The Pharmaceutical Supply Chain & Impacts of Advance Price Notification

The pharmaceutical supply chain is set up to enable the seamless, safe and reliable flow of medicines from a manufacturer to a patient. The entities behind the scenes that make this process work include the following:



Pharmaceutical Manufacturers

Manufacturers ship medicine through contracts with distributors and other direct purchasers, such as pharmacies, hospitals or physician's offices



Wholesale Distributors

Wholesale distributors act as the shipping centers for manufacturers and pharmacies and maintain the proper supply needed for distribution to pharmacies



Pharmacies

Pharmacies serve as the point of sale for patients and rely on manufacturers and distributors to deliver the correct amount of product

Consequences of of Advance Price Notification on the Pharmaceutical Supply Chain

There are proposals popping up nationwide that would require pharmaceutical manufacturers to submit reports to the government, public and private insurers, and pharmacy benefit managers (PBMs) relaying increases in the list price of a medicine prior to the price increase taking effect. While these proposals purport to be a way to lower prescription drug prices, the actual impact of advance price notifications could have serious unintended consequences.

1. It Will Not Save Money for Consumers or the Government



Patients: A patient's out of pocket cost for medicines is determined by their insurance benefits. Mandatory price reporting of a medicine's list price has little bearing on what patients actually pay for their medicine.



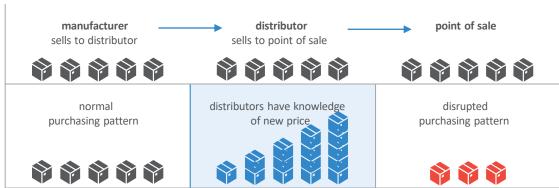
Government: State and federal government agencies that purchase medicines would have to contend with constantly shifting medicine prices, the administrative burden of which would not give them any benefits.

2. It Could Lead to Speculative Purchasing

In the past, speculative purchasing was a practice used by distributors to profit from fluctuations in medicine prices, a problem that the pharmaceutical industry and the federal government have nearly eliminated in recent years. Advance price notification creates a new incentive for some distributors – especially those that do not enter into contractual agreements with manufacturers to manage medicine supplies – to profit from purchasing medicines at the "old price" and selling them at the "new price" when an increase is made public.

Normal pharmaceutical purchasing pattern

Knowledge of advanced price notification leads to stockpiling

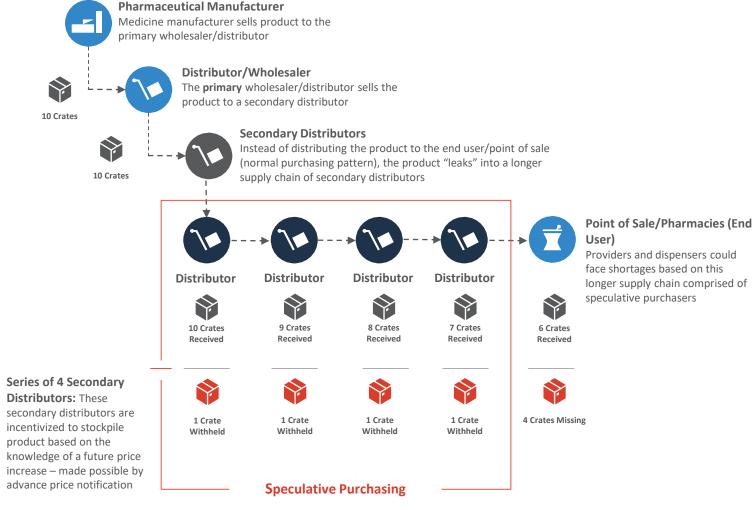


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3. It Could Lead to Medicine Shortages

While medicine shortages can be caused by a variety of factors, including production delays due to a lack of raw materials and components from suppliers, or discontinuations of medicine production, they can also be caused by disturbances within the pharmaceutical supply chain. Those disturbances are often the result of distribution methods that restrict or deviate from the usual pharmaceutical supply chain. A prime example of these atypical distribution methods is the practice of stockpiling medicine in advance of a price increase or hoarding in response to an impending shortage. In this scenario, a supply chain entity may be incentivized to re-sell a medicine to another intermediary, also known as "secondary distributor."

In the event this happens, product supply may be stretched thin and downstream prices may increase, exacerbating a medicine shortage.



^{*}This graphic is based on a Congressional investigation into drug shortages which resulted in a bicameral report titled: "Shining Light on the Gray Market"

- 1 https://www.congress.gov/bill/113th-congress/housebill/3204/text?q=%7B%22search%22%3A%5B%22H.R.+3204%22%5D%7D&r=1
- $2 \quad \underline{\text{http://www.drugchannels.net/2017/10/thanks-california-sb17-will-trigger.html}}\\$
- 3 https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q4
- 4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/
- Fox E, Birt A, James K, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. Am J Health Syst Pharm. 2009;66:1399–1406.
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- 6 Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply. National Association of Boards of Pharmacy. August 2013 https://aps.pharmacy./www.content./unloads/2016/07/Wholesale-Drug-Distribution-08-2013.pdf
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