

Proposed opioid litigation comprehensive settlement and injunctive relief terms that may impact retail pharmacy customers

On February 25, 2021, AmerisourceBergen Drug Company (ABDC), Cardinal Health (CAH), and McKesson Corporation (McKesson) announced that there was sufficient participation nationwide to move forward with the previously-announced national settlement with states and local government entities. The settlement resolves the vast majority of opioid-related lawsuits filed by state and local government entities across the country. Under the agreement, the three wholesale distributors will pay up to approximately \$19.5 billion over 18 years to resolve these lawsuits and unfiled opioid claims.

As part of the agreement, court-ordered injunctive relief will apply to each distributor's Controlled Substance Monitoring Program (CSMP). The injunctive relief will become effective a short time after the settlement agreement becomes effective and continues for ten years thereafter. Pharmacy customers will be notified when the injunctive relief terms go into effect, which we expect will occur in July 2022.

The purpose of this communication is for AmerisourceBergen Drug Corporate (ABDC) to provide its retail pharmacy customers with an overview of the court-ordered injunctive relief terms that may impact their dealings with these wholesale distributors.

What Injunctive Relief Terms Apply to Retail Pharmacy Customers?

The injunctive relief terms include requirements relating to the distribution of controlled substances to independent and chain retail pharmacy customer locations. Certain changes to existing practices will be made around customer diligence reviews, data collection and analysis, setting monthly limits on controlled substances ordering, and suspicious order reporting. The distributors' compliance with these requirements will be subject to reviews by an independent, third-party monitor for the first five years of the ten-year term. The distributors will continue to maintain anti-diversion programs consistent with the requirements of the federal Controlled Substances Act, DEA regulations, and applicable state laws and regulations.

Customer Diligence Reviews. The injunctive relief terms set out standardized principles for the distributors to follow when conducting due diligence of retail pharmacy customers at onboarding and throughout the distribution relationship. They include the continuation of industry practices that retail pharmacy customers are likely familiar with, such as the completion and collection of pharmacy questionnaires, site visits, and interviews with pharmacy staff.

Customer Data Analysis. Under the injunctive relief terms, distributors must regularly analyze retail pharmacy customers' ordering and dispensing of controlled substances and monitor for any licensing or other regulatory actions involving the customer or pharmacists working for the customer. Although distributors have been analyzing pharmacy ordering and dispensing practices for many years, the injunctive relief terms standardize these practices and necessary datasets.

Ordering Thresholds and Suspicious Order Reporting. Under the injunctive relief terms, distributors will also use primarily statistical model-based thresholds to set customer-specific ordering limits on individual DEA base codes. Orders that cause a pharmacy customer to exceed an established threshold will generally be blocked, not shipped, and reported as suspicious to states that request such reporting and to the DEA.

Independence of CSMP Personnel. Under the injunctive relief terms, each distributor's CSMP personnel are responsible for decisions related to customers' receipt of controlled substances, including whether to distribute controlled substances to a particular customer or the setting or adjusting of controlled substance thresholds. CSMP personnel make these decisions independently, without input or involvement from the distributor's Sales personnel. Customers should engage with CSMP personnel regarding decisions about the setting or adjusting of thresholds.

Data Clearinghouse. The injunctive relief also contemplates the creation of a “Clearinghouse,” which will be used to collect and analyze data from distributors and potentially other parties, including retail pharmacy customers. It is anticipated that the Clearinghouse will be operational approximately one year after the settlement agreement becomes effective.

What does this mean to retail pharmacy customers?

You will receive more information about the anticipated timing surrounding the implementation of the injunctive relief. After the injunctive relief terms are implemented, pharmacy customers should expect more frequent interactions with CSMP personnel, including requests for specific information in connection with these injunctive relief terms.

Most significantly, under the injunctive relief terms, retail pharmacy customers will need to provide specific datasets regarding their dispensing so that their distributors may:

- Review the total number of prescriptions and dosage units for each NDC for all dispensed prescription medications;
- Evaluate a pharmacy’s sales of controlled substances to cash-paying patients;
- Review information related to a pharmacy’s top prescribers of certain controlled substances considered to be highly abused or diverted; and
- Consider the extent to which a pharmacy services out-of-area patients.

Although some of this data may be currently provided to one or more of the distributors, implementation of the injunctive relief will necessitate a change to the format and scope of the data.

Additionally, retail pharmacy customers can expect that the pharmacy questionnaires, customer interviews, and due diligence requirements currently in use by one or more distributors will also change as the distributors adapt to the specific injunctive relief terms regarding customer diligence. Lastly, under the injunctive relief terms, retail pharmacy customers that are terminated from, or declined to be onboarded for, controlled substances ordering due to concerns regarding the customer’s ability to provide effective controls against the potential diversion of controlled substances will be reported to the state attorney general’s office for their location.

What will happen next?

We appreciate that this initial description of the injunctive relief terms will require additional communications and discussions about how it will affect your distributor relationship. You can expect that, as AmerisourceBergen prepares to implement the changes, we will contact you to provide additional information to assist you.