



Capitol Agenda

THE INDEPENDENT FORUM

INDEPENDENT PHARMACY COOPERATIVE
Winter 2017

FDA Continues to Signal Limits on Office-Use Compounding

The DQSA law enacted in 2013 clearly retained to the states the ability to regulate pharmacy compounding operations within their borders – including those compounded products for office-use.

However, final FDA guidance states that “anticipatory compounding” by pharmacists under Section 503A can only be done in “limited quantities” of “no more than a 30-day supply ... to fill valid prescriptions it has not yet received.” Otherwise, only “outsourcing 503B facilities can compound and distribute sterile and non-sterile nonpatient-specific drug products to hospitals, clinics, and health care practitioners for office use.” In response, pharmacy champion Rep. Morgan Griffith (R- VA) along with Rep. Henry Cueller (D- TX) introduced the “Compounded Medications Act of 2017”

(H.R. 2871). This bill clarifies that the DQSA preserves the state pharmacy boards’ role in regulating compounded facilities and clearly allows for office-use of compounded products. Many patient and physician groups have expressed support for the legislation.



IPC anticipates that FDA will provide further guidance early next year that will help alleviate the financial burden on small pharmacies in meeting the onerous 503B compliance requirements. IPC continues to work with industry stakeholders and patients to preserve office-use compounding and the national system of state based regulation of compounded prescriptions.

CVS Aetna Merger: Bad Medicine

The question on many people’s minds is how is it legal for a company that sells medications to own the company that is supposed to keep them affordable? The CVS and Aetna merger creates this unwelcomed reality for patients and providers. The Coalition to Protect Patient Choice stated “mergers like these have a dismal history,” adding, “consumers suffer by paying more and getting less choice for the vital drugs they need.”

The companies have indicated that there would be strong firewalls to address confidentiality and conflicts of interest, but that same promise was made with the CVS-Caremark merger and resulted in numerous lawsuits and a FTC investigation. While vertical business integration has historically drawn less regulatory scrutiny, FTC should take a close look at the anti-competitive impact of this merger.

California AB 315 Seeks to Regulate Pharmacy Benefit Managers

At the request of Governor Jerry Brown, stakeholders including IPC will sit down this month to develop a robust PBM regulatory scheme that will withstand legal challenges. Assemblyman Jim Wood’s office is going to convene meetings between the Governor’s Office, pharmacy industry representatives and the Department of Managed Health Care to assist in the development of the regulatory framework and bill language. The goal is to have legislative language completed by mid-December so the measure could be

taken up, with improved pharmacy amendments, when the legislature reconvenes in January. Once approved, the bill will go back to the Assembly Floor for concurrence in the Senate before going to the Governor for consideration. If all goes as planned the measure will be on the Governor’s Desk by the end of January 2018. IPC and the California Pharmacists Association conducted an extensive media campaign in support of AB 315 that included engaging community pharmacists and meeting with the LA Times.

PBM Pharmacist “Gag Clauses” and Patient Slamming Draws Consumer Outrage



clauses” in their contracts they are prevented from discussing the questionable practice with customers or from volunteering lower-cost options. Patients may also be the victims of a PBM practice that utilizes private health information to steer patients to their own mail order pharmacies.

NBC recently reported in a segment titled, “Could Your Health Insurance Be Costing You Money at the Pharmacy,” that many patients are charged more for the same drug than if they had paid cash at the counter. They also reported pharmacists are prevented by some pharmacy benefit managers (PBMs) and insurance plans from suggesting lower cost payment alternatives. Pharmacists complain that because of so-called “gag

The Federal Courts have also taken notice as patients seek legal redress for higher costs. In Kimberly A. Negron v. Cigna, Case No. 3:16-cv-01702 (D. CT) plaintiff alleges violations of ERISA and RICO: that the company required network pharmacies to charge insured patients unauthorized and excessive amounts for prescription drugs, and established the spread and took illegal “claw backs.”

IPC Board of Directors Participate in Congressional Fly In



(L to R) Mike Flint, IPC CFO Chuck Benjamin, Mona Ghattas, Paul Grisnik, Kari VanderHouwen, Scott Patterson, KPSC CEO Pete Stern, Senator Jon Tester, IPC SVP of Government Relations Mark Kinney, John Coler, David Vasenden, Chris Darling, IPC President/CEO Don Anderson

The IPC Board of Directors descended on the nation's capital to deliver the message of how independent pharmacies are an integral part of a comprehensive health care solution. The two-day Congressional event included direct meetings with Senator John Tester (D-MT), Congressman Buddy Carter (R-GA) and John Coster of CMS. In addition, the Board conducted 28 Hill visits communicating legislative priorities directly with lawmakers. Issues important to independent pharmacies included: Medicare Part D transparency, DIR reform, Provider Status, office-use compounding and solutions to the opioid epidemic.

The 2017 IPC fly-in afforded the IPC Board the valuable opportunity to communicate their concerns to key members of Congress and their staffs. The fly-in enabled

IPC to provide firsthand, real-world examples of how legislation and regulation impact our business and our customers. The meetings reinforced the importance of pharmacists engaging with elected officials.

“This is a great opportunity for the IPC team to express our need for legislative support and to represent the needs of our members and their communities.” said Mark Kinney, IPC SVP of Government Relations. “It is crucial that we speak for our members and actively work to achieve legislative and public policy successes important to independent pharmacy.”



IPC Board of Directors with Rep. Buddy Carter (R-GA)



Chris Darling, Paul Grisnik, John Coler and Mark Kinney outside the office of Sen. Sherrod Brown (D-OH)



Mike Flint and John Covello with the health professional staff for Sen. David Perdue (R-GA)



1550 Columbus Street
Sun Prairie, WI 53590

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