

## 2023 Quarter 3 Analysis

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### FTC

**PBMs:** Last month the Federal Trade Commission voted unanimously to warn that some of its previous advocacy statements related to PBMs are outdated and no longer reflect current market realities.

**Why is this important?** The decision stops the PBMs from using some of their last remaining arguments against transparency and oversight. This is something that pharmacists can cite when advocating for change or whenever there is a legal dispute against a PBM or whenever there is an arbitration proceeding.

**Merger Guidelines:** The Federal Trade Commission and the Department of Justice are releasing a [draft update of the Merger Guidelines](#), which describe and guide the agencies' review of mergers and acquisitions to determine compliance with federal antitrust laws. The goal of this update is to better reflect how the agencies determine a merger's effect on competition in the modern economy and evaluate proposed mergers under the law. Both agencies encourage the public to review the draft and provide feedback through a public comment period that will last 60 days.

**Why is this important?** NPSC will be submitting comments for this draft solicitation. The deadline is 60 days from July 19th.

### CMS

**Physician Schedule Proposed Rule:** The Centers for Medicare and Medicaid Services has released its proposed [physician fee schedule](#) for CY 2024 which includes changes to the Electronic Prescribing Controlled Substances (EPCS) program. Among those proposed changes, prescriptions that are prescribed and dispensed within the same legal entity would be included in CMS EPCS program compliance calculations as part of the 70 percent compliance threshold.

CMS maintains that this arrangement offers flexibility to prescribers and dispensing pharmacies that are the same entity to choose either of the electronic standards to conduct e-prescribing appropriate for their internal systems without CMS having to exclude these prescriptions completely from the CMS EPCS program.

CMS also proposes to count renewals as an additional prescription in the CMS EPCS program compliance threshold calculation but will not count refills as an additional prescription in the CMS EPCS program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year. The proposed rule also seeks to make changes to the Medicare Diabetes Prevention Program (MDPP), including extending certain COVID-19 PHE flexibilities for a period of 4 years. Comments to the proposed fee schedule are due on Sep. 11.

**DIR:** NCPA submitted [comments](#) to the Office of Information and Regulatory Affairs within the Office of Management and Budget addressing our concerns with Medicare Part D and the DIR final rule provisions that become effective Jan. 1, 2024, focusing on the economic implications of DIR fees to independent pharmacies.

## DSCSA

NCPA, NACDS and APhA submitted a [joint letter](#) to the FDA on Friday, Aug. 4th, asking it to delay implementation of the Drug Supply Chain Security Act. Specifically, NCPA requested FDA use its authority under the law for dispensers to comply with the enhanced drug distribution security (EDDS) requirements, currently set to be in effect Nov. 27, 2023, no earlier than Feb. 27, 2026. The joint letter follows a [similar letter](#) sent by HDA last month to FDA also calling for a delay in DSCSA implementation. Last week all the wholesalers are also voicing their support for a delay until 2026. NPSC will advise the network if there are any changes to the November 2023 date.

## Congressional Pro-Pharmacy Bills

The Strengthening Pharmacy Access for Seniors Act would increase transparency measures on pharmacy benefit managers (PBMs) and provide seniors with additional options to fill their prescriptions. The bill would specifically require PBMs to reveal the criteria used to classify drugs that are dispensed by certain pharmacies and prevent PBMs from steering patients to certain pharmacies that limit patients' options. The bill is sponsored by Senators Thune (R-SD), Brown (D-OH), Barrasso (R-WY) and Stabenow (D-MI).

The Neighborhood Options for Patients Buying Medicines (NO PBMs) Act seen [here](#) seeks to improve options and access to prescription drugs for seniors bringing pharmacy benefit managers or PBMs in alignment with Medicare plans, therefore, allowing seniors to shop at their local pharmacy. The bill would modernize Medicare and enhance PBM accountability by preventing them from discriminating against pharmacies that are willing to contract with them, helping seniors to seek care closer to home. The bill is sponsored by Senators Manchin (D-WV) and Blackburn (R-TN).

S. 127: The Pharmacy Benefit Manager Transparency Act of 2023 is sponsored by Sen. Cantwell and co-sponsored by Sen. Grassley. The bill bans deceptive unfair pricing schemes, prohibits arbitrary claw backs of payments made to pharmacies and requires PBMs to report to the FTC how much money they make through spread pricing and pharmacy fees. The bill's description can be found [here](#).

Additionally, The Prescription Pricing for the People Act of 2023 (S113). Sponsored by Sen. Grassley and co-sponsored by Sen. Cantwell, the bill requires the Federal Trade commission (FTC) to examine the effects of consolidation in the PBM industry on pricing, as well as other potentially abusive behavior by PBMs. The bill instructs the FTC to provide policy recommendations to Congress to improve competition and protect consumers. That bill description can be found [here](#).

## DEA

Partial Fills: The DEA published a final rule on partial filling of controlled substances that can be viewed [here](#).

Why is this important? When a prescribing practitioner has properly specified their intent to partially fill a prescription for a schedule II-controlled substance, this rule will require the pharmacist to record the partial filling (similar to what's required under the existing regulations for other circumstances).

The dispensing pharmacist must make a notation of the quantity dispensed in one of three places: on the face of the written prescription or in the pharmacy's electronic records; in the written record or the pharmacy's electronic records of the emergency oral prescription; or in the record of the electronic prescription (similar to current requirements when the pharmacist is unable to supply the full quantity

called for in the schedule II prescription). For each such partial filling, the pharmacy must maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and other information for schedule III and IV prescription refills.

**Form 106:** The DEA recently published a [final rule](#), effective July 24, 2023, which amends the regulations regarding DEA Form 106, used by registrants to formally report thefts or significant losses of controlled substances. The final rule requires that all DEA Form 106s be submitted electronically. DEA will allow registrants 45 days from discovery of the theft or significant loss to submit the form, up from the agency's original proposal of 15 days. The final rule does not change the requirement that registrants preliminarily notify their area DEA Field Division Office of the theft or significant loss of any controlled substances in writing within one business day of discovering such loss or theft. Paper copies of DEA Form 106 will no longer be accepted once the final rule becomes effective.

## **Pharmacist in Charge Legislation**

NH Representative David Rochefort has had his sponsored legislation enacted by the NH Governor last week. The bill which can be viewed [here](#), eliminates the PIC position and assigns pharmacy liability to the appropriate pharmacist.

Why is this important? This may be the start of a new trend around the position of PIC and whether eliminating this makes workflow more efficient.

## **Webinar/Podcast**

NPSC will host a webinar, in September so I am able to update the network on everything that has happened federally and within the region this year.

## **Massachusetts Legislative Update**

You may have seen the picture from the July 13th meeting I had with Senator Moore and Representative Khan. We had a great joint meeting for about an hour on the details surrounding the legislative briefing that will occur this fall, as well as planned for how we are going to advance HD4325/S.1425. On the 13th I also did a round on Beacon Hill with a few legislators informing them of our health promotion screening bill.

Additionally, I am speaking occasionally with the Massachusetts pharmacy coalition and have made sure that our health promotion screening bill has been included on the pharmacy coalition's priority list.