

DEA launches new ARCOS enhancement to help manufacturers and distributors "know your customer" and detect suspicious orders

March 5, 2019

The U.S. Drug Enforcement Administration (DEA) announced last week that it launched a new tool for its Automated Reports and Consolidated Orders System (ARCOS) Online Reporting System that "will allow DEA-registered manufacturers and distributors to view and download the number of distributors and the amount (anonymized data in both grams and dosage units)" of a controlled substance that "each distributor sold to a prospective customer in the last available six months of data."

Under the Controlled Substances Act (CSA) and DEA regulations, manufacturers and distributors are required to design and operate a system that discloses suspicious orders of controlled substances, and to report such suspicious orders to DEA upon discovery. The agency has stated that in order to fulfill this obligation, manufacturers and distributors should "know your customer." According to DEA, "manufacturers and distributors have consistently expressed a desire for assistance from DEA in fulfilling these obligations and have requested ARCOS information to help them make informed decisions about whether new customers are purchasing excessive quantities of controlled substances."

ARCOS is DEA's online system that monitors the distribution of controlled substances from the point of manufacture through commercial drug supply-chain channels to the point of sale to the retail level (e.g., pharmacies, hospitals/clinics, and practitioners). The new ARCOS tool will provide additional information to manufacturers and distributors to assist them in their suspicious order monitoring obligations. According to the agency, "if a query resulted in a large number of suppliers who have recently sold unusual quantities of opioid analgesics to a prospective purchaser, this may represent a 'red flag' to the new distributor and foster a dialogue between that distributor and the pharmacy."

This new ARCOS tool is required by the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act," which we summarized [here](#). The law requires DEA to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates.

The SUPPORT Act amended the CSA to require manufacturers and distributors to review this information now made available through the new ARCOS tool. The amendments also provided for civil penalties or criminal fines for manufacturers and distributors of opioids who fail to review the most recent information related to their customers that has been made available through the new ARCOS tool. Additionally, the amendments allow the U.S. Department of Justice (DOJ) and DEA to "take into account" ARCOS data made available to a registrant through the new ARCOS tool in determining whether to initiate proceedings against the registrant for failure to maintain effective controls against diversion.

We will continue to closely monitor the implementation of the new ARCOS tool and its functionality. To the extent that you would like additional information on the new ARCOS tool or would like assistance in evaluating the robustness of your firm's suspicious orders monitoring and reporting system, please contact one of the authors of this article or the lawyer at Hogan Lovells with whom you regularly work.

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