of them, beginning with Sanofi in 2020, only honor contract pharmacy arrangements if the covered entity submits its contract pharmacy claims data to 340B ESP™, a software program owned by Second Sight Solutions, LLC. Most of these manufacturers allow covered entities to access 340B pricing at an in-house pharmacy or one designated contract pharmacy. Many of the manufacturers impose restrictions on hospital-covered entities and not grantee-covered entities, though increasingly manufacturers are amending their policies to include FQHCs or all covered entities. These actions are dramatically reducing resources available to

[113] HRSA, *Manufacturer Notices to Covered Entities* (July 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.
[114] Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products*, 340B Health (Sept. 1, 2020), https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.
[115] These are Abbvie, Alkermes, Amgen, Astellas, AstraZeneca, Bausch Health, Bausch & Lomb, Bayer, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, EMD Serono, Exelixis, Genetech, Gilead, GlaxoSmithKline, Incyte, Jazz Pharmaceuticals, Johnson & Johnson, Liquidia, Merck, Novartis, Novo Nordisk, Organon, Pfizer, Sandoz, Sanofi, Sobi, Sumitomo, Takeda, Teva, United Therapeutics, UCB, Vertex, and Viatris.

safety net providers, harming their ability to meet the needs of vulnerable patients and jeopardizing patient access to affordable and accessible prescription drugs.

These manufacturers' refusal to provide 340B pricing to eligible covered entities, simply because the drugs they purchase are shipped to and dispensed by contract pharmacies, appear to be a clear violation of the 340B statute and their PPAs with HHS. The statute broadly requires manufacturers to provide discounts on all covered outpatient drugs regardless of how covered entities dispense the drugs to their patients. These restrictions have deprived covered entities of the revenue and savings that Congress intended under the 340B Program, which reduces the resources available to covered entities to meet the needs of their vulnerable patients, including the need for affordable and accessible prescription drugs.

Congress has traditionally left regulation of the complex U.S. drug distribution system to the states.[116] The absence of any mention in the 340B statute of any of the multiple channels and entities typically involved in drug distribution—including not only contract pharmacies but also wholesalers, re-packagers, brokers, and third-party logistics providers, among others—demonstrates Congress's intent that covered entities obtain discounted drugs through existing mechanisms, including contract pharmacies. The 340B statute, by design, leaves those practical decisions to the covered entity within the preexisting and complex laws of the state(s) in which they operate. The covered entity community believes that the statute's silence on contract pharmacies, dispensing, and distribution should not be viewed as a grant of authority to drug manufacturers to limit their own 340B obligations.

The House of Representatives report accompanying the 340B statute underscores that Congress's

[116] *See, e.g.*, W*yeth v. Levine*, 555 U.S. 555, 578–79 (2009); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 940–41 (8th Cir. 2011); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021) ("the practice of pharmacy is an area traditionally left to state regulation.").

silence on distribution was intended to accommodate covered entities' distribution needs rather than limit their purchases. The report stated, "The committee bill does not limit the amount of drugs that a 'covered entity' may procure[,] … does not authorize the secretary to limit in any way the volume of purchases that can be made at the [340B] price," and "does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, *or through some other mechanism*."[117] That report further stated, "A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS Drug Assistance Programs," and "[t]he committee expects that the Secretary of HHS … will use the mechanism that is the most effective and most efficient *from the standpoint of each type of 'covered entity*.'"[118] The report demonstrates Congress's clear intent to provide covered entities broad flexibility to procure 340B drugs, including through contract pharmacies used by many healthcare providers.

The legislative history of the 340B statute clearly demonstrates that Congress considered adding provisions to restrict access to 340B drugs by requiring providers to dispense them through on-site pharmacies. However, after hearing testimony from covered entities, Congress chose to refrain from enacting that limitation.[119]

D. Current Litigation Landscape and Potential Changes

After several manufacturers implemented restrictive contract pharmacy policies, the HHS Office of General Counsel ("OGC") issued an Advisory Opinion ("OGC Advisory Opinion") in December 2020 in which the OGC affirmed that drug manufacturers must offer covered outpatient drugs to covered entities at or below

[117] H.R. Rep No. 102-384, pt. 2, at 15 (1992) (emphasis added).
[118] *Id.* (emphasis added).
[119] S. Rep. No. 102-259, at 2 (1992) (considering S. 1729, 102d Cong. (1992)).

the 340B ceiling price regardless of how the covered entity distributes those drugs.[120] Several manufacturers responded by filing lawsuits to challenge the OGC Advisory Opinion.[121] HHS withdrew the advisory opinion on June 18, 2021, choosing instead to rely on cease-and-desist letters that it sent directly to the manufacturers at issue. HRSA sent these cease-and-desist letters ("HRSA Violation Letter") on May 17, 2021 and Oct. 4, 2021 to the manufacturers that had adopted these policies, stating its position that the manufacturers' policies violated the 340B statute and informing them that the matter had been referred to the HHS Office of Inspector General to consider whether manufacturers are liable for civil monetary penalties (CMPs).[122]

On Jan. 30, 2023, the Third Circuit Court issued a decision that the contract pharmacy restrictions imposed by Sanofi, Novo Nordisk, Inc., and AstraZeneca are lawful and not subject to enforcement actions by HHS.[123] The Third Circuit found that the OGC Advisory Opinion and HRSA Violation Letter were "unlawful" and that "restrictions on delivery to contract pharmacies do not violate Section 340B."[124] The Third Circuit remanded the case to the U.S. District Court for the District of Delaware with instructions to enjoin HHS from enforcing its reading of the 340B statute as requiring delivery of discounted drugs to an unlimited number of contract pharmacies.[125] Consequently, on May 5, 2023, the U.S. District Court for the District of Delaware entered a final judgment implementing the Third Circuit's view that manufacturers may restrict shipments of

[120] HHS Gen. Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020), https://ppsv-my.sharepoint.com/:b:/g/personal/mark_ogunsusi_powerslaw_com/EboUPFF1J_VBkPpp25mnXEoB7dZ8YtxSGbSMx3enT6eGZA?e=YV8avH (withdrawn June 18, 2021).
[121] Second Amended Complaint, *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. July 9, 2021), ECF No. 86; Second Amended Complaint, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. May 27, 2021), ECF No. 103; Second Amended Complaint, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. May 25, 2021), ECF No. 78; Amended Complaint, *Novo Nordisk Inc. v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. May 21, 2021), ECF No. 40.
[122] HRSA, *Program Integrity,* https://www.hrsa.gov/opa/program-integrity/index.html (last visited Sept. 2023) (the letters are listed under HRSA Correspondence to Stakeholders).
[123] *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023).
[124] *Id.* at 706.
[125] Mandate of USCA, *AstraZeneca Pharms.*, No. 1:21-cv-00027 (D. Del. Apr. 25, 2023), ECF No. 118.

340B discounted drugs to contract pharmacies ("Final Judgment").[126] The D.C. Circuit Court agreed with the Third Circuit, issuing an opinion on May 21, 2024 holding that manufacturers are not "categorically prohibited from limiting distribution of discounted drugs by contract."[127] Both courts also held that "[t]he text [of 340B] is silent about delivery."[128]

The Seventh Circuit Court is currently considering whether HHS can enforce its policy to require pharmaceutical manufacturers to make 340B drugs available at contract pharmacies without restrictions.[129] Because three circuits will eventually decide the same question of law, a circuit split is still possible, in which case the issue must be resolved by the U.S. Supreme Court. Even if the Seventh Circuit rules against HHS, HHS may still request that the Supreme Court hear the case.

The decisions from the Third Circuit and D.C. Circuit are difficult to reconcile with the plain text and intent of the 340B statute. The law is a pricing law, not a distribution law. The 340B statute mandates discounts on covered outpatient drugs, but does not regulate the dispensing of drugs, and its silence on contract pharmacy arrangements is understandable in that context. Why would Congress allow hundreds of manufacturers to create their own rules for a program designed to shift resources from those same manufacturers to safety net providers? Nevertheless, courts have already taken contrary views, and it is impossible to predict the outcome of the litigation.

When the statute is viewed as governing pricing not distribution, it is understandable that the statute does not address contract pharmacies or other distribution models, and this silence does not give

[126] Final J., *AstraZeneca Pharms.*, No. 1:21-cv-00027 (D. Del. May 5, 2023), ECF No. 123.
[127] *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024).
[128] *Sanofi*, 58 F.4th at 703; *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024).
[129] *See Eli Lilly*, No. 21-03128 (7th Cir.); *Novartis Pharms. Corp*, No. 21-5299 (D.C. Cir.). The D.C. Circuit and the Seventh Circuit each heard oral arguments in October 2022. *See Novartis Pharms. Corp*, No. 21-5299 (D.C. Cir. Oct. 27, 2022), ECF No. 1970905; *Eli Lilly*, No. 21-03128 (7th Cir. Oct. 31, 2022), ECF No. 73.

manufacturers the right to condition their obligation to "offer" 340B discounts based on where the drugs are shipped. This is the analysis of the OGC Advisory Opinion, and the Supreme Court or Seventh Circuit could adopt something similar. Some believe that this type of straightforward textual analysis would be attractive to the court's six conservative justices. The OGC Advisory Opinion's author, Robert Charrow, is a well-known conservative lawyer, having served in both the Reagan and first Trump administrations, and the reasoning of the OGC Advisory Opinion reflects a conservative textual analysis. The intent of the 340B statute is to provide low-cost drugs to covered entities, and many covered entities cannot participate without contract pharmacies. Therefore, contract pharmacy shipments are necessary to give effect to the statute. The more liberal justices may be swayed by this argument. Our assessment is that the government has a better argument than the manufacturers.

In the meantime, while litigation progresses, more manufacturers are likely to adopt policies to restrict access to 340B pricing at contract pharmacies (in states that do not prohibit restrictions, as discussed below). Some covered entities, particularly large health systems with many contract arrangements and smaller rural hospitals, are losing significant amounts of revenue because they cannot access 340B pricing through contract pharmacies. Some covered entities are mitigating their losses by submitting claims through 340B ESP™ so that they can have access to 340B pricing at any contract pharmacy of their choosing. Some covered entities may also open their own in-house pharmacies to mitigate losses.

If manufacturers ultimately prevail in the litigation, the significant contraction of the 340B Program would likely accelerate, unless Congress or states intervene. Hospitals, in particular, would see contract pharmacy shipments diminish or disappear. Depending on the breadth of a decision in favor of manufacturers, covered entity participation in the 340B Program could be limited to their in-house pharmacies or ship to one

contract pharmacy, particularly in hospitals since all restrictive policies apply to them. Many manufacturers with restrictive contract pharmacy policies exclude federal grantees from those restrictions. If the courts hold that manufacturers are not obligated at all to ship to contract pharmacies, those current policies would not be guaranteed to continue. On the other hand, if the government prevails, the 340B Program will likely expand because covered entities would be free to contract with an unlimited number of pharmacies.

E. Current Legislative Landscape and Potential Changes

Litigation regarding contract pharmacy restrictions has stretched across four years already. If the circuit courts split on their decisions, the issue may see resolution in the Supreme Court, meaning even more time for the pharmaceutical industry to remain unchecked. Congress has inserted itself into the debate in multiple ways and on multiple occasions in the last five years but not through legislative action. For example, hundreds of members of Congress signed onto letters urging HHS to exercise its authority under the CMP rule to stop manufacturers from limiting contract pharmacy arrangements.[130]

Given that at least 37 drug manufacturers[131] have enacted policies to limit contract pharmacy use, some covered entities are between the proverbial "rock and a hard place" and are anxious for immediate relief. While HHS has been fighting in the courts and making its views clear that manufacturers must stop their unlawful actions, HHS appears unable to levy any fines or take any other enforcement action on the offending companies. Even if HHS instituted such penalties, manufacturers might not acquiesce and reverse their restrictive policies. In fact, drug industry messaging on social media and through earned media appears to be

[130] E.g. Letter from David B. McKinley, U.S. House of Representatives, to Alex Azar, Sec'y of HHS (Sept. 14, 2020), https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf; Letter from Frank Pallone, Chairman of U.S. House of Representatives Committee on Energy and Commerce, to Alex M. Azar II, Sec'y, HHS (Sept. 3, 2020), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/HHS.2020.9.3.%20Final.pdf.
[131] *See* https://www.340besp.com/resources.

increasing, often a signal of industry's entrenchment in its legal position and advocacy agenda.[132] While Congress is not known for speed, the faster and more promising approach for relief for the safety net appears to be congressional action rather than state protections and litigation.

Congress must take a stand against manufacturers' unilateral and damaging restrictions on 340B contract pharmacy arrangements. It must recognize covered entities' right to enter into such arrangements and protect state laws that enable access to them. Section 340B(a)(1) of the Public Health Service Act should be amended to prohibit: (i) manufacturers from limiting or obstructing in any way a covered entity's access to 340B drugs at contract pharmacies, including by refusing to pay wholesaler charge-backs or requiring information on 340B drug claims; and (ii) wholesalers from refusing to deliver 340B drugs or to provide access to a manufacturer's 340B pricing file. Such legislation should also (i) contain a "savings clause" to protect state laws from preemption if they are not less restrictive on drug manufacturers and not more restrictive on covered entities than federal law; (ii) impose CMPs and other consequences on drug manufacturers and distributors that violate the above protections; and (iii) define a manufacturer violation as an "overcharge" for purposes of the alternative dispute resolution (ADR) process.

A more likely scenario is that, to secure protection of the contract pharmacy program, covered entities would have to make concessions to accommodate the reform demands by industry. Such concessions could include reducing the number of hospitals in the program by tightening up hospital eligibility criteria, decreasing the number of drugs purchased through the program by narrowing the definition of "patient," or increasing transparency on hospital use of 340B revenue and savings. It is difficult to imagine that manufacturers would allow Congress to give covered entities unfettered use of contract pharmacies. More

[132] PhRMA, Policy Issues: 340B, https://www.phrma.org/policy-issues/340b (last visited Feb. 22, 2022).

likely, industry would insist on some kind of numeric or geographic limits on contract pharmacy arrangements.

F. Finally, state law provides another avenue for reform. Those developments are discussed below. Contract Pharmacy Fees

Most contract pharmacy arrangements charge a "dispensing fee" or "administrative fee" for the service that the contract pharmacy is providing to the covered entity. The fee covers the services that the pharmacy is providing for the covered entity – dispensing, inventory management, and billing. The fee could be a flat fee (a fixed dollar amount for each dispense to an eligible patient), a percentage-based fee (a percentage of the reimbursement for the drug or profit margin, intended to reflect the effort needed to dispense the drug and receive payment for it), a combination of both, or a "reference price" (discussed below).[133]

Though contract pharmacies are partners for covered entities, many feel that the pharmacy takes advantage of the fact that the covered entity's patient need or desire to go to a particular pharmacy. Large chain pharmacies like CVS, Walgreens, and Walmart could be the only provider of pharmacy services for many patients. Specialty pharmacies, especially those owned by pharmacy benefit managers like CVS/Caremark and Express Scripts, might be the only pharmacy a patient can use to fill certain prescriptions. Pharmacies in that position can effectively offer "take it or leave it" deals to covered entities with unfavorable pricing. If a covered entity's patients prefer to use a particular pharmacy, or must use a particular pharmacy, the entity faces the predicament of either paying whatever fee the pharmacy wants or trying to convince the patient to use another pharmacy that provides services to the covered entity on more favorable terms.[134]

[133] Any fee must be otherwise legally permissible including under federal and state antikickback statutes.
[134] Note that covered entities cannot require patients to use a particular pharmacy. Patients must have the freedom to choose their pharmacy provider (understanding that the patient will typically choose a pharmacy that takes their insurance, offers the best pricing, or both. Covered entities typically may not offer patients anything of value to use a particular pharmacy due to federal and state anti-kickback statutes and patient brokering/inducement prohibitions.

Some have suggested that pharmacies should be limited in the amount or type of fees that they can charge covered entities. Others have noted that it is difficult to respond to manufacturer restrictions by claiming that contract pharmacies are our valued partners on one hand while complaining that someone needs to regulate them on the other.

A significant issue for some covered entities within the 340B Program involves the "reference price" model, commonly utilized by grocery store pharmacies and specialty pharmacies. In this model, covered entities agree to pay the contract pharmacy a flat or percentage-based dispensing/administrative fee. However, rather than remitting the full amount received from the payer to the covered entity after subtracting the agreed-upon fee, the pharmacy instead remits only what it would have typically paid for the drug outside the 340B Program.

This approach allows the pharmacy to retain the usual reimbursement margin plus the dispensing/administrative fee, while the covered entity receives only the value of the 340B discount on the drug, reduced by the dispensing/administrative fee. While many covered entities view these reference price models as potentially abusive due to their impact on the financial benefits intended by the 340B Program, pharmacies defend the practice as a means to preserve their standard profit margins.

G. Third-Party 340B Administrators

The proliferation of contract pharmacies following the 2010 expansion of HRSA contract pharmacy guidance also directly led to the growth of a cottage industry of 340B administrators (also called third-party administrators or TPAs). As discussed above, covered entities are singularly responsible to HRSA for compliance with contract pharmacies with the diversion and duplicate discount prohibitions. A covered entity must be able to communicate to the pharmacy whether a prescription is eligible to be filled with 340B drugs,

how much to charge an uninsured or underinsured patient, and how to maintain adequate inventory at the contract pharmacy to fill eligible prescriptions (or, more often, to manage replenishment of non-340B drugs dispensed to eligible patients with the covered entity's 340B drug inventory).

TPAs offer to manage those matters on behalf of covered entities. They often sit between the covered entity and contract pharmacy, reviewing the covered entity's electronic medical records on one hand and comparing them to the claims billed by the pharmacy on the other. When a prescription is eligible to be filled with 340B drugs, the TPA identifies it and "captures" it for the benefit of the covered entity. The pharmacy receives its dispensing fee and replacement inventory, and the covered entity receives whatever reimbursement the pharmacy received for the drug (except in reference price models, as discussed in the section immediately above).

Some contract pharmacies require the covered entity to use a particular TPA. CVS, for example, requires covered entities to use WellPartner. Walgreens requires covered entities to use their internal proprietary management solution. In those scenarios, covered entities have complained that they lose the ability to pick their management partner and must pay whatever fee the pharmacy dictates to the required TPA.

Pharmacies have also increasingly begun using their own TPAs, typically called "gateways," to perform a first pass that might filter certain claims from even reaching the covered entity's TPA. Particularly pernicious issues have arisen when the TPA or gateway mismanages 340B inventory or billing, and the two can point fingers at each other.

H. State Laws Protecting Contract Pharmacy

Because the Third and D.C. circuit opinions held that the 340B statute silent on distribution, one

argument is that Congress intended for states, not the federal government, to regulate distribution, at least until and unless Congress chooses to step in.[135] Congress has traditionally left the regulation of drug distribution to the states, and Congress did the same in the 340B statute.[136]

Fourteen states – Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Mexico (FQHCs only), North Dakota, South Dakota, Tennessee, Utah, and West Virginia – have enacted laws prohibiting drug manufacturers from restricting access to contract pharmacies, but covered entities in the rest of the country enjoy no such protection.[137] State laws recognizing covered entities' right to use contract pharmacy arrangements are especially important, given the continued lack of federal action. Multiple states have or are considering legislation that would protect covered entities from manufacturer contract pharmacy restrictions.

Drug manufacturers have launched waves of litigation – often multiple cases per state – challenging the state protections. Most frequently, the challenges allege that the state laws are "preempted" by federal law because they conflict with it, though no such challenge has been successful in a ruling on the merits to date. In 2021, PhRMA filed the first lawsuit challenging Arkansas's Act 1103, which protects contract pharmacy arrangements in Arkansas, arguing that the federal 340B statute preempted Act 1103.[138] Both the district court and the Eighth Circuit Court upheld Act 1103's constitutionality.[139] The Supreme Court declined to

[135] *See Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143-44 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024)
[136] *See* W*yeth v. Levine*, 555 U.S. 555, 578–79 (2009); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 940–41 (8th Cir. 2011); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021) ("the practice of pharmacy is an area traditionally left to state regulation.").
[137] *See, e.g.,* Ark. Code Ann. § 23-92-604(c); La. Stat. Ann. § 40:2884.

review the Eighth Circuit's decision, meaning that ruling will stand and apply to other states in that circuit including Missouri and Minnesota as to the issue of preemption.[140]

In addition to the Eighth Circuit's *PhRMA* decision, there have been several decisions favoring covered entities and the state law that protects contract pharmacy arrangements. For instance, judges in Mississippi and Maryland denied manufacturer motions for preliminary injunction.[141] The Missouri judges dismissed several manufacturer claims on a variety of legal theories.[142] Additionally, the District Court for the District of Louisiana upheld the constitutionality of Louisiana's contract pharmacy protection law (Act 358).[143] AbbVie, AstraZeneca, and PhRMA appealed these decisions to the Fifth Circuit Court where the district court's decision is currently being reviewed. Aside from a preliminary injunction in West Virginia that is still pending and a voluntary concession made by Kansas, all such suits have failed to overturn the state laws. Nevertheless, each state that passes contract pharmacy protections can expect to be sued, and likely more than once.

I. So, What Should Be Done? Congress Needs to Intervene.

The world of contract pharmacies will never be resolved until Congress decides what covered entities are and are not allowed to do. The courts have ruled that HRSA does not have the statutory authority to really govern contract pharmacies. If Congress does not speak, then the program could be subject to multiple court

[141] *PhRMA v. Fitch*, No. 1:24-cv-00160, 2024 WL 3277365 (S.D. Miss. July 1, 2024) (order denying motion for Preliminary Injunction); *Novartis v. Fitch*, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024) (order denying motion for Preliminary Injunction); *AbbVie v. Fitch*, No. 1:24-cv-00184, 2024 WL 3503965 (S.D. Miss. July 22, 2024) (order denying motion for Preliminary Injunction); Novartis v. Brown, No. 1:24-cv-01557-MJM (D. Md. Sept. 5, 2024) (order denying motion for Preliminary Injunction for Novartis, PhRMA, AbbVie, and AstraZeneca).

[142] *PhRMA v. Bailey*, No. 2:24-cv-04144-MDH (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss in its entirety, except for PhRMA's Commerce Clause claim); *Novartis v. Bailey*, No. 2:24-cv-04131-MDH (W.D. Mo. Feb. 13, 2025) (granting motion to dismiss for Novartis' preemption claims; denying motion to dismiss for Novartis' Dormant Commerce Clause claim); *AstraZeneca v. Bailey*, No. 2:24-cv-04143-MDH (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss AstraZeneca's preemption and constitutional takings claims; denying motion to dismiss on AstraZeneca's contract clause claim).

[143] *PhRMA v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (the court issued one opinion for three cases).

interpretations and areas of ambiguity, only making the confusion worse.

The ongoing debate in Congress and state legislatures focuses on whether covered entities should be allowed unlimited numbers of contract pharmacies, among other factors. Congress should enact legislation to establish uniform guidelines on how much 340B revenue a contract pharmacy (independent or chain) may be allowed to retain under the 340B Program. Reimbursement for 340B drugs, whether dispensed at contract pharmacies or by covered entities, should always exceed the non-340B cost of the drug to ensure that the 340B Program savings are available to the covered entity. Special care should be given to protecting independent pharmacies, generally and specifically as part of the 340B Program. Beyond this, several critical issues require careful consideration:

1. **Flexibility for entities without in-house pharmacies**: Should covered entities lacking in-house outpatient pharmacies be granted more flexibility compared to those with their own pharmacies?
2. **Mandating Medicaid prescriptions at entity pharmacies**: Should Congress mandate that all Medicaid prescriptions (Medi-Cal in California) be filled at a covered entity's outpatient pharmacy where one exists?
3. **Patient adherence**: Could the above mandate improve patient adherence to medication regimens?
4. **Insight into barriers**: Might this requirement offer greater insight into the barriers patients face when filling prescriptions?
5. **Impact on pharmaceutical harassment**: Could enforcing this rule reduce harassment from PhRMA regarding access to medications through contract pharmacies?
6. **Emergency medications**: How should covered entities handle the dispensing of emergency medications when the entity's own pharmacy is closed?
7. **How much 340B revenue stays in a community:** We are long overdue to understand how 340 B impacts low-income communities compared with affluent communities. Where is the revenue really going, and who wins and who loses?

As legislative debates continue, the lack of definitive Congressional action coupled with the potential for conflicting court rulings may lead to an increase in litigation. This underscores the need for clear, decisive legislative guidance to address these pressing issues within the 340B Program.

III. ACCOUNTING FOR AND INVESTING 340B PROGRAM SAVINGS: MOVING AGGRESSIVELY TOWARDS TRANSPARENCY

Unlike other 340B covered entities, hospitals are not required to report how they utilize their 340B savings. In contrast to some other eligible entities in the 340B Program, hospitals do not need to disclose how the revenue generated from the program is used to serve vulnerable populations.

Rural hospitals typically have very small operating margins, but some disproportionate share hospitals (DSHs) are large, financially healthy healthcare systems like UPMC and the Cleveland Clinic. Should the 340B Program treat DSH hospitals differently from other covered entities?

1. **Eligibility criteria**: DSH hospitals qualify for the 340B Program based on their DSH patient percentage, which reflects the care they provide for low-income and uninsured populations. This differentiates them from other covered entities, such as community health centers, whose eligibility may be based on different criteria.

2. **Scope and volume**: DSH hospitals frequently deliver substantial uncompensated care and address a broader range of medical cases. Consequently, 340B discounts are crucial for sustaining their operations and enabling them to serve vulnerable populations effectively.

3. **Greater cost savings**: DSH hospitals can achieve significant savings under the 340B Program due to their purchase and dispensing of various drugs. These savings are intended to enhance services and expand access to care for underserved communities.

4. **Compliance and oversight**: Despite the lack of disclosure requirements, DSH hospitals are still bound by stringent regulations and oversight concerning the proper application of 340B savings. They must maintain detailed records that demonstrate compliance with the program's statutory requirements.

2025 marks a pivotal moment for reform in the 340B Program. It is important that all covered entities, including DSH hospitals, adhere to a uniform standard of transparency and ensure that all contract pharmacy arrangements are grandfathered in and protected. This will ensure that governors, state legislators, Congress, and pharmaceutical manufacturers clearly understand how the 340B savings are being utilized to support healthcare initiatives for vulnerable populations.

To this end, Congress should establish the following requirements:

1. **Uniform reporting**: All covered entities participating in the 340B Program should implement uniform reporting standards.

2. **Required reporting from all covered entities**:

    - The total acquisition cost for 340B drugs and the total payment received.
    - Gross and net revenue is generated annually from 340B.
    - Any sharing of 340B revenue with non-340B entities, such as PBMs, chain or independent drug stores, insurers, or brokers.
    - The percentage of the covered entity's uninsured patients compared to the overall patient population.
    - The number of uninsured patients who benefited from free medications funded by 340B revenue.
    - The number of uninsured patients who received partial assistance from 340B revenue.
    - The reasons why some patients received only partial assistance rather than free medications.
    - A detailed explanation of how 340B revenue was utilized, including free medical care, medical or pharmacy care subsidies, transportation assistance, etc.
    - The percentage of patients with incomes at or below 200% of the federal poverty level (FPL) relative to total patients.
    - Projections on how this percentage would increase if the sliding fee scale were raised to 300% or 400% of the FPL.
    - With regard to patient care, how was 340B revenue used? Specifically:

        - Subsidizing care provided at the covered entity or specialist.
        - Covering 100% of medication costs.
        - Providing transportation services for patients.
        - Offering food assistance to patients.
        - Funding capital improvements to serve more patients.
        - The 340B revenue allocated for staffing (with detailed breakdowns).
        - The amount dedicated to facility improvements.
        - The amount used for patient transportation (specific to each vendor).
        - Whether a third-party administrator or PBM is used to purchase 340B medications.
        - Confirmation if the third-party administrator or PBM retains any portion of the 340B revenue, and what percentage and annual amount?
        - Whether chain drug stores or chain supermarkets are involved in the 340B Program, including transaction fees charged by each contract pharmacy and annual revenue paid by the covered entity.

To further promote transparency, HRSA should:

- Receive an annual report containing the above information; and
- We should make all relevant data available to the public (excluding HIPAA-protected patient information) to ensure that stakeholders, including state legislators, Congress, and pharmaceutical manufacturers, have access to detailed, actionable information on using 340B savings.

IV. ELIMINATING DUPLICATE DISCOUNTS

The 340B Program requires covered entities to adhere to specific requirements to maintain their 340B eligibility. One specific requirement is that a covered entity cannot claim both 340B price reductions and assistance under Medicaid (Medi-Cal in California) - the duplicate discount rule.[144] Duplicate discounts occur at the intersection of Medicaid and 340B.

A. The Duplicate Discount Problem

Drugs provided to Medicaid beneficiaries are subject to discounted prices under the 340B Program and are also eligible for Medicaid rebates; drug manufacturers are at risk of providing duplicate discounts. As per Section 340B(a)(5)(A), manufacturers are only required to give a price concession for a particular drug under one program. However, with the rapid expansion of types of covered entities, it has become very challenging for state Medicaid agencies to comply with federal rules without incurring additional operational costs.[145]

To help prevent duplicate discounts, in 1993, HHS (through CMS and the precursor to HRSA) established the Medicaid Exclusion File (MEF), which is a list of covered entities that use 340B drugs for beneficiaries under the Fee-For-Service (FFS) model.[146] Once registered, covered entities on this list must notify the agency if they intend to use—or "carve in"—340B drugs for Medicaid beneficiaries, and states then exclude claims from providers on the MEF from their rebate invoices.

Since 2010, ACA-related changes also required manufacturers to provide rebates for drugs provided by

[144] 42 U.S.C. § 256b(a)(5)(A).

[145] National Association of State Medicaid Directors, NAMD Working Paper Series, Medicaid and the 340B Program: Alignment and Modernization Opportunities May 2015. See also Tram Nguyen, PhD, and Rajshri Suresh, "What You Need to Know About 340B Duplicate Discounts" March 4, 2024, Edgeworth/Economics; Emily Jane Cook, Drew Elizabeth McCormick, and Steven J. Schnelle, "2020 Starts Off with Two Government Publications Critical of 340B Program Oversight", January 13, 2020, McDermott Will & Emory,

[146] HRSA, OPA, Duplicate Discount Prohibition, *at* https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion.

managed care organizations (MCOs). Unlike FFS, which is based on reimbursement of individual services, managed-care states typically contract with MCOs using a capitated payment model that pays each plan a set amount per beneficiary per month. The expansion of drug dispensing by contracting pharmacies under the MCO model makes it more difficult for states to identify beneficiaries covered by MCOs and track if a 340B drug was dispensed to a Medicaid beneficiary.

Some states, such as Delaware, have chosen to "carve out" 340B drugs from Medicaid entirely, preventing their use by covered entities and contract pharmacies for any Medicaid patients. Thus, the state is able to obtain rebates on every drug Medicaid covers. Other states, including New York, California, and West Virginia, have eliminated managed Medicaid drug coverage altogether, instead providing all Medicaid drug benefits through an FFS mechanism.

In recent years, states have also expressed concerns regarding the reliability of the MEF.[147] Two main concerns include:

- The lack of flexibility in updating the list during extraordinary market conditions, such as drug shortages, where 340B and non-340B drugs are substitutable; and
- Difficulty in identifying which covered entities have changed carve-in and carve-out decisions.

The effect of duplicate discounts can be complicated to unravel and can lead to pressure on manufacturers and states. For example, the resultant impact on CMS's best price calculations could increase manufacturers' hidden costs of 340B participation. IQVIA estimates that duplicate discounts accounted for about one-quarter of total 340B drug sales in 2021, representing approximately $20-25 billion in total.[148] This

[147] https://www.macpac.gov/wp-content/uploads/2018/05/340B-Drug-Pricing-Program-and-Medicaid-Drug-Rebate-Program-How-They-Interact.pdf
[148] Luke Greenwalt, Trends to Watch Through 2023: The 340B Drug Discount Program (IQVIA Blog March 21,2022).

level of potential duplicate discounts borne by manufacturers increases their costs substantially.

B. So, What Should Be Done - Adopting the California Medi-Cal 340B Model in Every State?

California's Medicaid program (Medi-Cal) is the largest in the nation, easily double the size of the next largest program (New York), and second only to the federal Medicare program in terms of the number of publicly funded lives and spending. Given the number of enrollees (over 14.5 million in 2025) and projected budget ($188 billion in 2025-26), each gubernatorial administration has struggled to balance the progressive tendencies of the state to expand eligibility, add optional benefits, and reimburse providers with the competing fiscal limitations of state budgeting. Due to California's revenue volatility and high dependence on capital gains tax as a significant component of the state's general fund revenue, Medi-Cal is frequently targeted for cost-cutting measures due to the inflexibility of other state programs (i.e., education and Proposition 98 guarantee) when state deficits occur.

Pharmacy is an optional benefit in a Medicaid program, but every state Medicaid program currently provides this benefit because the costs of obtaining a prescription drug would be exponentially higher. After all, Medicaid patients are entitled to prescription drugs in an inpatient setting (or emergency room). California has always prioritized more generous eligibility and optional benefits and, in doing so, has been forced to fund the Medi-Cal program via a series of revenue-generating mechanisms that provide the "non-federal share." One of those revenues is from the state's supplemental drug rebate program, administered through the Department of Health Care Services' Pharmacy Division.

Started in 1991, the Medi-Cal Supplemental Rebate Program[149] negotiates with drug manufacturers an additional rebate amount in addition to the mandatory rebates required under federal law (currently at 23.1%

[149] https://www.dhcs.ca.gov/provgovpart/Pages/Medi-Cal-Drug-Rebate-Branch.aspx.

for brand drugs). Manufacturers interested in having their product placed on the Medi-Cal Contract Drug List (CDL) have negotiated drug rebate contracts on a drug-by-drug basis for over 30 years. In exchange for providing the state with a supplemental rebate, manufacturers typically have their drug placed on the CDL with no prior authorization requirement. As the rebate program grew significantly in the mid-to-late 1990s, the mandatory enrollment of Medi-Cal populations into managed care changed the state's market leverage with manufacturers. It reduced the amount of supplemental rebate revenue received.

As the state and manufacturers grew more comfortable over time with the negotiation and rebate process, there was an increasing frequency of manufacturer disputes, some of which were attributed to "duplicate discounts." Duplicate discounts occur when a covered entity under the federal 340B Program obtains a prescription drug at a discount but then bills Medicaid for the same drug without identifying it as being dispensed as a 340B drug. Manufacturers have been known to dispute the payment of rebates (both supplemental and mandatory) down to a single pill, much less thousands or hundreds of thousands of pills. DHCS staff sought additional statutory changes in 1997 to authorize charging interest and penalties for late state supplemental rebate payments due to manufacturer disputes.

In 2014, amidst ongoing budgetary pressures, Gov. Jerry Brown, during his second term, directed the California Department of Finance to curb new spending and continue to identify savings across various state programs. A particular focus for the administration was the expenditures and rebate processes associated with the Medi-Cal pharmacy program. This area was targeted as a critical point for achieving potential cost reductions, reflecting the broader state strategy to manage healthcare expenses effectively without compromising service quality.

In investigating whether savings were potentially available in the Medi-Cal program, discussions took place with the state's largest Medi-Cal managed care plans. When asked whether 340B providers billed the health plan at the 340B discount rate, one plan CEO laughed and said, "Oh, goodness, no."

Further scrutiny revealed that while a covered entity might purchase and dispense a discounted drug to a managed care patient for $100, they would bill the plan at the established PBM rate of $200. Because covered entities are permitted to bill MCOs at contracted rates, state capitation rates, which are set annually and determine the fixed amount per patient managed care plans receive, were set in a manner that did not take advantage of 340B pricing. This system not only affects the fiscal efficiency of Medi-Cal's managed care operations but also suggests a need for regulatory adjustments to align managed care reimbursements with 340B pricing, ensuring that the state's healthcare expenditures reflect actual drug costs more accurately.

Based on an internal assessment of the excess pharmacy spending as a component of the managed care capitation rates, the Department of Health Care Services proposed a statutory change as part of the governor's May revision in 2017. This statutory change sought to eliminate the use of contract pharmacies in the Medi-Cal program. This was also accompanied by proposed statutory changes to implement new federal rules regarding FFS Medicaid coverage of 340B drugs. The legislature adopted the proposed changes on the covered outpatient drugs but rejected the language eliminating the use of contract pharmacies.[150] Based on the legislature's rejection of the proposed contract pharmacy language as part of the 2017-18 budget process, the department proposed new language in the governor's 2018-19 budget release. The new proposal sought to eliminate the use of 340B drugs in the Medicaid program. The item was heard on March 22, 2018, and

[150] *See* page 548 of analysis; vote to reject was 3 -0) extension://efaidnbmnnnibpcajpcglclefindmkaj/https://archive.senate.ca.gov/sites/archive.senate.ca.gov/files/committees/2017-18/sbud.senate.ca.gov/sites/sbud.senate.ca.gov/files/SUB3/2017Sub3.pdf

received significant opposition from covered entities (hospitals and clinics). The proposal was summarily rejected as part of the budget subcommittee hearing process on May 15, 2018.[151] This rejection was in spite of a favorable analysis from the nonpartisan Legislative Analyst's Office.[152]

Gov. Gavin Newsom was elected in November 2018. Several items were developed with his incoming leadership team during the transition period between his election and his inauguration. One of those items was his first executive order pertaining to prescription drugs.[153] Of the multiple actions directed by this executive order, one required the Department of Health Care Services to carve the pharmacy benefit out of the Medi-Cal managed care delivery system and return the benefit to fee-for-service. This change in delivery system did not require any statutory change and effectively eliminated the use of 340B drugs in the Medi-Cal program. The governor's reasons for returning the pharmacy benefit to fee-for-service were threefold:

- Standardize the prescription drug benefit for all Medi-Cal beneficiaries across the state rather than having each managed care plan maintain a formulary.
- Increase the ability for the state to negotiate supplemental rebates with manufacturers.
- Eliminate the excess spending by the state Medicaid program for discounted drugs under the 340B Program.

In California, the two highest items in the annual state budget are education (K-12 and higher education) and health and human services (including Medicaid and other welfare programs). These two categories often account for the majority of state spending. [154] Newsom, like all of his predecessors, was interested in maximizing savings in a program that is otherwise difficult to control. Between the potential savings of hundreds of millions annually, the policy argument for greater transparency in the state's

[151] https://sbud.senate.ca.gov/sites/sbud.senate.ca.gov/files/SUB3/2018Sub3.pdf (see discussion starting on page 101).
[152] ihttps://lao.ca.gov/Publications/Report/3790) (indicating that there were state savings available)
[153] https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf
[154] *See e.g.,* https://ebudget.ca.gov/2025-26/pdf/BudgetSummary/SummaryCharts.pdf

pharmaceutical purchasing was a strong basis for taking action when the legislature had previously rejected those efforts.

As part of their analysis of the governor's first 2019-2020 budget, the Legislative Analyst's Office also analyzed the governor's executive order and concluded that significant state savings were likely.[155] The last official budget savings documents that note the savings from the pharmacy carve out were included in the governor's 2023-2024 Medi-Cal Estimate and estimated that $2.87 billion were due to mandatory rebates (with little to no duplicate discount disputes and higher brand utilization) and $386 million in state supplemental rebates[156] These savings continue on, but are no longer called out specifically in the Medi-Cal budget, but considered part of the "base" policy.

While no statutory changes were necessary, there was significant opposition from the hospital and FQHC stakeholders. As the main target of this opposition, the legislature held hearings and expressed concern over the reduction in funding to covered entities due to the governor's executive order. After many months of negotiation, the administration agreed to establish a small, directed payment to 340 eligible entities (non-hospital based) and appropriated $50 million to help offset 340B revenue losses. When the clinics voiced concern that the amount was "too low" to compensate for the loss of revenue, the department asked for clinic financial information that supported a higher amount. When no additional financial information was forthcoming, the amount remained at $50 million for the past two fiscal years (*California State Plan Amendments 23-0031 and 24-0045*).

Because no additional authority was needed to effectuate this change, the department moved to

[155] https://lao.ca.gov/Publications/Report/3997;
[156] https://www.dhcs.ca.gov/dataandstats/reports/mcestimates/Documents/2023_May_Estimate/MAY-2023-Medi-Cal-Local-Assistance-Estimate.pdf at 440-41.

execute the administrative and programmatic activities to return the pharmacy benefit to the fee-for-service delivery system starting in summer 2019. This included releasing a request for proposal (RFP) for a vendor to process and administer the claims associated with pharmacy and removing the outpatient drug component from the managed care plan rates. The Medi-Cal Rx system went live on Jan. 1, 2022.

The downside to Medi-Cal RX is that it shifts the benefit of the 340B discount from the clinics to the Medi-Cal program. This comes at a time when many clinics are in financially perilous condition.

Regarding duplicate discounts, clinics still must report 340B drugs on their claims, and failure to do so can result in duplicate discounts. The risk is minimized because more clinics are carving out Medicaid patients from 340B, though many covered entities have struggled with properly identifying and billing for 340B drugs used within clinics and hospital settings (as opposed to pharmacy-dispensed drugs).

Clinics can also “carve in” drugs to their PPS rates (and forego billing Medi-Cal RX). However, there is no real reason to do this because PPS rates are reimbursed based on projected allowable costs.

The state enacted a Medicaid supplemental payment program for clinics designed to compensate for some of the lost revenues from the transition to Medi-Cal RX. However, the program has not yet received federal approval for Fiscal Year ‘24 and is now being consolidated into Proposition 35 reimbursements.

C. Medicare Part D Now Poses Duplicate Discount Risks

The Inflation Reduction Act (IRA) of 2022 introduces controversial reforms to reduce prescription drug costs, notably through the Medicare Drug Price Negotiation Program. These provisions empower Medicare to negotiate prices for select high-cost drugs, establishing a maximum fair price (MFP) to enhance affordability for beneficiaries. The first set of negotiated prices, comprising 10 drugs, is scheduled to take effect on Jan. 1, 2026, with an additional 15 drugs selected for 2027. While the MFP

mechanism is in place to lower drug prices, this runs in parallel with the 340B program that offers select drugs at a reduced price.

These independent plans are in place to create a balance among increasing access, sustainable pricing models, and a commitment to innovation for continued drug development, but they intersect and create problems for all parties as well. Manufacturers are required to offer the covered entities the lower cost of the MFP or the 340B price, but not both. This stipulation introduces complexities, particularly concerning the potential for duplicate discounts, where both discounts might apply to the same drug, leading to financial and compliance challenges for manufacturers and covered entities.

The IRA has introduced an additional level of concern about duplicate discounts. Beginning January 2026, the IRA will require drug manufacturers to implement a maximum fair price (MFP) for certain high-cost drugs covered under Medicare parts B and D. An MFP will reflect a negotiated price between the Centers for Medicare and Medicaid Services ("CMS") and drug manufacturers. The resulting MFP for any given drug may end up lower or higher than the 340B ceiling price for that same drug—the IRA requires drug manufacturers to offer the lower of the two prices to covered entities.

However, without a neutral clearinghouse that would prevent duplicate discounts (i.e., where covered entities would receive both the 340B price and the MFP), there is a high risk of duplicate discounts. Under a clearinghouse model, covered entities would send 340B claims data to a third party, who would de-duplicate discounts as applicable. While CMS rejected calls for a clearinghouse model, it stated that it would monitor the approach and explore the feasibility of incorporating 340B transactional data from 340B TPAs.

Despite the critical nature of preventing duplicate discounts, the CMS has clarified that it will not assume responsibility for preventing duplicate discounts between 340B and the MFP. This absence

of a standardized mechanism has prompted manufacturers to develop their own compliance solutions to manage and validate claims, aiming to prevent duplicate discounts and streamline the reimbursement process. However, these manufacturer-driven models have raised concerns among covered entities regarding potential shifts from up-front discounts to rebate-based systems, which could impact cash flow and administrative processes. In addition to paying the wholesale price up front, impeding their ability to care for vulnerable patients, they would have to submit claims, which could delay reimbursement or even risk denials.

In response to these developments, covered entities are encouraged to advocate for the continuation of upfront discount models, proactively invest in advanced tracking and compliance systems to distinguish between 340B and MFP-eligible transactions and advocate for transparent, equitable solutions that safeguard their financial and operational interests. Furthermore, there is a pressing need for unified data standards and clear.

In the end, the question remains: will HRSA proactively respond or encourage more chaos in the 340B program?

V. Is The Current Sliding Fee Scale of Up To 200% of the Federal Poverty Level Equitable?

FQHCs and Title X family planning clinics must provide a sliding fee scale to help ensure that patients with incomes under 200% of the FPL pay less for certain primary care services than other clients of the covered entity. Ryan White Clinics must ensure that patients below 100% of the FPL do not pay out of pocket. While the federal effort is essential, it is long overdue for re-examination.

A. Background

Health centers are required to have a sliding fee discount program.[157] For individuals and families whose incomes are at or below 100% of the FPL, health centers may offer a full discount or elect to have a nominal charge. For individuals with incomes above 100% and at or below 200% FPL, partial discounts are provided using a sliding-fee scale, with discounts based solely on the patient's family size and income. No assistance is provided to individuals and families with annual incomes above 200% of the current FPL.

The primary factor in determining a patient's sliding fee is their income relative to the federal poverty guidelines, which also consider their household size. Individuals with lower incomes receive more significant discounts on healthcare services than those with higher incomes.

The sliding fee program is an initiative created to offer primary healthcare at a discounted cost to low-income individuals. Patients must meet requirements to be eligible for the discounted services.

While the sliding scale allows for discounted medical services, this does not mean that all medical services are offered for free. A patient may have to pay a small fee or a certain percentage of the total cost as required. Your FQHC can provide a more detailed estimate based on your eligibility.

[157] Rural Health Information Hub, "**Federally Qualified Health Centers (FQHCs) and the Health Center Program" See Chapter 9 Chapter 9: Sliding Fee Discount Program, HRSA Health Center Program.**

B. How Did the Sliding Fee Requirements Emerge?

Forty-nine years ago, the Health Centers Consolidation Act (Pub. L. 104-299) and the published Senate committee report do not reference the sliding fee discount.[158] In 1976, the U.S. Department of Health, Education and Welfare (HEW, the precursor to HHS) promulgated the health center regulations.[159] Since that time, the sliding-fee scale has never been updated.

The irony is that tens of thousands of Americans or more do not qualify based on the outdated sliding fee scale. Neither Congress nor the White House has made this a legislative priority at a time of continued rising costs.

C. Why Change Is Needed

Forty-nine years ago, the sliding-fee scale regulations were promulgated, setting 200% of the FPL as a ceiling for all covered entities to offer patients subsidized care. This standard will soon celebrate its 50th birthday. It no longer makes sense.

Our economy continues to change. The cost of living in California, New York, Pennsylvania, New Jersey, Texas, and most states across America is staggering for middle-income families – many with incomes just above 200% of the poverty threshold.

The growing prevalence of high-deductible health plans, which offer lower premiums in exchange for higher deductibles, highlights an urgent issue: increasing numbers of working families require access to affordable healthcare that considers their income, health plan type, family size, and other factors. The sliding-fee scale, capped at 200% of FPL, does not account for these middle-income families. This limitation not only

[158] *See* https://www.govinfo.gov/content/pkg/CRPT-104srpt186/pdf/CRPT-104srpt186.pdf.
[159] 41 Fed. Reg. 52,977, 53,203 (Dec. 3, 1976), available at https://www.govinfo.gov/content/pkg/FR-1976-12-03/pdf/FR-1976-12-03.pdf.

underscores an inequitable healthcare system but also exacerbates economic deprivation among those who do not qualify as experiencing poverty yet struggle with significant healthcare expenses.

This situation calls for critically reevaluating the sliding-fee scale thresholds to include a broader spectrum of income levels. This would ensure that a more substantial portion of the population can access necessary medical care without financial hardship. Adjusting this scale is essential to address the disparities in healthcare accessibility and prevent middle-income families from being disproportionately impacted by high medical costs.

To address the equity issue, a national standard should be eliminated and replaced by a state-by-state standard to ensure against inequitable access. The new standard would, where appropriate, maintain the 200% of FPL limit. However, in cities and counties across the nation where the cost of living exceeds the rest of the state, Congress should either give state legislators and governors the authority to implement sub-state FPL guidelines that recognize the rising cost of living in those communities vs. others or allow the Secretary of Health and Human Services to work with governors and state legislators to set the standard for every state and its communities both rural and urban.

In addition, if Congress grants this authority to the Secretary of HHS, the secretary should create a working group of all covered entities (with urban, rural, and other geographically diverse representation) to ensure their opinions are heard. However, this group should not be represented by national or state trade associations representing the various covered entities; instead, the CEOs, Chief Medical Officers, and Chief Nursing Officers of covered entities who see patients every day and understand firsthand the challenges faced by all patients coming to the covered entity, both the uninsured and insured. These voices, experiences, and expertise will help ensure that real people offer the secretary real solutions.

VI. ORPHAN DRUGS: IS IT TIME TO COVER ALL ORPHAN DRUGS?

The current orphan drug prohibition only applies to critical access hospitals, rural referral centers, sole community hospitals, and freestanding cancer hospitals.[160] Why not enable all patients under the 340B Program to access necessary orphan drugs? Today, over 7,000 diseases are classified as rare, and the Orphan Drug Act of 1983 defines a "rare" disease as affecting fewer than 200,000 people in the U.S. The National Organization for Rare Disorders (NORD) estimates that 25 to 30 million Americans are living with a rare disease. Unfortunately, over 90 percent of rare diseases still lack FDA-approved treatments, and the available treatments are often termed "orphan drugs."[161] Rare diseases generally have limited clinical trial data, complicating broad drug efficacy and safety assessments. This limitation impacts access to orphan drugs under federal programs like 340B. In 2014, HRSA reminded pharmaceutical companies to continue offering discounts on specific uses of orphan drugs within the 340B Drug Pricing Program. Under the ACA, medications with orphan drug designation are exempt from 340B discounts, which can be as substantial as 50 percent. Consequently, drugs affecting fewer than 200,000 people do not qualify for these discounts unless the orphan drug has multiple indications or treatment use.[162] Effectively communicating these complexities requires a strategic approach to ensure critical points resonate with the target audience. Contextual information must be clear and compelling. Rare diseases such as cystic fibrosis, muscular dystrophy, Huntington's disease, ALS (Lou Gehrig's disease), Tourette's syndrome, sickle cell disease, and hemophilia are well-known examples, though there are many more. Many rare diseases can lead to the premature death of infants or can be fatal in early childhood. In reality, rare diseases are far from rare. According to the National Library of Medicine, individuals

[160] 42 U.S.C. § 256b(e).
[161] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions
[162] 21 U.S.C. § 360bb(a)(2)(B).

with rare diseases often endure long wait times from symptom onset to diagnosis, facing challenges due to clinical heterogeneity and non-specific symptoms that overlap with many common diseases.[163]

NORD highlights that living with a rare disease poses numerous challenges. Patients frequently require multiple consultations with doctors and specialists to achieve an accurate diagnosis, which can take years. Once diagnosed, treatment options are often limited or non-existent; even when available, they can be prohibitively expensive. Currently, covered entities can purchase nearly all self- or physician-administered drugs at the 340B discounted price for outpatient settings, with a few exceptions. Vaccines are not eligible for the 340B discount, and orphan drugs—those treating rare diseases—are excluded from discounts for covered entities qualifying under the ACA (rural hospitals and free-standing cancer hospitals). Drugs obtained via group purchasing organizations by DSHs, cancer centers, and children's hospitals are also excluded from these discounts.

The "340B orphan drug debate" revolves around eligible healthcare providers being allowed to purchase discounted drugs but often being excluded from discounts on orphan drugs when prescribed for non-orphan uses, leading to disputes about the applicability of this exclusion. The incidence of rare diseases is increasing globally and domestically. These conditions affect seven in every 10,000 people.[164] Since 2021, orphan drugs have accounted for more than half of the novel drugs approved by the FDA, positioning North America as the global leader in orphan drug revenue.[165] Unfortunately, the same orphan drugs available for 340B disproportionately share hospitals in acute outpatient settings and are subject to an exclusion that places discounts at manufacturers' discretion. This exclusion mainly affects critical access hospitals and rural

[163] https://pmc.ncbi.nlm.nih.gov/articles/PMC11973084/
[164] https://pmc.ncbi.nlm.nih.gov/articles/PMC10290406/
[165] *Id.*

referral centers. Their local facility may be the only care option for many patients, making access to orphan drugs crucial.

Ending the Orphan Drug Exclusion: Not Yet. Many advocates have called for the repeal of the 340B exemption for orphan drugs. However, a more sensible approach would limit 340B discounts for orphan drugs to mandated treatments for designated rare conditions, with a three-year review initiated by the Secretary of HHS. This review should report to Congress on the initiative's outcomes, including successes and failures, to determine whether to continue, expand, or eliminate orphan drugs from the 340B Program. If a manufacturer demonstrates that a specific orphan drug can also treat additional conditions, it should automatically qualify for the 340B Program at that time. However, all orphan drugs will remain excluded from any HHS price negotiations through Medicare, Medicaid, and other public programs until Congress and the administration agree to include them in the 340B Program.

VIII. UNDERSTANDING THE COMPLEXITIES OF INFUSION THERAPY IN THE 340B PROGRAM

Infusion therapy, involving the administration of medication intravenously via needle or catheter, is crucial for treating conditions where oral medications are ineffective. This treatment method is commonly used for serious health issues, including infections, cancer, dehydration, autoimmune disorders, and chronic diseases requiring biologics. Depending on patient needs, the therapy can be administered in diverse settings, from hospitals and outpatient centers to home settings.

A. Unique Challenges of Infusion Therapy

The infusion of medications, especially costly biologics, and specialty drugs for rare and complex diseases, presents unique financial and operational challenges. These drugs, including enzyme replacements for lysosomal storage disorders or monoclonal antibodies for certain cancers, are prohibitively expensive. Annual costs for such treatments can range between $32,000 and $136,000, potentially rendering them inaccessible without 340B discounts.[166]

Infusion therapy requires specialized facilities, trained personnel, and proper equipment to administer treatments and monitor patient responses safely. The operational costs are significant, encompassing not only the direct expenses of the medications but also the infrastructure required for safe delivery.

B. 340B Program Impact

The 340B Program's discounts are vital in making these high-cost therapies available to underprivileged patients. The program reduces drug acquisition costs and enables covered entities to maintain or expand their service offerings. For instance, some hospitals have leveraged 340B savings to broaden their chemotherapy

[166] https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges.

services, significantly reducing the travel burden on patients who otherwise might need to seek treatment far from home.

C. Criticism and Scrutiny

Despite the benefits, the high costs associated with infusion therapy have drawn scrutiny and criticism, particularly from drug manufacturers and payors. Critics argue that the 340B Program's intent—supporting safety-net providers in serving vulnerable populations—has been overshadowed by the financial gains from discounted drugs. They contend that the substantial revenue generated from high-cost biologics and specialty infusions strays from the program's original purpose, even as these operations remain confined to serving 340B-eligible patients.

D. Shifting Infusion Therapy Services to Hospital Outpatient Departments

The landscape of infusion therapy has seen a significant shift, with services moving from independent physician offices to hospital outpatient departments. This transition has been fueled by hospital acquisitions of physician practices, which have increased the volume of high-cost infusion drugs eligible for 340B discounts. Notably, since 2013, the Medicare program has documented a marked increase in the administration of expensive chemotherapy drugs in hospital settings. This consolidation has expanded hospitals' access to 340B discounts and increased their bargaining power with insurers, enabling them to negotiate higher reimbursement rates for these drugs.

E. Financial Dynamics and Implications

Hospitals stand to benefit financially from this arrangement by pocketing the difference between the high insurance reimbursement rates and the lower acquisition costs afforded by 340B discounts. This growing volume of drugs and the advantageous reimbursement structures have spurred concerns regarding the potential influence of the 340B Program on clinical and business decisions. There is a growing perception

among manufacturers that some covered entities might prefer high-cost infusion therapies over more affordable alternatives, even when the latter are clinically appropriate. This preference could be distorting care delivery and escalating healthcare costs unnecessarily.

F. Contract Pharmacy Arrangements and Manufacturer Concerns

Furthermore, contract pharmacy arrangements for infusion drugs have been intensely scrutinized, especially concerning the high fees many pharmacies levy on biologics and specialty drugs. These fees are often significantly higher than those charged for standard medications, prompting questions about the financial structures of the 340B Program. Critics argue that these structures, particularly in the context of specialty infusion drugs, may not align with the program's intended purpose of supporting healthcare for underprivileged and vulnerable populations.

G. 340B Program Compliance for Infusion Therapy

While governed by the general principles of the 340B Program, infusion therapy presents unique challenges due to its high costs, specialized care settings, and complex administration. Ensuring compliance involves meticulous attention, particularly verifying patient eligibility and maintaining integrity within non-traditional clinical settings.

1. HRSA's 1996 Patient Definition for Infusion Therapy

HRSA’s 1996 “patient” definition guidelines apply generally to infusion situations:

1. **Established relationship**: The patient must have an ongoing relationship with the covered entity, typically demonstrated by a visit within the last 12 months, with the entity maintaining comprehensive records of the patient’s care.
2. **Healthcare services**: The patient must receive care from a healthcare professional employed by or under contractual or other arrangements with the covered entity. If care is referred to a specialist, the covered entity must remain responsible for the care (for example but maintaining a documented referral and obtaining notes of the specialist care) to ensure eligibility under the 340B Program.

3. **Service alignment**: The healthcare services must align with those for which the covered entity receives federal funding unless the entity is a hospital.

2. Challenges in Home Infusion Therapy

Home infusion therapy, often coordinated through specialty pharmacies or home health agencies, introduces further complexities. To manage these, covered entities must rigorously document and oversee treatments to confirm patient eligibility and prevent drug diversion. Documentation must link home infusion therapy to an outpatient encounter at the covered entity, verify ongoing care provision, and confirm that the prescribing provider is associated with the covered entity through employment or contract.

3. Legislative Clarifications Needed

To address ambiguities and enhance program integrity, Congress should consider specifying:

- **Patient treatment duration**: Patients receiving infusion therapy must have been under the care of the covered entity for at least two years.
- **Provider contracts**: Infusion providers must have an explicit contract with the covered entity to deliver therapy.
- **Medication provision**: Infusion medications may be supplied to the provider directly from the covered entity ("white-bagging").
- **Provider eligibility**: If an infusion provider is not a contracted provider for or part of a covered entity, the medication does not qualify for 340B reimbursement.

IX. SUMMARY:

Since its inception, the 340B Program has faced calls for reform to uphold its mission of helping nonprofit healthcare providers increase access to necessary medications.

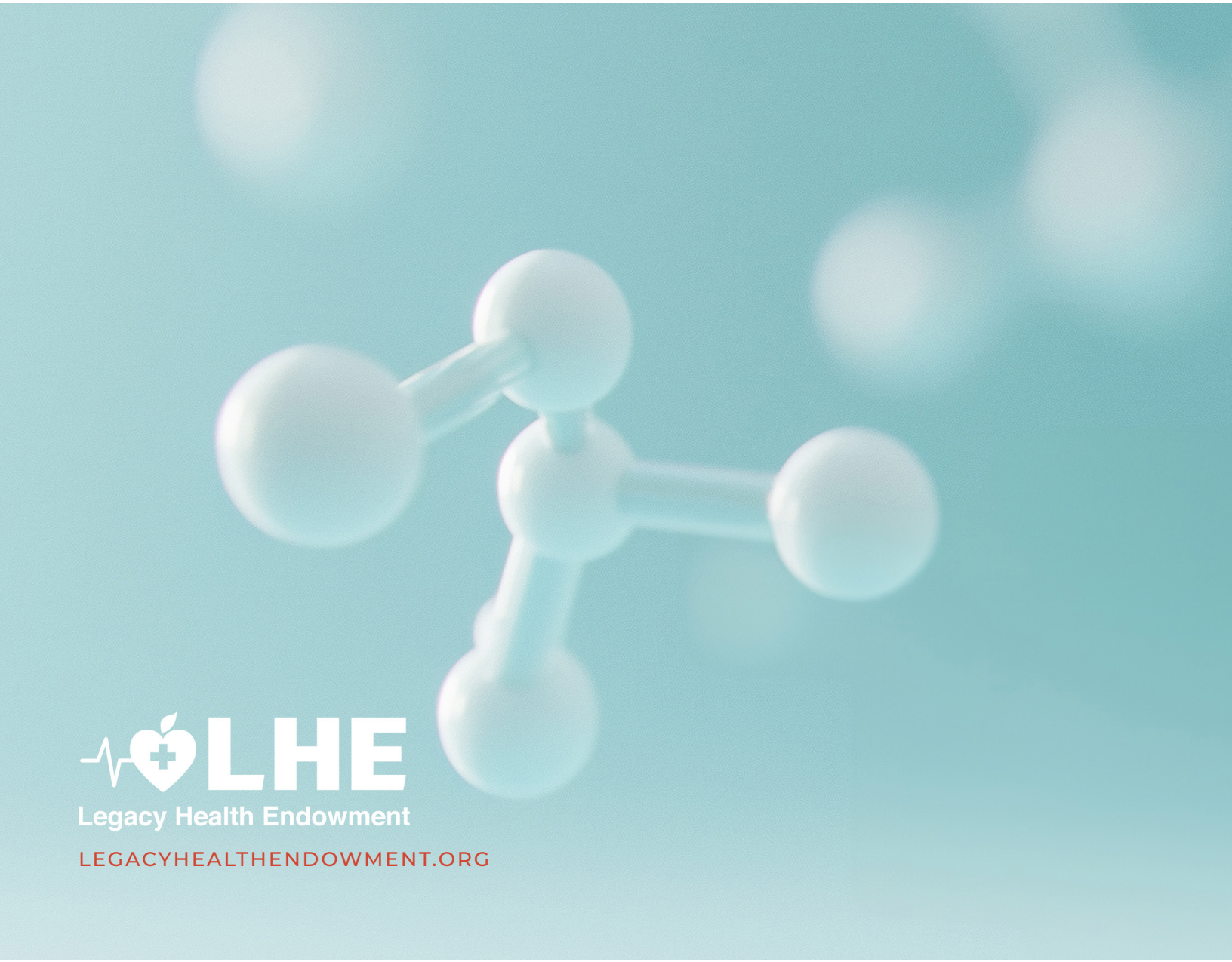
A key issue is the lack of transparency, which has led to concerns that third-party entities may benefit beyond the program's original intent.

Virtually all reports and white papers have urged Congress and state legislators to address potential abuses and clarify key aspects such as defining who a patient is, ensuring transparency in revenue disclosures by covered entities, and preventing duplicate billing.

The program's future depends on Congress's ability to clearly define issues, particularly concerning patient definition, geographical limitations on the location of covered entity sites, the role of high-risk populations, revenue tracking by third parties, and the regulation of contract pharmacies.

While some advocate for expanding the program, further growth should not occur without addressing these core concerns. Additionally, the pharmaceutical industry and covered entities seek clarity from Congress to prevent misinterpretation by federal courts, ensuring the program serves its intended vulnerable populations.

The challenges facing the 340B Program are not new. With a Republican-controlled Congress and White House, there is an opportunity to refocus congressional intent or allow the courts to continue shaping the program. This Congress has a unique chance to either correct course or maintain the status quo.


LHE
Legacy Health Endowment
LEGACYHEALTHENDOWMENT.ORG