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FDA Proposed Rule is Game Changer for U.S. Pharmacy Supply Chain

(Source: An Article by Martha Rumore for Pharmacy Times)

Earlier this year the U.S. Food and Drug Administration (FDA) published a long anticipated proposed rule which will essentially change the landscape for regulation of wholesale drug distributors (WDD), third-party logistic providers (3PLs) as well as pharmacy-to-pharmacy and pharmacy-to-wholesaler product sales. The goal is to reduce diversion of pharmaceutical products via sales by unlicensed distributors and to further secure the supply chain by vetting trading partners in the U.S.

Forum shopping by diverters for states with less stringent licensure and regulatory requirements will be prevented by a uniform regulatory framework. Pursuant to the 2013 Drug Quality and Security Act, the FDA has now developed national standards and a federal licensing system for WDD and 3PLs, which would eventually replace the state regulatory patchwork that currently exists. FDA is also proposing to replace the current 21 CFR, Part 205, which provides guidelines for state licensing of WDDs.

State licensure programs consistent with federal licensure standards would be permitted to remain, although it is assumed these would be eventually phased out by the individual states. For states that choose not to license, absent a state licensure program, the national program would apply. States with requirements that differ from those on the national level (e.g., for "designated representatives," Florida's exam, California's self-assessment, or New Mexico's training program) will be preempted.

Federal licensure standards will decrease both the administrative and cost burdens for these entities that currently are subject to varied state licensure requirements, as well as "ship to" license requirements. WDDs and 3PLs would be required to report to the FDA, undergo routine inspections every 3 years or more often, write, and revise standard operating procedures required for equipment maintenance, personnel, transportation, and authorized trading partners, and conduct criminal background checks for all designated representatives and facility managers. The FDA may also evaluate certain approved organizations as appropriate and designate them to conduct licensing and inspections on its behalf. For 3PLs, the proposed rule establishes many new requirements.

For retail pharmacies, the proposed rule has several provisions. Stricter state requirements, such as Oklahoma's rule that a wholesaler cannot be physically located in a pharmacy, would be preempted. The proposed rule will codify the 5% rule, which currently states that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use are considered minimal and do not constitute wholesale distribution if the total dollar volume of these sales does not exceed 5% of the total dollar

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In Brief...

- Global healthcare company **AmerisourceBergen (ABC)** announced its partnership with **Chronicled**, the administrator of the MediLedger Network, to leverage a new blockchain-powered solution designed to enhance pharmaceutical chargeback accuracy and significantly reduce chargeback rejections. The blockchain solution will allow ABC to streamline and optimize the complex process of pharmaceutical chargebacks while creating greater connectivity for its suppliers and customers. Over the past three years, ABC has collaborated closely with Chronicled to design and pilot the technology for commercial use. Separately, ABC announced it has exceeded 5 million COVID-19 vaccine doses allocated to independent pharmacies across the U.S. This effort is a part of the Federal Retail Pharmacy Program for COVID-19 Vaccination, a collaboration between the Federal Government, U.S. states and territories, and 21 national pharmacy partners, including **Good Neighbor Pharmacies**.
- For the 8th year in a row, **Walgreens** will celebrate *Red Nose Day* as the exclusive retailer of the nationwide campaign to help end the cycle of child poverty. After two years of only the digital red nose filter being available, customers will once again be able to purchase the iconic Red Nose at their local Walgreens now through May 31, in addition to using the Red Nose filter.
- French pharma manufacturer **Sanofi** kicked off construction

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IQVIA Reports Medicine Spending Rose due to COVID-19 Vaccine Therapies

(Source: A U.S Medicines Trends 2022 Report by IQVIA)

Spending on medicines in the United States, at estimated net manufacturer prices, reached US$407 billion in 2021, up 12% over 2020, as COVID-19 vaccines and therapeutics became widely available and added US$29 billion in related spending, according to a new U.S. Medicines Trends 2022 Report, released by the IQVIA Institute for Human Data Science.

In the same year, the non-COVID medicines market grew at a much slower rate of 5% due to the impact of biosimilars, which increased significantly, offsetting increased use of branded medicines, according to the report. The report also revealed that patient out-of-pocket costs in aggregate rose US$4 billion, or 5.3%, in 2021 to a total of US$79 billion, back to the level seen in 2018 after two years of declining costs. Those out-of-pocket costs remain a significant burden for a relatively small part of the population, even as average costs per prescription were flat or slightly declining.

"The rise in U.S. medicine spending was largely driven

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U.S. Supply Chain (cont.)...

volume of that retail pharmacy's annual prescription sales.

Sales above 5% for office use, or any sales to a wholesale distributor, require the pharmacy to become licensed and regulated as a wholesale distributor. This will eliminate diversion caused by pharmacies purchasing product from an unlicensed wholesaler or another pharmacy and selling their inventory to wholesalers. Transfers or sales between pharmacies or from pharmacies to practitioners for a specific patient are already not considered wholesale use.

+Currently, some states allow for the 5% distribution by pharmacies to other entities, e.g., pharmacy-to-pharmacy or pharmacy-to-contract research organization, which are not for a specific patient. The FDA has indicated in the proposed rule that this is not permitted under the statutory language of the FDC Act and is seeking comments on it.

According to the National Association of Boards of Pharmacy (NABP)'s 2013 report entitled "Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply," drug diverters seek to take advantage of gaps in the distribution chain, specifically seeking out states whose licensure framework is less stringent. This proposed rule, when finalized, and the preemption of inconsistent state provisions will remedy this forum shopping for diverters seeking to take advantage of the lack of uniform framework. Additionally, NABP's 2013 report also contends that the so-called 5% rule is a policy that has been ripe for exploitation due to the policy being inconsistently legislated, interpreted, and enforced from state to state.

Interpretation of the 5% rule was not classified and NABP observed that "pharmacies acting as wholesalers have been found to take advantage of the parameters set by some states (regarding minimal quantities) when it comes to drug distribution. Rather than dispensing the drugs as mandated, these pharmacies retain them to resell to wholesalers at an amount exceeding the specified quantity of prescription medications as permitted in certain states (oftentimes 5% of annual sales.)

Some have gone as far as to sell their entire inventory into the gray market." This proposed rule, when finalized, satisfies the principle that the 5% rule only applies to pharmacy sales for office use. Stakeholders are currently analyzing the proposed standards as they prepare to deal directly with the FDA rather than the states. The deadline to provide comments on the proposed rule is June 6, 2022.

IQVIA Report (cont.)...

by the increased availability of pandemic vaccines, boosters, and treatments. It's a testament to the resiliency of the biopharmaceutical ecosystem to respond successfully to a healthcare crisis at both the global- and country-level, while continuing to improve outcomes across the broader healthcare spectrum," said Murray Aitken, IQVIA Senior Vice President and Executive Director of the IQVIA Institute for Human Data Science. "However, the US$4 billion increase in out-of-pocket costs for patients matched the historical high previously seen in 2018, which is a trend we will need to continue to watch."

Also pf note was that utilization of health services returned to near pre-pandemic levels by the end of 2021 but has yet to make up for the existing backlog of missed health services. *The IQVIA Health Services Utilization Index* — which tracks patient visits, screening and diagnostic tests, elective procedures and new prescription starts — increased to a level of 99 at the end 2021 compared to a baseline of 100 during the first eight weeks of 2020. This reflects a strong recovery in activity since the second quarter of 2020, when the index stood at 66.

Additionally, prescription drug use reached a record level of 194 billion daily doses in 2021 as new prescription starts for both chronic and acute care recovered from the slowdown recorded in 2020 during the height of the pandemic. Days of therapy for all types of prescription medicines were up 3.3% last year, rebounding from the 1.9% growth in 2020.

Differences between list price spending and payer net spending exceeded by US$190 billion in 2021, representing a 24% discount off of average list price, up from US$118 billion, or 20% discount, in 2016 as negotiated discounts and rebates to payers and providers increased in competitive markets and 340B organizations accounted for a larger share of medicine use. That increase was largely driven by growth in auto-immune and oncology treatments, which have tripled in spending over that period while traditional drug classes have declined by 3% in aggregate, according to the report.

Lastly, the report projects that U.S. use and spending on medicines are expected to return to pre-pandemic growth trends by 2023 despite year-to-year fluctuations and incremental spending on COVID-19 vaccines and therapeutics.

"We expect to see compound annual growth of 2.1% (range of 1-4%) through 2026 and total market size of about US$450 billion on a net manufacturer price basis. Those levels are comparable to pre-pandemic rates," IQVIA stated.

In Brief (cont.)...

on the first of two *"Evolutive Vaccine Facilities"* (EVFs) with a combined investment of €900 million euros (US$976 million). Together, the two EVFs will help "pave the way for future vaccine innovation across the world," the company said in a release. The EVFs are designed for "agile and flexible" production of "multiple" vaccine and biologics platforms, including mRNA, enzymes and monoclonal antibodies, Sanofi said.

- *Joseph Romanelli* will return to **Merck** to lead its international health business in August after a briefly leading Ji Xing Pharmaceuticals. Romanelli, who launched his career at Merck in 1996 when he joined as a business manager, ascended through the ranks of the company, ultimately being tapped to lead Merck's business in China, a position he held from 2016 to 2021. In his new position, Romanelli will oversee the Human Health International division which includes 14,000 employees covering 75 markets outside of the U.S.
- The **World Health Organization** announced that it has strongly recommended use of **Pfizer's** *Paxlovid* for mild and moderate COVID-19 cases at the highest risk of hospitalization. The oral antiretroviral is "the best therapeutic choice for high-risk patients to date" the UN agency said, also urging for better availability, price transparency and the need for prompt and accurate testing.

(Sources: Business Wire, Company Press Releases, Drug Store News, Fierce Pharma, and World Pharma News)