A Practical Look at OIG's New Compliance Guidance

 On November 6, 2023, for the first time in 15 years, HHS OIG issued a new reference guide for the health care compliance community – **the General Compliance Program Guidance, or GCPG**. While the GCPG does not set new legal standards and largely reinforces existing guidance, it is a tremendous tool to help health care and life sciences companies advance their compliance efforts. Indeed, within its 91 pages, the GCPG provides the most comprehensive and user-friendly trove of health care compliance insights, tips, and guidance ever provided by the federal government.

Read the full alert **here**.

Significant 340B Drug Pricing Program Litigation May Impact 340B Scope

 Two recent federal court cases signal new significant developments with respect to the 340B Drug Pricing Program. Specifically: (1) new federal district court litigation challenging a recent HRSA Notice involving 340B Program "child site" registration and eligibility; and (2) a court decision in other litigation that implicates the scope of the 340B "eligible patient" definition. Details regarding these developments are in the client alert.

Read the client alert **here**.

2023 State Drug Transparency Law Development Update

 In October 2021, we **reported** on an uptick in the passage of state drug price transparency legislation. As an update to that report, as of October 2023, approximately 22 states have now passed drug price transparency laws creating new requirements for drug manufacturers.

Each state has its own unique set of requirements, but reporting is often completed via an online portal administered by the state's implementing agency. Generally, these laws require manufacturers to report pricing and other information related to the cost, development, and sale of drugs to the state or state-affiliated entities. Some states will use this data to produce public reports about the cost of prescription drugs with the goal of creating pricing transparency for drug manufacturers as well as to educate the state legislature and public about the drug pricing process.

Read the full alert **here**.

Federal Court Strikes Down Copay Accumulator Programs

 **Summary:**

On September 29, 2023, the U.S. District Court for the District of Columbia **vacated** a Trump-era rule from 2021 that allowed insurers to exclude drug manufacturer co-pay support coupons and assistance from a patient's annual cost-sharing caps. This practice, commonly referred to as a copay accumulator program, is typically used by insurance companies and pharmacy benefit managers to control drug spending, especially for high-cost specialty drugs, like those required by HIV patients.

Under typical prescription drug insurance programs, patients are obligated to pay a deductible and

cost-sharing (i.e. a copay) throughout the plan year, up to an out-of-pocket spend cap. Once the patient hits that spend cap, the insurance company is responsible for the patient's prescription drug costs.

Under an accumulator program, on the other hand, an insurance company does not count a manufacturer's copay support (for example, a copay card that a patient presents at a pharmacy to cover the cost of the copay) towards a patient's annual deductible or out-of-pocket maximum. By excluding manufacturer copay support and coupons from patients' cost-sharing cap, this means that, even after a manufacturer's copay support is exhausted for the year, patients remain on the hook for all cost sharing obligations up to the insurance plan's out of pocket maximums. Many states have implemented laws to ban copay accumulator programs, asserting that such programs actually increase the financial burden on patients, especially with respect to specialty or more expensive drugs. As of June 2023, 19 states have implemented copay accumulator program bans.

HIV and Hepatitis Policy Institute et al v. HHS was brought by patient advocacy groups including the HIV and Hepatitis Policy Institute and the Diabetes Patient Advocacy Coalition, among others, who challenged a May 2020 rule from HHS, the "Notice of Benefit and Payment Parameters for 2021" (85 Fed. Reg. 29164, 29230-35, 29261 (May 14, 2020)) (the "2021 NBPP") that permitted insurers to impose accumulator polices. Plaintiffs opposed the accumulator program, asserting that manufacturer copay support should count *towards* calculating patients' cost sharing obligations and should not be excluded from such calculations.

In ruling in favor of the plaintiffs on their motion for summary judgment, the U.S. District Court set aside the 2021 NBPP, largely supporting plaintiffs' challenges that the 2021 NBPP rule's language is internally contradictory, that it runs counter to the statutory definition of "cost sharing" found in the Affordable Care Act, and that it runs counter to the agencies' pre-existing regulatory definition of "cost sharing." HHS had previously defined "cost sharing" in a 2012 regulation as "any expenditure required by or on behalf of an enrollee with respect to essential health benefits," which by its terms includes "deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services." *See* 45 C.F.R. 155.20. In other words, the regulation treats cost sharing is an "expenditure" by or on behalf of a plan enrollee. According to plaintiffs, and as affirmed by the court, this includes manufacturer copay assistance support.

The court disagreed with the government's technical arguments regarding the language of the 2021 NBPP (i.e. that manufacturer copay support is actually a "reduction" in the amount the patient owes towards cost sharing or a reduction in the "actual economic impact" on the drug manufacturer and not an "expenditure"), concluding that the 2012 regulation was likely intended to define "cost sharing" as costs that are (1) required of an insurance plan enrollee and (2) paid by or on behalf of that enrollee – including manufacturer copay coupons and assistance.

It is unclear if the ruling will be appealed; however, as a result of the District Court's ruling, the government will use an earlier 2020 version of the rule which allowed insurers to exclude from cost-sharing caps only copay support coupons for branded drugs that have available generic equivalents; if there is no generic equivalent, under the 2020 version of the rule, manufacturer copay support must be counted toward cost sharing.

Conclusions: The U.S. District Court ruling is a significant development for drug manufacturers who offer copay support as a means of providing relief to patients with respect to cost-sharing requirements under their insurance coverage as opposed to offering significant rebates, discounts, or other contracting strategies. However, manufacturers of branded drugs with a generic equivalent will still need to consider how copay accumulator programs could affect access in those states that

have not yet banned the practice. Notably, in the wake of this ruling, patient advocacy organizations have indicated that they will continue to advocate for a comprehensive state and federal level ban on copay accumulator programs (*e.g.* **Immune Deficiency Foundation**).

Goodwin will continue to monitor any further developments in this case and the impact of copay accumulator programs on the market.

HHS to Create New Potential Medicare Pricing Models for Cell and Gene Therapy, Drugs Subject to Accelerated FDA Approval, and "High-Value" Generics

On February 14, 2023, the U.S. Department of Health and Human Services (HHS) published a **report** identifying three models that the Center for Medicare & Medicaid Services' (CMS) Center for Medicare & Medicaid Innovation (CMMI) will test to try to improve the affordability and accessibility of prescription drugs. The report responds to the state of prescription drug costs and access in America, as well as the widespread changes introduced by the Inflation Reduction Act of 2022 and President Biden's **Executive Order 14087** (October 2022), both intended to help lower prescription drug costs for Americans. The three selected models will test the feasibility of methods to: (i) offer generic prescription drugs at $2 or less for Medicare patients; (ii) reduce Medicaid costs for novel cell and gene therapies through outcomes-based agreements with manufacturers on a multistate level; and (iii) improve the safety and efficacy of drugs approved through the FDA's Accelerated Approval Program by aligning payment methods with stakeholders' incentives. More detail on these three models is expected, and Goodwin attorneys will continue to monitor for additional guidance and any opportunities for public comment.

Read the client alert **here**.

340B Drug Pricing Program Reform Considerations

 The 340B Drug Pricing Program is a government program, administered by the Health Resources and Services Administration (HRSA), that allows qualifying hospitals and clinics that treat low-income and uninsured patients to buy certain prescription drugs at a steep discount from drug manufacturers. Drug manufacturers participate in the 340B Program as a condition of obtaining Medicaid coverage of their drugs. For the many drug manufacturers who want their products to reach the broadest patient population, participation in the 340B Program is essentially mandatory.

The program is intended to help safety-net health care providers' financial resources reach more financially vulnerable patients and deliver comprehensive services.[1] At the same time, drug manufacturers have concerns about the program:

- Manufacturers are concerned that deeply discounted prescription drugs should only go to covered entity patients and not diverted to individuals who are not covered entity patients, i.e., a practice commonly known as drug diversion.
- Manufacturers are concerned that the covered entities do not get both a deep Section 340B discount and any additional discounts and rebates under Medicaid, i.e., duplicate discounts.

Balancing the interests of covered entities and drug manufacturers has been a challenge, and one that has come under scrutiny in recent years. Drug manufacturers have no way of tracking how covered entities use the discounts paid under the Section 340B program, and there is no legal requirement for covered entities to pass the savings they received from manufacturers to patients.

There are four emerging areas of tension between the interests of covered entities and drug manufacturers related to the 340B program :

- Section 340B telemedicine standards and patient eligibility;
- Contract pharmacy utilization;
- Section 340B covered entity child sites; and
- Drug manufacturer audit limitations.

Until these four key areas are addressed, the Section 340B program will not serve its true goals; and drug manufacturers and covered entities will face increasing conflict over ambiguous and outdated regulations.

For more information regarding these controversies in the 340B Program, please see our recent Health Law360 and Life Sciences Law360 article, "**4 Key Issues Driving Drug Discount Abuse Must Be Addressed**" (Jan. 9, 2023) as well as our recent Goodwin Procter LLP client alert, **Federal Court of Appeals Rejects HHS Stance on Section 340B Contract Pharmacies** (Feb. 1, 2023).

[1] Health Resources & Servs. Admin., 340B Drug Pricing Program (Dec. 30, 2022).

Medicare Agrees to Limited Payment for New Alzheimer's Drug

On January 11, 2022, the Centers for Medicare and Medicaid Services (CMS) **released** a proposed National Coverage Determination (NCD) decision memo limiting Medicare coverage for Biogen's new Alzheimer's drug, Aduhelm. Under the terms of the NCD – despite FDA's 2021 approval of the drug – CMS will only pay for Aduhelm for Medicare beneficiaries who are enrolled in a qualifying clinical trial to assess the drug's safety and its effectiveness in slowing the progression of Alzheimer's. CMS **stated**, "[B]ased on the public comments submitted previously and evidence CMS reviewed, the potential for harm, and important questions that remain, we have determined that coverage with evidence development through clinical trials is the right decision for Medicare patients, clinicians, and caregivers, and we look forward to receiving feedback on the proposal." The proposed NCD is **open** to public comment for thirty (30) days, and a final decision from CMS is expected **on April 11**. If the proposed NCD is finalized, CMS must evaluate each submitted clinical trial to verify that it meets the qualifying criteria specified in the proposed NCD.

Aduhelm has been approved by FDA for the treatment of Alzheimer's since June 2021. This is the first drug approved by FDA for the treatment of Alzheimer's in almost 20 years. In 2019, two clinical trials for Aduhelm were **paused** due to data showing the drug was of no benefit to patients' cognitive function. However, after Biogen re-analyzed one of its trials, it decided to apply to the FDA for approval. The FDA used the accelerated approval process but can withdraw Aduhelm from the market if Biogen's new clinical trial demonstrates that the drug is ineffective. The FDA **pivoted** on the approval itself, later **recommending** Aduhelm only in patients with mild cognitive impairment or mild dementia. Patient advocacy groups such as the Alzheimer's Association **played** an important role in pressuring FDA to approve Aduhelm, given the minimal advancements in drug treatment in the space.

Since receiving FDA approval, Biogen has faced tough scrutiny about Aduhelm's efficacy and cost. Aduhelm's initial annual price of $56,000 elicited widespread criticism. In December 2021, Biogen **announced** that it would reduce the drug's price to $28,200 for some patients. Biogen most likely reduced the price in response to slower than anticipated sales and CMS's announcement it would increase Medicare's monthly Part B premium for outpatient care in anticipation of the Aduhelm's price impact. Adding to Biogen's challenges, an FDA advisory committee agreed almost **unanimously** that the clinical trials did not provide strong enough evidence to corroborate Aduhelm's efficacy data. However, based on the clinical trials it did review, FDA **claimed** that Aduhelm could reduce clumps of plaque in the brain, which is likely to slow dementia. The discrepancy between the advisory committee's and FDA's findings coupled with broad criticism of the FDA led the Department of Health and Human Services Office of Inspector General to conduct a **probe** into the FDA's approval process for Aduhelm.

Adding to the complexity, State Medicaid programs have also been vocal in protesting CMS's decision. Unlike Medicare, Medicaid is required to cover all FDA-approved drugs regardless of a drug's clinical efficacy. Therefore, had Medicare determined not to cover Aduhelm, all costs would **shift** to the state Medicaid programs. Though some states and insurers have already **declined** to cover Aduhelm, CMS's ruling is likely to influence other payors to refuse coverage.

While some commenters and industry observers have questioned whether CMS's decision with respect to Aduhelm somehow creates a new, default secondary clinical testing and approval threshold for drug makers, it is more likely that the Medicare agency's decision on Aduhelm reflects the unique circumstances posed by the drug (*i.e.* unclear efficacy concerns, conflicting FDA guidance, and an unusually high price point). Whether CMS will make a habit of limiting coverage for innovative drugs only to beneficiaries participating in additional clinical trials remains to be seen, but is not likely. We will continue to monitor trends and developments at CMS with respect to coverage and payment decisions on new therapeutics and treatments, including additional research and testing requirements that the agency may impose.

Pharmaceutical Manufacturers Beware: New State Drug Transparency Laws and Enforcement Mechanisms Are Coming In 2022

In 2016, states began passing pharmaceutical price reporting laws. These laws are designed to bring transparency to a pharmaceutical manufacturer's drug pricing process by requiring drug manufacturers to report pricing and other information related to the cost, development, and sale of drugs. By October 2021, approximately twenty states have passed or are implementing transparency laws. While many of these laws are applicable to drug manufacturers, pharmacy benefit managers, and health carriers, recent enforcement of these laws has focused only on drug manufacturers.

Each state has its own set of unique requirements that drug manufacturers must meet in order to distribute drugs within each individual state. Reporting is often completed via an online portal administered by the state's implementing agency. Some states will use this submitted data to produce public reports about the cost of prescription drugs with a goal of educating the state legislature and the public about the cost of drugs and to provide accountability for increased prices.

Enforcement of these state reporting laws is beginning to take shape as states pass legislation and

implement administrative guidance – the majority of which provide for civil or administrative penalties. Enforcement authorities typically assess fines for each day a manufacturer is in violation and may increase penalties the longer the violation persists. Additionally, the appeals process for any enforcement action typically follows either a prescribed process codified by the state law or defaults to the appeals process under the state's administrative procedure act.

Accordingly, pharmaceutical manufacturers will need to be vigilant as more sates pass and implement drug transparency laws. These laws require different reporting deadlines, the reporting of different information, disclosures based on different dollar thresholds, and have different requirements and processes for protecting confidential information and trade secrets. For the latest developments in this area, please see Goodwin's recent **client alert**. For an in-depth analysis of these laws, please see our publication, **State Drug Transparency Laws: Considerations for Pharmaceutical Manufacturers**, in Chapter 8 of the American Health Law Association's 2021 edition of *Health Law Watch*.

President Trump Signs Four Executive Orders Designed To Reduce Drug Prices

President Trump recently announced four Executive Orders that direct the Secretary of the Department of Health and Human Services (HHS) to implement policy changes to reduce out-of-pocket costs and the price of prescription drugs. All but one of the Executive Orders has been issued with the remaining order on hold until August 24, 2020 pending discussions between the White House and leaders of the pharmaceutical industry. The Executive Orders include some prior policy proposals aimed at lower the cost of drugs and generating savings across the health care system. If implemented, many of these proposals will likely be challenged in court.

Most Favored Nations Policy

If issued, this Executive Order could tie the price that Medicare pays for certain drugs administered by doctors to prices negotiated by other economically comparable countries. This proposed Order is similar to a **2018 prior proposal** by the Center for Medicare and Medicaid Services ("CMS") to use its demonstration authority to test reimbursement changes for certain separately payable Part B drugs and biologicals using an international pricing index ("IPI"). The IPI model would result in lowering Medicare reimbursement for select drugs in certain geographies covered by the model to better match prices paid by similar economically situated countries. Health officials estimate this change would save Medicare $17 billion in the first five years. This order will be held until August 24, 2020 pending discussions with pharmaceutical industry leaders about alternative measures for

lowering costs.

Increase Drug Importation

This **Executive Order** is designed to minimize international disparities in drug prices by increasing the trade of prescription drugs between nations with lower prices and those with persistently higher ones. The Administration argues that "reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs." The Administration aims to expand safe access to lower-cost importuned prescription drugs via three primary strategies.

First, the Order requests the Secretary of HHS to consider "facilitating grants to individuals of waivers of the prohibition of importation of prescription drugs" provided that it "poses no additional risk to public safety and results in lower costs to the American People" under the Federal Food, Drug, and Cosmetic Act (FDCA).

Second, it addresses "authorizing the reimportation of insulin products" where the Secretary of HHS finds that it is "required for emergency medical care" under section 801(d) of the FDCA. Section 801(d) generally places limitations on the reimportation of U.S. manufactured insulin products unless an exception is met.

Third, it requires the Secretary of HHS to complete the rulemaking process regarding a **December 23, 2019** proposed rule to import prescription drugs from Canada. The proposed rule contemplates allowing states and certain other non-federal government entities to import certain prescription drugs from Canada if the certain requirements under the FDCA are met.

Access to Affordable Life-saving Medications

This **Executive Order** is designed to help low income American's without access to affordable insulin and injectable epinephrine through commercial insurance or Federal health care programs, such as Medicare and Medicaid, to purchase these products from a Federally Qualified Health Centers ("FQHC") at a price that aligns with the cost at which the FQHC acquired the medication. FQHCs are community-based health care providers that provide primary care services in underserved areas. FQHCs receive discounted prices through the 340B Prescription Drug Program on prescription drugs.

The Order directs the Secretary of HHS to condition future grants available to FQHCs on establishing practices to make insulin and injectable epinephrine available at the 340B discounted price paid by the FQHCs, plus a minimal administration fee, to individuals with low incomes. The Order specifies that low income individuals include those who (a) have a high cost-sharing requirement for either insulin or injectable epinephrine, (b) have a high unmet deductible, or (c) have no healthcare insurance.

Lowering Prices for Patients by Eliminating Kickbacks to Middlemen

This **Executive Order** directs the Secretary of HHS to finalize a February 2019 **proposed rule** that would revise the discount safe harbor to the federal Anti-Kickback Statute ("AKS") with respect to pharmaceutical manufacturer rebates to health plans and pharmacy benefit managers ("PBMs"). Prior to finalizing the rule, the Order requires the Secretary of HHS to publicly confirm that the rule "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." Specifically, the Order directs the Secretary of HHS to "complete the rulemaking process he commenced seeking to:

> (a) exclude from safe harbor protections under the anti-kickback statute, section 1128B(b) of

> the Social Security Act, 42 U.S.C. 1320a-7b, certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs operating the Medicare Part D program; and
>
> (b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale in order to lower the patient's out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees."

The Order makes it clear the Administration view rebates as the "functional equivalent of kickbacks" that "erode savings that could otherwise go to the Medicare patients taking those drugs. Yet currently, Federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law." The policy objective of the order is to ensure that discounts offered on prescription drugs are passed on to patients. The Order states that, narrowing the safe harbor for discounts under the AKS will allow for billions in dollars of rebates in the Medicare Part D program to go patients at the point of sale.

The Administration's policy positions and proposals in the Order and the prior proposed rule have elicited strong reactions from various stakeholders who suggested they may challenge any changes implemented as a result of this Order.