340B Duplicate Discounts:

Enforcement Inconsistent and Weak Due to Lack of Data Transparency and Despite Federal Prohibition

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EXECUTIVE SUMMARY

At the intersection of the federal 340B Drug Pricing program and the federal Medicaid Drug Rebate Program (MDRP), a potentially large set of Medicaid claims are generating duplicate discounts, which pharmaceutical manufacturers provide to eligible entities. These two complex federal programs were designed to reduce the costs of prescription drugs for providers that serve low-income patients. They do so through the use of related but distinct mechanisms.

Duplicate discounts occur when for a single sale a manufacturer is required to: (1) prospectively reduce the price of the product (a discount) they sell to a 340B covered entity in advance of the delivery of care to the patient; and (2) provide a retrospective payment (a rebate) to a state Medicaid program or managed care plan under the MDRP after care is delivered to a Medicaid enrollee. When duplicate discounts occur the manufacturer's product is discounted twice for the same sale, contravening federal law, which prohibits duplicate discounts.

Despite the statutory prohibition, duplicate discounts remain a concern. Both state and federal policymakers have been actively addressing duplicate discounts but have been unable to identify clear and consistent policy solutions that neutralize this inefficiency. On the state level, Medicaid agencies and state legislatures have implemented policies to address duplicate discounts. On the federal level, the Health Resources and Services Administration (HRSA) and the Centers for Medicare & Medicaid Services (CMS) have conducted audits and published best practices for states to eliminate duplicate discounts. Nonetheless, duplicate discounts persist.

To gain deeper insights into how Medicaid agencies navigate duplicate discounts, Health Management Associates (HMA) conducted semi-structured interviews with former and current Medicaid directors and pharmaceutical policy experts in 14 states. Interviewees were asked about the frequency of duplicate discounts, the extent to which Medicaid agencies devote resources to tracking them, the policies states have implemented to address them, and the extent to which state or federal authorities are working to eliminate duplicate discounts.

Based on interviews, four key themes emerged:

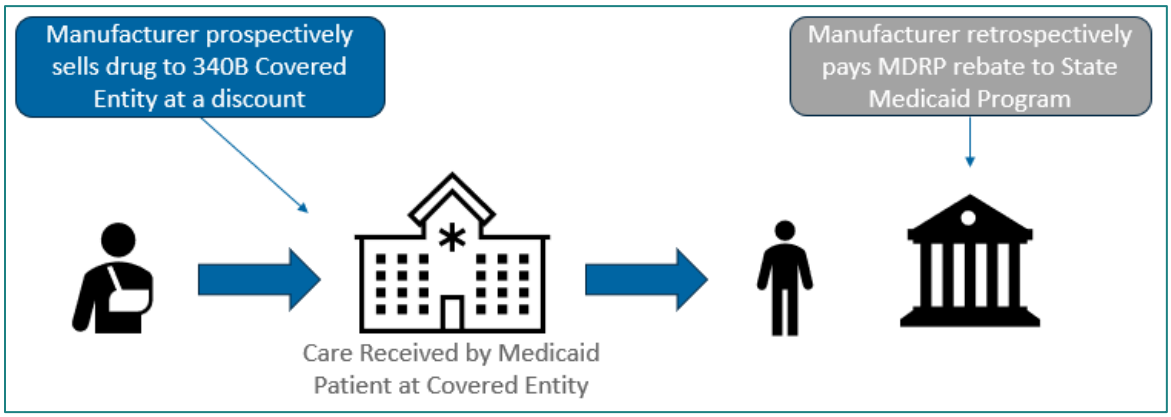
- Duplicate discounts remain a problem, the scope of the problem is unclear, and better data collection from covered entities is necessary.
- The opacity and complexity of duplicate discounts create a burden for state Medicaid agencies, influencing the policies they implement, resulting in variable state policy strategies.
- Contract pharmacies add an additional layer of complexity, exacerbating the burden that duplicate discounts create.
- State and federal authorities could take more decisive action to address duplicate discounts.

Policymakers should consider that the environment for addressing duplicate discounts may become more complex in the future, which may increase the need for a federally coordinated policy solution. The complexity of the environment may deepen due to the increasing presence of contract pharmacies, the increasing presence of managed care in Medicaid programs, and the implementation of the drug pricing policies of the Inflation Reduction Act of 2022. Policy action coordinated across the various stakeholders (e.g., HRSA, CMS, state Medicaid agencies, covered entities, and manufacturers) may represent the best opportunity for success in eliminating duplicate discounts.

BACKGROUND

The U.S. Congress established the 340B Drug Pricing Program in 1992 to provide safety net providers (eligible covered entities) with access to lower cost drugs. This program is administered by the Health Resource and Services Administration (HRSA) and is the second largest federal prescription drug program.[1,2,3] The Medicaid Drug Rebate Program (MDRP), is a co-existing program created separately by the U.S. Congress in 1990 to enable State Medicaid programs to obtain rebates from manufacturers to lower their cost of covered outpatient drugs. This program is administered by the Centers for Medicare & Medicaid Services (CMS).[4] Both the 340B and MDRP are complex federal mechanisms intended to reduce drug prices, but the two programs approach this goal from different perspectives and duplicate discounts are a product of their overlap. (See Exhibit 1)

Exhibit 1: Timing of Duplicate Discounts paid by Manufacturers



Operationally, duplicate discounts occur when a manufacturer is required to (1) prospectively sells its product at a reduced price (a discount) to a 340B covered entity in advance of the delivery of care to the patient; and (2) the state Medicaid program (or Medicaid managed care plan) obtains a retrospective payment (a rebate) under the MDRP on the drug for that same patient sale (or case). Duplicate discounts may occur when individuals enrolled in state Medicaid programs receive a drug from a provider deemed a “covered entity” under the 340B program.

Given the overlap between the two programs and the financial impact duplicate discounts can impose on pharmaceutical manufacturers, Congress chose to prohibit duplicate discounts. Under federal law, drugs prescribed to Medicaid beneficiaries and obtained through the 340B program are ineligible for a MDRP rebate.[5,6] In addition, the Accountable Care Act (ACA) of 2010 authorized HRSA to improve the integrity of the 340B program by conducting audits and issuing regulations regarding the imposition of civil monetary penalties for manufacturers and covered entities that are noncompliant with duplicate discount rules and other 340B requirements.[7]

Despite the federal prohibition on duplicate discounts and the audit authority granted to HRSA, duplicate discounts remain a concern for manufacturers and Medicaid agencies, and policymakers have been unable to identify clear and consistent policy solutions.[8,9,10] A 2021 report estimated duplicate discounts totaled between $900 million and $1.6 billion in 2019.[11]

DUPLICATE DISCOUNT DEFINITION

"Duplicate discounts" occur when a manufacturer is required to (1) prospectively sell their product at a reduced price (a discount) to a 340B covered entity in advance of the delivery of care to the patient; and (2) the state Medicaid program (or Medicaid managed care plan) obtains a retrospective payment (a rebate) under the MDRP on the drug for the same patient.

Three factors in the environment may be contributing to the growth of sales experiencing duplicate discounts. First, since its inception, the number of covered entities participating in the 340B program has increased and its interaction with the MDRP has expanded. Under the ACA of 2010, Congress expanded the list of entities eligible for the 340B program, which now includes hospitals, federally qualified health centers, and a variety of other health care facilities.[12,13,14] Between 2014 and 2022, covered entity participation in the 340B program increased threefold, from roughly 28,000 in 2014 to 53,000 in 2022.[15] [16]

Second, Medicaid enrollment growth over the last decade has also increased the potential for duplicate discounts to occur.[17] Third, the use of contract pharmacies to dispense 340B drugs has grown in recent years, with about one-third of covered entities now using contract pharmacies.[18,19,20] A growing number of stakeholders have asserted that covered entities' use of contract pharmacies has increased the frequency of duplicate discounts.

Recent research has found that state governments or state Medicaid agencies have taken a range of policy approaches to address duplicate discounts. An electronic survey of 46 state Medicaid agencies showed that, in 2024 most states employ multiple strategies to avoid duplicate discounts.[21] Approximately 67 percent of Medicaid agencies (31 of 46) used data from the Medicaid Exclusion File (MEF) to avert duplicate discounts.

GROWTH OF DUPLICATE DISCOUNTS

Three factors are likely to result in an increase in the volume of duplicate discounts:

1) An increase in the number of 340B covered entities

2) Medicaid enrollment growth

3) An increase in the use of contract pharmacies

In addition, 63 percent of agencies (29 of 46) implemented prohibitions on the use of contract pharmacies in Medicaid and/or relied on the use of claims data variables pharmacies may use to flag the use of 340B drugs. Importantly, three states (Maine, New Hampshire, and South Dakota) reported prohibiting covered entities that serve Medicaid beneficiaries from dispensing 340B drugs to Medicaid beneficiaries entirely. Furthermore, some states, such as California and New York, have opted to carve out pharmacy benefits from managed care organizations (MCOs) to fee-for-service (FFS) benefits, partially as a method of identifying and reducing duplicate discounts.[22]

INTERVIEW FINDINGS

To gain deeper insights into how Medicaid programs navigate duplicate discounts, HMA conducted a series of semi-structured interviews with Medicaid and pharmaceutical experts in 13 states and the

District of Columbia. Interviews included current and former Medicaid Directors, Medicaid pharmacy program managers, 340B-eligible covered entity leadership, MCO leadership, federal policy experts, and other subject matter experts. States targeted for analysis were: California, Delaware, Florida, Illinois, Indiana, Maryland, New Mexico, Oklahoma, Ohio, Oregon, South Dakota, Tennessee, Texas, and Washington, D.C.

HMA asked 20 interviewees a series of questions about how often duplicate discounts occur, the extent to which Medicaid programs devote resources to tracking and addressing duplicate discounts, the policies state Medicaid programs have implemented to address duplicate discounts, and how much state or federal authorities should be working to eliminate duplicate discounts. Interviewees' responses to these and other questions are aggregated below centered on four themes.

1) Duplicate discounts remain a problem, the scope of the problem is unclear, and better data collection from covered entities is necessary

All of the interviewees acknowledged that duplicate discounts between the 340B Drug Pricing Program and the MDRP continue to occur despite the federal prohibition and are an ongoing concern. Most interviewees believe that most Medicaid agencies and covered entity pharmacy personnel are aware of the federal prohibition on duplicate discounts, but have little authority or resources to prevent duplicate discounts from occurring. In addition, none of the interviewees could quantify the scope and scale that duplicate discounts occur on the state or federal level.

Though interviewees widely agreed that duplicate discounts are occurring and their scope is large, all agreed that quantifying their scope is currently infeasible on the state or national level. One interviewee stated, "The national scale of duplicate discounts is enormous but there is not a good method for calculating it at this time." Another interviewee indicated that federal authorities have been unable to provide scope to this concern, stating, "HRSA audits, Government Accountability Reports, Health and Human Services Office of Inspector General testimony, and other oversight reveals that duplicate discounts occur rather frequently, but there is no official state or federal government estimate identifying the number, scope, or dollar amount associated with duplicate discounts."

SCOPE OF DUPLICATE DISCOUNTS

"The national scale of duplicate discounts is enormous but there is not a good method for quantifying their scope at this time."

"There is variation across states in the scope of duplicate discounts."

At the state level, none of the interviewees could quantify the volume of Medicaid claims involving duplicate discounts, the dollar amount of duplicate discounts, the growth rate of duplicate discounts across years, or the types of cases/drugs most common to duplicate discounts. One interviewee said it would be "shocking" to learn "if duplicate discounts did not occur in every state". Another person HMA interviewed stated, "It is hard to imagine any state where there is not duplication of discounts occurring." A third interviewee noted, "There is variation across states in the scope of duplicate discounts. The scope is likely to be smaller in states where the MEF and claims level modifiers are used to flag 340B covered entities, because this practice will reduce the volume of Medicaid rebate requests, and the scope of duplicate discounts is likely to be higher in states where the Medicaid Exclusion File and claims modifiers are not used." Further, we believe that the scope of duplicate discounts is likely to be near to zero in

states that have implemented policies prohibiting Medicaid providers from participating in the 340B program. As another interviewee said, “No one is able to quantify the scope of duplicate discounts.”

Interviewees pointed to significant gaps in data as the main limitation on information about the scope of duplicate discounts and poor transparency about the issue. Interviewees stated that agency staff are distrustful of the claims data they receive from covered entities, because covered entities are inconsistent with their use of claims modifier codes. One interviewee, a former Medicaid pharmacy official, said ,“state Medicaid agencies are largely at the mercy of the 340B covered entities in terms of counting which Medicaid claims are receiving duplicate discounts.” This situation often makes it difficult for state agency staff to know whether data from covered entities under or over-state the volume of 340B claims.

Further, interviewees asserted that the claims data they receive from covered entities often include data entry errors and the accuracy of the data can depend on covered entities being aware of changes to the states’ claims processing guidelines, such as the use of claims modifiers, and ongoing changes to the definition of 340B drugs. For example, drugs that were identified as 340B drugs retrospectively may have already been billed via the MDRP and may have already received duplicate discounts or been placed into the dispute resolution process.[23]

TRANSPARENCY OF DUPLICATE DISCOUNTS CLAIMS

“State Medicaid agencies are largely at the mercy of 340B covered entities in terms of counting which Medicaid claims are receiving duplicate discounts.”

Despite the gaps in data, several interviewees noted that the consistent use of HRSA’s MEF by state Medicaid agencies and covered entities has the potential to improve data transparency if paired with a 340B claims modifier codes. Interviewees noted that the MEF has been a helpful platform to support Medicaid programs as they seek to identify the volume of duplicate discounts, but that the MEF is only effective at preventing duplicate discounts when it is up to date and accurate. If a covered entity is not clearly identified in the MEF, a state’s Medicaid program may still submit a request for a rebate on that drug. One interviewee indicated that the use of the MEF in combination with a modifier code that identifies Medicaid enrollees who received a 340B drug, can serve as an important second line of defense to duplicate discounts. Several interviewees underscored that the use of the MEF, absent the 340B modifier codes, would be an inadequate strategy for identifying instances of duplicate discounts and, therefore, would have little effect on policymakers’ ability to reduce duplicate discounts.

Interviewees highlighted the role Medicaid MCOs play in exacerbating the lack of information regarding the scope of duplicate discounts. One interviewee, a former Medicaid managed care executive from a western state, said Medicaid agencies anticipate that Medicaid managed care plans will play a role in tracking and preventing duplicate discounts, but they typically have no incentive to do so. Another interviewee stated that “Medicaid managed care plans are not tracking or preventing duplicate discounts because Medicaid agencies are not holding them accountable for this responsibility.”

Finally, despite not being able to quantify the scope of duplicate discounts, some interviewees stated that this problem has grown in recent years. Interviewees asserted that the scope of duplicate discounts has increased as the number of 340B covered entities has increased and as Medicaid enrollment has increased. Interviewees believe that the growth of these two factors will expand the overlapping nature of the 340B program and the MDRP and increase opportunities for duplicate discounts to occur.

2) The opacity and complexity of duplicate discounts create a burden for state Medicaid agencies, influencing the policies they implement, resulting in variable state policy strategies

State Administrative Burden

All state Medicaid agency officials interviewed said that agency resources are required to address duplicate discounts and comply with the federal prohibition on duplicate discounts. They stated that to some degree all programs must devote some level of administrative resources to this problem and highlighted that the agencies all must:

- Develop policies to combat duplicate discounts;
- Conduct ongoing oversight of duplicate discounts; and
- Review and resolve Medicaid claims involving duplicate discounts when they are identified.

Though all states have devoted resources to this issue, none of the individuals we interviewed could quantify the administrative burden on their agencies to addressing duplicate discounts.

Variation in State Policymaking

Interviews revealed wide variability in the extent to which state Medicaid agencies devote resources to addressing duplicate discounts. Interviewees agreed that Medicaid agencies are driven to address duplicate discounts to comply with the federal prohibition on duplicate discounts and to adhere to the statutory requirement that they ensure duplicate discounts are averted. However, interviewees stated that because duplicate discounts little impact on Medicaid enrollees, state agencies place emphasis on other issues. Agencies tend to prioritize challenges that have the potential to directly improve care for Medicaid enrollees. Interviewees stated that "state agencies are only doing what the law requires and what CMS enforces," and that "some states are putting little to no administrative effort forward beyond what is required." As one interviewee said, "This issue is not a priority for my state."

STATE ACTION ON DUPLICATE DISCOUNTS

"State agencies are only doing what the law requires and what CMS enforces."

"Some states are putting little to no administrative effort forward beyond what is required."

"This issue is not a priority in my state."

In contrast, one interviewee said the "variability in state administrative burden associated with duplicate discounts is due to the fact that every Medicaid agency handles the management of pharmacy benefits differently, and they each have different processes." One interviewee noted that a state's commitment to ensuring duplicate discounts are averted can depend on whether the state's Medicaid pharmacy benefit is carved in or out of state MCO plans. When carved out, a pharmacy benefit manager could better conduct these monitoring activities; when carved in, understaffed Medicaid agencies often lack the bandwidth to monitor claims.

Some interviewees attributed states' hesitancy to address duplicate discounts to the administrative burden of claims audits and a lack of staff resources. Interviewees said that given the lack of staff resources, state policymakers must evaluate the potential impact on staff when considering policies that address duplicate discounts. One interviewee added that some states may be

hesitant to address duplicate discounts because they are unable "to quantify the financial benefit of doing so."

Interviewees highlighted three states—Maine, New Hampshire, and South Dakota—that have instituted policies completely prohibiting covered entities from distributing 340B drugs to their Medicaid enrollees. These guidelines comply with the federal prohibition on duplicate discounts, and because they nullify the potential for duplication, it is unnecessary that the state track or audit claims, which is an activity associated with a high degree of administrative burden. Interviewees described these policies as protective measures specifically intended to eliminate duplicate discounts and result in minimal ongoing administrative burden for the state.

Interviewees also noted that some states have opted to implement policies that may improve the transparency of duplicate discounts by requiring covered entities to include 340B modifier codes in their Medicaid MEF claims data. These states often experience high levels of administrative burden, but lower levels of duplicate discounts. Interviewees stated that these modifier code policies require significant agency resources initially because the agency must communicate the new data requirement to each covered entity and then track whether covered entities are adhering to the new policy to ensure it is being implemented correctly. However, interviewees noted that the administrative burden of these modifier code policies declines over time as covered entities more fully comply. Nonetheless, interviewees added that once state agencies possess the claims data they need to assess the scope of duplicate discounts, the process of auditing Medicaid claims and resolving disputes carries a high level of administrative burden that does not diminish over time.

In addition, some interviewees stated that covered entities, which also are required to prevent duplicate discounts under federal law, have little incentive to prevent duplicate discounts.

3) Contract pharmacies add an additional layer of complexity, exacerbating the burden that duplicate discounts create

Interviewees stated that the use of contract pharmacies by 340B-covered entities is among the factors driving duplicate discounts and exacerbating the burden of duplicate discounts on Medicaid agencies. Covered entities commonly use contract pharmacies to improve the management of patients' prescriptions. Interviewees said that drug spending subject to 340B has expanded significantly over the past several years, in part because of the use of contract pharmacies to capture the 340B discount for more prescriptions.

In addition to improving the efficiency of capturing 340B discounts for covered entities, several interviewees stated that the use of contract pharmacies complicates the duplicate discount problem for Medicaid agencies because these entities add an intermediary between the covered entity and the Medicaid program. Covered entities ask their contract pharmacies to accept the requirement of submitting claims data to Medicaid agencies. Interviewees stated that when Medicaid agencies send guidance to covered entities about data submission requirements, they have no guarantee that the information is passed along to the

CONTRACT PHARMACIES

"One of the biggest problems contributing to duplicate discounts is the use of contract pharmacies."

contract pharmacies. At times Medicaid agencies do communicate with the contract pharmacies directly, but at other times they do so through the covered entity, which creates administrative complexity.

One interviewee stated, "The presence of contract pharmacies represents one of the biggest barriers to identifying claims associated with duplicate discounts." This individual said that contract pharmacies often submit flawed data that Medicaid agencies must later reconcile with individual covered entities or contract pharmacies, which may lead to retrospective MDRP invoicing and reimbursement to the state.

4) State and federal authorities could take more decisive action to address duplicate discounts

Several interviewees said their perception is that federal law places significant responsibility on the covered entities to limit the frequency of duplicate discounts but that federal and state authorities could provide greater assistance in preventing the occurrence of duplicate discounts.

Federal

Most interviewees said that federal authorities could play a more active leadership role in improving the audits of duplicate discounts, enhancing their transparency, establishing best practices for states to follow, and promoting consistent policy across the states.

Several interviewees stated that the US Congress should consider legislative action that provides clearer direction, policy and procedural options, and authority for federal agencies to address duplicate discounts. One interviewee stated, "It is generally understood in federal health policy circles that congressional action is needed to improve the 340B program…and one of the policy issues generally understood to be in need of action is the establishment of a mechanism to prohibit duplicate discounts in Medicaid." Some interviewees added that federal agencies may need explicit statutory instruction to audit Medicaid managed care data more thoroughly for duplicate discounts and to assist states in their efforts to identify duplicate discounts

FEDERAL OVERSIGHT

"It is generally understood in federal health policy circles that congressional action is needed to improve the 340B program…and one of the policy issues generally understand to be in need of action is the establishment of a mechanism to prohibit duplicate discounts in Medicaid."

Some interviewees stated that federal agencies like HRSA and CMS could be doing more to assist Medicaid agencies, covered entities, managed care plans, and contract pharmacies with their efforts to limit duplicate discounts. Some of these interviewees echoed the findings and recommendations of the Government Accountability Office's 2018 report on this subject, which stated that "HRSA had not issued guidance on, and did not audit for, duplicate discounts in Medicaid managed care and recommended the agency do so as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care." One interviewee specifically suggested that CMS create an audit structure to track and monitor duplicate discount claims nationally. Another interviewee suggested HRSA limit the volume of duplicate discount claims by revising regulations to limit the diversion of 340B discounts to locations that covered entities own but are not co-located with the covered entity. In addition, one interviewee said that federal agencies should play a larger role than Medicaid agencies in regulating duplicate discounts.

State

Interviewees generally agreed that state Medicaid agencies are an important part of the solution to duplicate discounts and need the support of federal authorities. One interviewee, a former Medicaid director from the Midwest, stated that "Medicaid agencies should remain involved in the oversight of duplicate discounts." Several interviewees indicated that Medicaid agencies are doing as much as they can to address repeat discounts given their staffing capacity but added that agencies need to take more action to implement CMS's best practices for identifying and avoiding duplicative discounts.[24] Published in 2020, these best practices include implementing overlapping strategies such as using the MEF file, implementing a 340B claims modifier, developing strategies for contract pharmacies, communicating directly with covered entities about their use of 340B drugs, including duplicate discount provisions in Medicaid managed care contracts, providing claims level data to manufacturers, and making claims coding for managed care individuals consistent with practices for Medicaid FFS members. Other interviewees suggested that states may need federal authorities to issue clearer requirements to track and eliminate duplicate discounts. In addition, two interviewees said that state audits should ensure that 340B discounts are not being used by covered entities with satellite locations serve largely insured populations.

STATE OVERSIGHT

"Medicaid agencies should remain involved in the oversite of duplicate discounts."

DISCUSSION

Given the overlap of the 340B program and the MDRP, our interviews with Medicaid and pharmaceutical experts in 13 states and the District of Columbia suggested that duplicate discounts are likely to persist absent policy changes. Interviewees agreed that despite the federal law prohibiting them, duplicate discounts remain a pervasive problem and their scope is unclear on the state and national levels. The existing data do not enable policymakers to determine how many sales (or cases) duplicate discounts affect and how much they cost manufacturers.

Interviewees asserted that state Medicaid agencies face increased burden because of the lack of transparency regarding duplicate discounts, and that state policymaking is consequently widely variable. A small group of states have had some success in reducing the occurrence of duplicate discounts through the use of data consistent collection or prohibiting Medicaid providers from participating in the 340B program, but for most states, success with limiting duplicate discounts has been an elusive goal. This inconsistency in policymaking creates added complexity for policymakers and manufacturers. Interviewees agreed that a clear solution to resolving this lack of transparency is improved and consistent data collection.

In addition, several interviewees stated that the use of contract pharmacies complicates the duplicate discount problem for Medicaid agencies because these entities add an additional actor between the covered entity and the Medicaid program. Interviewees generally agreed that state and federal authorities should take more decisive action to address duplicate discounts.

Policymakers should consider that the environment for addressing duplicate discounts may grow more complicated in the future, which may increase the need for a federally coordinated policy solution. The complexity of the environment may deepen as a result of the increasing presence of contract pharmacies, the increasing presence of managed care in Medicaid programs, and the implementation of the drug pricing policies of the Inflation Reduction Act of 2022. Policy action coordinated across the various stakeholders (e.g., HRSA, CMS, state Medicaid agencies, covered entities, and manufacturers) may have the best opportunity for success in eliminating duplicate discounts.

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ABOUT HMA

HMA is a leading independent national research and consulting firm specializing in publicly funded healthcare. Founded in 1985, HMA has over 700 consultants working in more than 20 state cities including Washington D.C. Our consultants support clients on Medicare, Medicaid, and commercial insurance policy topics as well as with public health, clinical, and organizational strategy. For this assessment, HMA's authors and analytic team included: Zachary Gaumer (Managing Principal), Kevin Kirby (Managing Director), Carl Mueller (Principal), and Danielle Swanson (Consultant).

ENDNOTES

[1] Health Resources and Services Administration. (n.d.). Veterans Health Care Act of 1992, Public Law 102-585. Health Resources and Services Administration. https://www.hrsa.gov/opa/program-requirements/public-law-102-585
[2] US Government Accountability Office. (2020, January 21). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. GAO. https://www.gao.gov/products/gao-20-212
[3] National Pharmaceutical Council. (n.d.). 340B Drug Discount Program. National Pharmaceutical Council. https://www.npcnow.org/topics/health-spending/340b-drug-pricing-program
[4]Centers for Medicare & Medicaid Services. (2024a, August 20). Medicaid Drug Rebate Program (MDRP). Medicaid.gov. https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html
[5] The Federal prohibition on Duplicate Discounts can be found at Social Security Act (section 1927(a)(5)(C)) and the Public Health Service Act (section 340B(a)(5)(A).
[6] Health Resources and Services Administration. (2020, July). Duplicate Discount Prohibition. Health Resources and Services Administration. https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion
[7] The ACA also established the administrative dispute resolution (ADR) process to settle disputes on 340B purchases between drug manufacturers and covered entities. This process was revised on April 18, 2024 to make the ADR process for administratively feasible and ensure claims are "resolved fairly, efficiently, and expeditiously"
[8] Gifford, Kathy, et al. How State Medicaid Programs are managing prescription drug costs: Results from a state Medicaid pharmacy survey for state fiscal years 2019 and 2020. Kaiser Family Foundation. April 29, 2020 (https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-state-strategies-to-manage-340b-programs/)
[9] US Government Accountability Office. (2020, January 21). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. GAO. https://www.gao.gov/products/gao-20-212
[10] Clark, Bobby et al. The Federal 340B drug discount program: What it is, and why its facing legal challenges. The Commonwealth Fund. September 8, 2022. (https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges)
[11]Kalderos. (2021). Making health policy work for patients. Kalderos. https://f.hubspotusercontent40.net/hubfs/7227094/2021%20Annual%20Report/Annual_report_2021.pdf
[12] Disproportionate share hospitals (DSHs), children's hospitals, cancer hospitals, and sole community or critical access hospitals, Rural referral centers, federally qualified health centers (FQHCs) and FQHC "look-alikes", State-operated AIDS drug assistance programs, Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics and programs, tuberculosis and Black Lung clinics, Title X family planning clinics, sexually transmitted disease clinics, hemophilia treatment centers, urban Indian clinics and Native Hawaiian health centers
[13]Rogers, H.-A. (2022, October). Overview of the 340B Drug Discount Program. Congressional Research Service. https://crsreports.congress.gov/product/pdf/IF/IF12232

[14] National Pharmaceutical Council. (n.d.). 340B Drug Discount Program. National Pharmaceutical Council. https://www.npcnow.org/topics/health-spending/340b-drug-pricing-m

[15]Rogers, H.-A. (2022, October). Overview of the 340B Drug Discount Program. Congressional Research Service. https://crsreports.congress.gov/product/pdf/IF/IF12232

[16]Mulligan, Karen. The 340B Drug Discount Program: Background, Ongoing Challenges and Recent Developments. Leonard D. Schaefer Cetner for Health Policy and Economics (USC Schaefer). October 14, 2021. https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/

[17] Williams, Elizabeth, et al. Medicaid Enrollment & Spending Growth: FY 2024 & 2025. Kaiser Family Foundation. October 23, 2024.

[18] US Government Accountability Office. (2018, June). Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. GAO. https://www.gao.gov/assets/d18480.pdf.

[19] HRSA granted covered entities the ability to contract with pharmacies to expand access to services and enable individuals with transportation barriers and other obstacles to access their prescriptions.

[20] Health Resources and Services Administration. (2010, March 5). Notice Regarding 340B Drug Discount Program-Contract Pharmacy Services. The Federal Register. https://www.federalregister.gov/documents/2010/03/05/2010-4755/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services

[21]Gifford, Kathy, Lashbrook, A., & Payne, C. (2024, August). https://www.healthmanagement.com/wp-content/uploads/2024-Medicaid-Rx-Survey-Rpt_FINAL.pdf

[22]The California Legislature's Nonpartisan Fiscal and Policy Advisor. (2019, April 5). Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care. Legislative Analyst's Office. https://lao.ca.gov/Publications/Report/3997#:~:text=Under%20the%20full%20carve%20out,for%20340B%20drugs%20at%20cost.

[23]Medicaid and CHIP Payment Access Commission. (2018, May). The 340B Drug Discount Program and Medicaid Drug Rebate Program: How They Interact. MACPAC. https://www.macpac.gov/wp-content/uploads/2018/05/340B-Drug-Pricing-Program-and-Medicaid-Drug-Rebate-Program-How-They-Interact.pdf

[24] Centers for Medicare & Medicaid Services. (2020, January 8). Best Practices for Avoiding 340B Duplicate Discounts in Medicaid. Department of Health and Human Services. https://www.hhs.gov/guidance/