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Legal Sidebar

National Opioid Litigation: Settlement Agreements as of January 2025

February 19, 2025

According to data from the Centers for Disease Control and Prevention, over a million Americans have died of opioid-involved overdoses since 1999, with deaths rising by 67% between 2017 and 2023. This increase in opioid-involved deaths since 1999 is often described as having occurred in several waves, including an initial wave attributable to the misuse and diversion of prescription opioids (e.g., OxyContin); a second wave attributable to the increased availability of heroin; and a third wave attributable to the misuse of pharmaceutical fentanyl and increased availability of illicit, non-pharmaceutical fentanyl. While 2023 saw the first annual decrease in opioid-involved deaths since 2018, with the trend continuing in 2024, the death toll remains high relative to the beginning of the opioid crisis. In response to the opioid crisis, federal, state, and local governments have undertaken numerous measures to curb opioid misuse and drug-related overdose deaths. Congress enacted several laws intended to address the crisis in part by providing federal funds to expand the availability of substance use prevention, treatment, and recovery services nationwide.

In addition to receiving these federal funds, state and local governments at the forefront of the opioid crisis buttressed their efforts to address the crisis by pursuing a substantial number of civil lawsuits against entities along the prescription opioid supply chain. These lawsuits—numbered in the thousands and filed all over the United States beginning around 2017—typically alleged that the supply chain entities engaged in various conduct, such as misleading promotion or inadequate control of prescription opioids, that fueled the initial wave of the opioid crisis. After several years of litigation, many of the parties in these lawsuits have reached finalized national settlement agreements under which state and local governments have begun to receive payments to be used to abate the opioid crisis. This Sidebar answers several frequently asked questions about those settlement agreements and highlights certain selected considerations for Congress.

What Are the National Opioid Settlement Agreements?

The national opioid settlement agreements each resolved the majority, if not all, of claims asserted by state and local governments from across the country against a particular settling prescription opioid supply chain entity. **Table 1** summarizes the key terms of the national opioid settlement agreements that have been finalized to date. The supply chain entities that are parties to these agreements include those

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LSB11270

that manufactured, promoted, distributed, or dispensed prescription opioids. Under these settlement agreements, the state and local government plaintiffs generally agreed to refrain from continuing to pursue the claims asserted in their lawsuits or from pursuing any future claims related to the prescription opioid products at issue in those lawsuits. In exchange, the settling supply chain entities generally agreed to pay certain settlement funds to the state and local governments and to engage in certain conduct to help mitigate potential opioid misuse or diversion.

What Are the Terms of the National Opioid Settlement Agreements?

Under the terms of these national opioid settlement agreements, as reflected in **Table 1**, the settling supply chain entities generally agreed (1) to pay a monetary settlement amount to be allocated among the settling state and local governments, often distributed over the course of several years, and (2) to undertake certain entity-specific business practices—pursuant to what are known as the injunctive relief terms—aimed at preventing the misuse or diversion of opioid products or to refrain from engaging in certain practices that may lead to misuse or diversion. The plaintiffs also generally agreed to use a majority of the settlement amounts received (often 85% or more) to abate the opioid crisis, using strategies specified in the agreements. Such strategies include, for instance, programs that expand availability of medication-assisted treatment, provide comprehensive wraparound services to individuals with opioid use disorders, and increase the availability of naloxone (a medication that can reverse an opioid overdose).

The injunctive relief terms included in the national settlement agreements generally differ depending on the role of a settling defendant in the prescription opioid supply chain. Manufacturers, for instance, generally agreed to refrain from engaging in certain marketing practices with respect to opioid products, such as providing incentives to its sales and marketing employees based on sales volume or sales quotas for such products. Their third-party consultants and advertisers, meanwhile, generally agreed to refrain from taking any future client engagements related to the promotion of opioid products. Pharmacies generally agreed to, for around a 10-year period, maintain a prescription validation process that identifies potential red flags associated with a controlled substances prescription. Distributors agreed to implement, for 10 years, various measures—such as establishing data-based ordering thresholds—to detect suspicious opioid orders from customer pharmacies. There have been reports that these thresholds—which the settlement agreement requires the distributors to set based on factors such as a particular customer's ordering history and the ordering history of customers within similar regions—have caused certain pharmacies to become hesitant to order and fill prescriptions for certain controlled substances such as buprenorphine, a Schedule III controlled substance prescribed by accredited opioid treatment programs to treat opioid use disorder.

Table 1. Overview of Monetary Settlement Amounts and Selected Nonmonetary Terms in Finalized National Opioid Settlements as of January 2025

Entity Type and Settling Supply Chain Entity	Reported Settlement Amount	Payment Distribution to States and/or Local Governments	Selected Nonmonetary (Injunctive Relief) Terms
Distributors			

Entity Type and Settling Supply Chain Entity	Reported Settlement Amount	Payment Distribution to States and/or Local Governments	Selected Nonmonetary (Injunctive Relief) Terms
McKesson, Cardinal Health, and AmerisourceBergen (now Cencora)	Up to $21 billion over 18 years	Began in May 2022	Until around April 2032, establish and maintain a centralized independent clearinghouse to provide all three distributors and state regulators with aggregated data and analytics about where drugs are going and how often; implement various measures to detect suspicious opioid orders from customer pharmacies, including establishing data-based thresholds and metrics to identify red flags; refrain from compensating sales personnel based on revenue or profitability targets for sales of controlled substances
Manufacturers			
Janssen Pharmaceuticals[a]	Up to $5 billion over no more than 9 years	Began in October 2022	Refrain from manufacturing and selling opioids; refrain from promoting opioid products in certain manners, including by contracting with third parties; refrain from providing financial incentives to manufacturer's sales and marketing employees based on sales volume or sales quotas for opioid products
Teva Pharmaceuticals	Up to $4.25 billion over 13 years[b]	Began in January 2024	Refrain from promoting opioid products in certain manners, including by contracting with third parties; refrain from providing financial incentives to manufacturer's sales and marketing employees based on sales volume or sales quotas for opioid products; monitor for off-label prescribing of certain fentanyl products
Allergan	Up to $2.02 billion over 7 years	Began in January 2024	Until around July 2033, refrain from manufacturing and selling opioids; refrain from promoting opioid products in certain manners, including by contracting with third parties; refrain from providing financial incentives to manufacturer's sales and marketing employees based on sales volume or sales quotas for opioid products
Mallinckrodt	$700 million	Completed in August 2023	Refrain from promoting opioid products in certain manners, including by contracting with third parties; refrain from providing financial incentives to manufacturer's sales and marketing employees based on sales volume or sales quotas for opioid products; refrain from manufacturing, promoting, or distributing any opioid products that exceeds 30 milligrams of oxycodone per pill
Endo Health Solutions	Approximately $450 million over 10 years	First payment not yet reported	Refrain from promoting opioid products in certain manners, including by contracting with third parties; refrain from providing financial incentives to manufacturer's sales and marketing employees based on sales volume or sales quotas for opioid products; refrain from manufacturing, promoting, or distributing any opioid products that exceeds 30 milligrams of oxycodone per pill

Entity Type and Settling Supply Chain Entity	Reported Settlement Amount	Payment Distribution to States and/or Local Governments	Selected Nonmonetary (Injunctive Relief) Terms
Pharmacies			
Walgreens	Up to approximately $4.95 billion over 15 years	Began in January 2024	Until August 15, 2032, maintain independent departments to oversee compliance with controlled substances laws and injunctive terms in the settlement agreement; prohibit pharmacists from facing negative employment consequences for failing to meet targets that depend on sales of controlled substances; maintain a prescription validation process that identifies potential red flags associated with a controlled substances prescription
CVS	Up to $4.9 billion over 10 years	Began in January 2024	Until August 15, 2032, maintain independent departments to oversee compliance with controlled substances laws and injunctive terms in the settlement agreement; prohibit pharmacists from facing negative employment consequences for failing to meet targets that depend on sales of controlled substances; maintain a prescription validation process that identifies potential red flags associated with a controlled substances prescription
Walmart	Up to approximately $3.1 billion over 6 years	Began in January 2024	Until around December 2032, maintain independent departments to oversee compliance with controlled substances laws and injunctive terms in the settlement agreement; prohibit pharmacists from facing negative employment consequences for failing to meet targets that depend on sales of controlled substances; maintain a prescription validation process that identifies potential red flags associated with a controlled substances prescription
Consultants/ Advertisers			
Kroger	Up to $1.4 billion over 11 years	First payment not yet reported	Until November 15, 2032, maintain independent departments to oversee compliance with controlled substance laws and injunctive terms in the settlement agreement; prohibit pharmacists from facing negative employment consequences for failing to meet targets that depend on sales of controlled substances; maintain a prescription validation process that identifies potential red flags associated with a controlled substances prescription
McKinsey	Nearly $600 million to states and $207 million to local governments	Completed in 2021	Adopt specified document retention plan; refrain from accepting any future client engagements related to the development, sale, or promotion of any opioid product; publicly disclose documents relating to McKinsey's past work for opioid manufacturers
Publicis	$343 million	Completed in 2023	Refrain from accepting client work related to opioid or other opioid-based Schedule II or Schedule III controlled substances; publicly disclose internal documents detailing firm's prior marketing work related to opioid products

Source: CRS analysis of relevant national opioid settlement agreements.

a. Janssen Pharmaceuticals is a subsidiary of Johnson & Johnson, which is also party to the settlement agreement.

b. The settlement amount includes, at the election of the states, a 10-year supply of a generic naloxone valued at up to $1.2 billion, or $240 million in lieu of product.

How Are the Settlement Funds Allocated Among the State and Local Government Plaintiffs?

In general, the relevant national opioid settlement agreements first allocate the settlement funds among settling states in proportion to an allocation percentage set forth in the agreement. A settling state, in turn, further allocates that amount among itself and settling subdivisions of that state. The agreements generally provide flexibilities to states in determining how to make that state-level allocation. The agreements contemplate, for instance, allocation based on the terms negotiated between a state and its subdivisions, based on the requirements of a state allocation statute or statutory trust, or pursuant to the terms of the relevant national opioid settlement agreements, which generally specify certain subdivision allocation percentages.

The national opioid settlement agreements generally require the settling states to designate an Opioid Settlement Remediation Advisory Committee (Advisory Committee) meeting certain requirements to provide input and recommendations regarding spending related to opioid abatement.

How Have the State and Local Governments Used Their Settlement Funds?

Not all states appear to make information publicly available regarding the use of their opioid settlement funds. States that have provided public information have provided different degrees of information. While some states have, for instance, made publicly available only the recommendations made by their respective Advisory Committees, other states have more specifically identified the activities supported by the settlement funds. In many states, the state legislatures have enacted statutes to establish a specific fund or account where opioid settlement agreement funds are deposited. These states explain that a portion of that fund, in accordance with the terms of the settlement agreement, directly provides funds to the states' local governments to be used at their discretion for opioid remediation purposes permitted by the settlement agreements. Another portion of the fund, these states further explain, is allocated to the state for opioid remediation. Use of that fund is determined and appropriated by the state legislature and subject to the state budgetary processes. Some states have itemized the programs supported by such state funds and the amount of support. Such programs include, for example, projects aimed at providing training for members of the substance use provider workforce, facilitating naloxone distribution, and educating youth about opioids and fentanyl.

Can the Federal Government Oversee How the State and Local Governments Use Their Settlement Funds?

It is not clear that the federal government is authorized to oversee the state and local governments' use of their settlement funds. Some commentators have suggested that certain federal agencies—namely, the Centers for Medicare & Medicaid Services (CMS) and the Substance Abuse and Mental Health Services Administration (SAMHSA)—may have authority to review how state and local governments are spending their opioid settlement funds. Such oversight, they argued, could help to ensure that the funds are being used in ways that complement the use of federal funds to address the opioid crisis. These commentators argue, for instance, that such authority may stem from CMS's obligation, under Social Security Act (SSA) Section 1903(d)(3)(A), to recoup from states "the pro rata share ... of the net [Medicaid overpayment] recovered during any quarter by the State or any political subdivision thereof." These commentators reasoned that this recoupment authority encompasses the authority "to examine the [states'] settlement spending to ensure that it is consistent with the settlement agreements and is not increasing future federal Medicaid obligations."

This theory of authority hinges on the presumption that the opioid settlement agreements—like the tobacco master settlement agreement negotiated by states in the 1990s—settled claims primarily intended to recover the states' Medicaid expenses used to treat the relevant illnesses caused by the defendants' conduct. Unlike the claims that formed the basis of the tobacco master settlement agreement, however, the claims that form the basis of the opioid settlement agreements sought to recover for injuries beyond Medicaid expenses, including expenses related to law enforcement and other social and emergency response services. Thus, as a threshold matter, the link between recovery of Medicaid expenses and the national opioid settlement agreements is weaker than the link between recovery of Medicaid expenses and the tobacco master settlement agreement. Further, to the extent a portion of the opioid settlement fund may be attributed to state Medicaid expenses, CMS's authority under SSA Section 1903(d)(3)(A) may be limited to determining the appropriate pro rata share of any such amounts considered to be the states' recovery of Medicaid overpayments already made. Section 1903(d)(3)(A) may not authorize CMS to more broadly review states' use of opioid settlement funds to *prevent* potential future overpayments. Construing the provision to provide such authority would potentially subject state and local governments to federal oversight on any funding use that could lead to increases in state Medicaid expenditure. This potentially expansive oversight authority may require a clearer grant of such authority to CMS.

Similarly, it is unclear whether SAMHSA's authority to administer various federal substance abuse and treatment-related grant programs, including the Substance Use Prevention, Treatment, and Recovery Services Block Grant (formerly the Substance Abuse Prevention and Treatment Block Grant [SABG]) and State Opioid Response (SOR) Grants, could be used to oversee funds other than the federal funds supporting these programs. Reporting requirements for these grant programs, for instance, are generally limited to reports about the use of relevant federal grant funds. These provisions may not provide clear notice to recipients of an obligation to publicly report the use of a separate funding stream that the federal government did not provide or help the states secure. Consistent with these provisions, the Office of National Drug Control Policy, a component of the Executive Office of the President that coordinates the development and implementation of federal drug policy, stated, during the Biden Administration, that it "does not have the statutory authority ... to require states that receive Federal funding—including ... from the [SOR Grants] and [SABG]—to adhere to and publicly report on the opioid abatement stipulations of the settlement agreements."

What Happened to the Settlement Agreement with Purdue Pharma?

One national opioid settlement agreement that was reached in 2021 but has not been finalized involves Purdue Pharma, the manufacturer of OxyContin (an oxycodone opioid pain medication). The intensified marketing of OxyContin and other prescription pain medications, together with an influential pain advocacy campaign that encouraged greater pain management, is generally considered to have contributed to the initial wave of the opioid crisis between 1999 and 2010. As a result, Purdue Pharma has been the subject of suits or investigations by not only state and local government plaintiffs but also the federal government, individuals, and various other entities.

In 2019, Purdue filed for Chapter 11 bankruptcy. The bankruptcy proceedings resulted in a reorganization plan, confirmed by the bankruptcy court, that would have—among other terms—established several trusts that would make payments to satisfy the claims brought by various plaintiffs, including a National Opioid Abatement Trust (NOAT). The NOAT would receive up to $6 billion to satisfy the claims of state and local governments and would also own a new company that would develop and distribute opioid addiction treatment and overdose reversal medications. This new company would be formed using the operating assets transferred from Purdue, which would cease to exist. The Sackler family, which owned and controlled Purdue but did not file for bankruptcy themselves, would contribute $4.325 billion to the bankruptcy estate under the plan. In exchange, the Sackler family would be released from all pending and future claims asserted against them that are related to Purdue's estate and for which Purdue's conduct was

a legally relevant factor. The bankruptcy court confirmed the plan over the objections of several creditors and the U.S. Trustee, who opposed the release provided to members of the Sackler family, who are not debtors in the bankruptcy proceeding.

Certain objecting parties appealed the bankruptcy court's confirmation order, arguing in part that the bankruptcy code does not permit the plan's inclusion of the release for the Sackler family. The appeal made its way to the Supreme Court. In June 2024, the Supreme Court, in *Harrington v. Purdue Pharma L.P.*, agreed with the objectors and held that the bankruptcy code does not authorize a release that seeks to discharge claims against a non-debtor without the consent of affected creditors.

Following the Supreme Court's decision, negotiations for a new plan of reorganization began. On January 23, 2025, a coalition of 15 states announced that they had reached an agreement in principle with Purdue that would require Purdue and the Sackler family to pay $7.4 billion to satisfy the claims of state and local governments. The agreement reportedly shields the Sackler family only from suits brought by entities that are parties to the agreement, which is being reviewed by additional states that will decide whether to join it. Any finalized agreement would also be subject to approval by the bankruptcy court.

Considerations for Congress

The monetary portions of the national opioid settlement agreements effectively provide state and local governments with a separate funding stream, in addition to federal funds, to address the opioid crisis. In addition, the agreements' injunctive relief terms impose certain requirements—some on a time-limited basis—on the settling supply chain entities outside of governmental requirements. As the opioid crisis continues to evolve, and to the extent Congress considers whether and how to provide additional federal support to address it, federal lawmakers may take into account the measures implemented pursuant to the settlement agreements; evaluate their impact on the crisis; and based on that assessment, determine whether to adopt or override certain measures.

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