6/10/2024

PDG-FDA Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint

June 17 12:30pm - 5:30pm | June 18 10:00am - 4:00pm | Washington, DC

This hybrid in-person/virtual meeting will serve as a checkpoint midway in the stabilization period, affording industry, FDA, and other stakeholders an opportunity to share stabilization progress that has been made, stabilization activity that remains, and areas of remaining concern. Discussion will seek to achieve two key meeting objectives:

1. Create and establish the current landscape that captures the demographics of industry readiness broken down by sector.
2. Establish a cross-stakeholder understanding of what it means for interoperable systems and processes to be "stabilized."

AGENDA

**All times are approximate and subject to revision. All times are ET.*

Monday, June 17	
Time*	**Description**
12:30-12:50	***Welcome and Introductory Remarks*** *Jacqueline Corrigan-Curay, Principal Deputy Center Director, FDA, CDER* *Eric Marshall, Executive Director, PDG* Representatives from FDA and PDG will provide opening remarks and discuss the goals and objectives of the public meeting.
12:50-1:15	***Key Takeaways from FDA's RFI on Implementation of Enhanced Drug Distribution Security Requirements*** *Abha Kundi, Team Lead, CDER, OC, ODSIR* FDA will summarize comments from its recent Request for Information (RFI), Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act.
1:15-1:40	***PDG Perspective on Stabilization Status*** *Matt Price, Board Chair, PDG* Each month, PDG's Interoperability Committee shares learnings, successes, and challenges in stabilization. PDG will share key takeaways and trends from those exchanges and its recent survey on stabilization.
1:40-2:30	***Manufacturer Perspectives on Stabilization*** *Moderator: Lysette Deshields, Regulatory Counsel, CDER, OC, ODSIR* *Gillian Buckley, Pharmaceutical Research and Manufacturers of America (PhRMA)* *E'lissa Flores, Biotechnology innovation Organization (BIO)* *Brian Rezach, Association for Accessible Medicines (AAM)* *Gil Roth, Pharma & Biopharma Outsourcing Association (PBOA)*

	Trade associations representing manufacturers will share their individual perspectives on industry progress toward stabilization and actions that all stakeholders can take to support continued progress. The presentations will be followed by a short discussion among the trade association representatives.
2:30-3:00	***BREAK***
3:00-3:45	***Wholesale Distributor Perspectives on Stabilization*** *Moderator: Sara Keller, Regulatory Counsel, CDER, OC, ODSIR* *Elizabeth Gallenagh, Healthcare Distribution Alliance (HDA)* *Christina Lavoie, Health Industry Distributors Association (HIDA)* Trade associations representing wholesale distributors will share their individual perspectives on industry progress toward stabilization and actions that all stakeholders can take to support continued progress. The presentations will be followed by a short discussion among the trade association representatives.
3:45-4:45	***Panel: Stabilization of Manufacturer-to-Wholesaler Data Exchange*** *Moderator: Elizabeth Gallenagh, Healthcare Distribution Alliance (HDA)* *Arthi Nagaraj, Sanofi* *Kristen Mattioni, Teva* *Maryann Nelson, Cardinal Health* *Pam Clements, Smith Drug* A diverse panel of manufacturers and wholesalers will discuss the status of stabilization as it relates to transactions between manufacturers and wholesale distributors. The panel will include an opportunity for audience Q&A.
4:45-5:30	***Facilitated Open Discussion: Reactions and Takeaways*** *Leigh Verbois, Office Director, CDER, OC, ODSIR* *Eric Marshall, Executive Director, PDG* FDA and PDG will facilitate discussion among all participants and seek to highlight takeaways and opportunities from the day's sessions.

TUESDAY, JUNE 18	
10:00-10:10	***Highlights and Conclusions from Day 1*** *Leigh Verbois, CDER, OC, ODSIR* *Eric Marshall, Executive Director, PDG* FDA and PDG will recap the conversations from Day 1 and identify key topics of discussion for Day 2.
10:10-11:10	***Dispenser Perspectives on Stabilization*** *Moderator: Tia Harper-Velazquez, Division Director, CDER, OC, ODSIR* *Ilisa Bernstein, (former) American Pharmacists Association (APhA)* *Lisa Schwartz, National Community Pharmacists Association (NCPA)* *Jillanne Schulte Wall, American Society of Health-System Pharmacists (ASHP)* Trade associations representing dispensers will share their individual perspectives on industry progress toward stabilization and actions that all stakeholders can take to support continued progress. The presentations will be followed by a short discussion among the trade association representatives.
11:10-12:15	***Panel: Stabilization of Wholesaler-to-Dispenser Data Exchange*** *Moderator: Ilisa Bernstein* *Scott Mooney, McKesson* *Jake Beck, Reliance Wholesale* *Denise Rodriguez, Rite Aid* *Christian Tadrus, Sam's Health Mart* *Marian Daum, VA Medical Center* A diverse panel of wholesalers and dispensers will discuss the status of stabilization as it relates to transactions between wholesalers and dispensers, including perspectives on data exchange when dispensers rely on EPCIS data feeds and when dispensers rely on wholesaler portals. The panel will include an opportunity for audience Q&A.
12:15-1:15	***LUNCH***
1:15-2:00	***Panel: Stabilization Progress from the Perspective of Supporting Organizations*** *Moderator: Matt Price, Board Chair, PDG* *Wyn Gary, ConsortiEX* *Tracy Nasarenko, GS1 US* *Mark Tate, Infinitrak* *Anil Suresh, SAP* A diverse panel of technology providers will share their perspective on the status of stabilization and the technical challenges that remain, including capacity, system maturity, and similar topics.
2:00-2:30	***Discussion: State Perspectives on Stabilization*** *Moderator: Josh Bolin, National Association of Boards of Pharmacy (NABP)* NABP and its members will provide reactions and reflect on their key takeaways and opportunities from the meeting.
2:30-3:15	***Stakeholder Comments*** Stakeholders who have requested the opportunity to make oral comments will be provided a three-minute time slot.
3:15-4:00	***Actions for Success*** *Leigh Verbois, Office Director, CDER, OC, ODSIR* *Eric Marshall, Executive Director, PDG* FDA and PDG representatives will discuss key takeaways and opportunities for drug supply chain members, FDA, and state regulators to support continued progress toward stabilization. This session will include an opportunity for audience Q&A.