



**CMS EPCS** | Electronic Prescribing for  
Controlled Substances

## CMS Electronic Prescribing for Controlled Substances (EPCS) Program



**Program Updates and Calendar  
Year 2024 Medicare Physician  
Fee Schedule Final Rule**

*January 11, 2024*

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## Welcome



**Mei Zhang**

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## Agenda



**Betty Seabrook, MPM, BSCS**  
**Health Services Advisory Group**  
**(HSAG)**

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- Please submit questions pertinent to the webinar topic via the Q&A panel. We will answer these questions at the end of the webinar, as time permits. Additional questions will be addressed in a Q&A document, to be published on the CMS EPCS [website](#) as soon as available.
- After this event, submit any additional questions through the [CMS EPCS Program Service Center](#). Include the webinar name and slide number.
- For questions unrelated to the webinar topic, we recommend first searching the CMS EPCS Program [website](#). If you do not find an answer, submit your question to us via the [CMS EPCS Program Service Center](#).

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## Agenda

- CMS EPCS Program Background
- 2023 CMS EPCS Program Measurement Year
- CY 2024 PFS Final Rule and the 2024 CMS EPCS Program Measurement Year
- CMS EPCS Program Resources
- Q&A session

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## CMS EPCS Program Background



**Mariana Grass, DHSc, MPH**  
**Health Services Advisory Group (HSAG)**

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## CMS EPCS Program Terminology

- **Program Compliance**

- **CMS EPCS Program**—Official title. We will refer to the program requirements for EPCS at § 423.160(a)(5) as the “CMS EPCS Program.”
- **Compliance Threshold**—The requirement that prescribers must electronically prescribe at least 70 percent of their Schedule II, III, IV, or V controlled substances for patients with Medicare Part D, after exceptions, each measurement year.
- **Non-compliance Action**—Refers to a consequence for not meeting the CMS EPCS Program compliance threshold after exceptions have been applied.

- **Time Periods**

Measurement Cycle		
Measurement Year	Compliance Analysis Period	Notification Period
The time period (beginning on January 1 and ending on December 31 of each calendar year) during which data is collected to calculate outcomes for the CMS EPCS Program	The time period after the measurement year where data are analyzed to determine whether prescribers have met the compliance threshold for the CMS EPCS Program	The time period during which we notify a prescriber of the prescriber’s initial compliance status and any associated review or waiver process that may be available prior to CMS determining the prescriber’s final compliance status

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## Statutory and Regulatory Authority

- Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) Act (Public Law 115-271) mandates that the prescribing of Schedule II, III, IV, and V controlled substances under Medicare Part D prescription drug plans and Medicare Advantage prescription drug (MA-PD) plans be done electronically in accordance with an electronic prescription drug program

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## Advantages of Electronic Prescriptions vs. Paper Prescriptions

### EPCS enhances patient safety

- Patient identity checks, reduces prescription tampering
- Medication recommendations that lower the risk of errors and potentially harmful interactions
- Timely and accurate transmission of time-sensitive prescriptions, reduces patient trips

### EPCS reduces prescriber burden

- Deter and detect prescription fraud and irregularities
- Improve workflow efficiencies
- Avoid data entry errors or pharmacy calls to clarify written prescriptions

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# CMS EPCS Program Regulatory Milestones

## CY 2020 RFI for EPCS

- CMS published a Request for Information (RFI) for electronic prescribing of controlled substances (EPCS) in Medicare Part D

## CY 2021 PFS Final Rule

- Physician Fee Schedule (PFS) Final Rule established the requirement that prescribers use the NCPDP SCRIPT standard version 2017071 for EPCS transmissions

## CY 2022 PFS Final Rule

- Mandated electronic prescribing of at least 70 percent of controlled substances (Schedule II-V) that are Part D drugs each measurement year, after exceptions are applied
- Extended the date of non-compliance actions to no earlier than January 1, 2023, and finalized a policy that compliance actions for prescriptions for beneficiaries in a long-term care (LTC) facility will begin January 1, 2025, and prescriptions written for a beneficiary in a LTC facility will not be included in determining compliance until that date.
- Established exceptions and limited 2023 compliance actions to a compliance letter

Sources:

[www.federalregister.gov/d/2020-16897](http://www.federalregister.gov/d/2020-16897), [www.federalregister.gov/d/2020-26815](http://www.federalregister.gov/d/2020-26815), [www.federalregister.gov/d/2021-23972](http://www.federalregister.gov/d/2021-23972), [www.federalregister.gov/d/2022-23873](http://www.federalregister.gov/d/2022-23873), [www.federalregister.gov/d/2023-24184](http://www.federalregister.gov/d/2023-24184) 11

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# CMS EPCS Program Regulatory Milestones (cont.)

## CY 2023 PFS Final Rule

- Finalized that the small prescriber exception will be assessed using current measurement year data instead of prior year data
- Identified Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan and Provider Enumeration System (NPPES) as the data sources to identify prescribers who are prescribing during a recognized emergency
- Extended the existing non-compliance action of sending a non-compliance notice for the 2024 measurement year

## CY 2024 PFS Final Rule

- Finalized the removal of the same legal entity exception while clarifying that the CMS EPCS Program will automatically align with Part D e-prescribing standards
- Finalized counting unique prescriptions in the measurement year by prescription number
- Updated the exception for emergencies to allow CMS to identify which emergencies qualify for the exception and the duration of the emergency exception would apply for the measurement year
- Finalized continuing the practice of issuing a prescriber a notice of non-compliance as a non-compliance action for subsequent measurement years and recognized that a prescriber's non-compliance information may be used in the processes for identifying potential fraud, waste, and abuse

Sources:

[www.federalregister.gov/d/2020-16897](http://www.federalregister.gov/d/2020-16897), [www.federalregister.gov/d/2020-26815](http://www.federalregister.gov/d/2020-26815), [www.federalregister.gov/d/2021-23972](http://www.federalregister.gov/d/2021-23972), [www.federalregister.gov/d/2022-23873](http://www.federalregister.gov/d/2022-23873), [www.federalregister.gov/d/2023-24184](http://www.federalregister.gov/d/2023-24184) 12

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## What Do I Need to Get Started?

- Set up electronic prescribing (e-prescribing)
  - Use a software application that meets all Drug Enforcement Administration (DEA) requirements
  - No additional software applications are needed for the CMS EPCS Program
- Work with your e-prescribing vendor
  - Complete identity proofing requirements
  - Obtain dual (two-factor) authentication device or process
  - Configure logical access control
  - Contact e-prescribing software vendor for technical issues related to using your software
- Check your state-specific EPCS requirements

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## 2023 CMS EPCS Program Measurement Year



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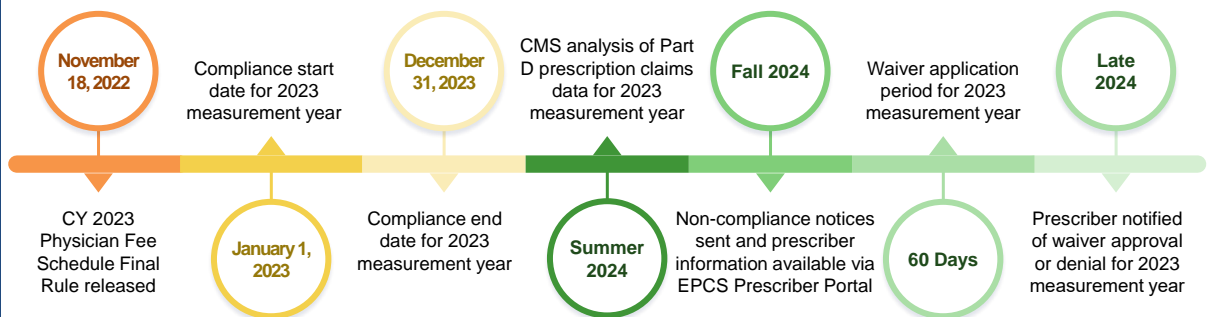
## Evaluation of Compliance— 2023 Measurement Year

- **Compliance:** Prescribers must electronically prescribe at least 70 percent of their Schedule II, III, IV, or V controlled substance prescriptions under Medicare Part D prescription drug plans and Medicare Advantage prescription drug (MA-PD) plans , after exceptions, each measurement year
- **Program Exceptions:**
  - Prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year (i.e., small prescriber exception)
  - Prescriptions for controlled substances issued when the prescriber and dispensing pharmacy are the same entity (i.e., same entity exception)
  - Prescribers located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity (i.e., recognized emergency exception)
  - Prescribers who receive a CMS-approved waiver
- **Waivers:** Prescribers may apply for and receive CMS-approved waiver because the prescriber is unable to meet the CMS EPCS requirement due to circumstances beyond the prescriber's control
- **Non-Compliance:** Notices will be sent to non-compliant prescribers for the 2023 measurement year

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## Timeline—2023 Measurement Year



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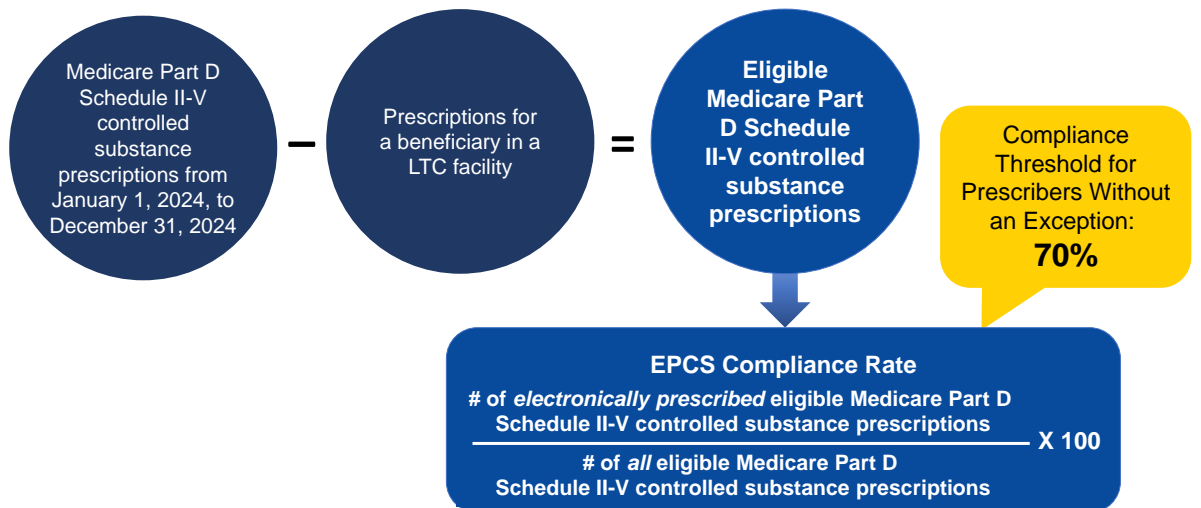
## CY 2024 PFS Final Rule and the 2024 CMS EPCS Program Measurement Year



**Valerie Mayorga, PharmD, BCPS**  
Health Services Advisory Group  
(HSAG)

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## Evaluation of Compliance— 2024 Measurement Year



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## Definition of Prescriptions for Compliance Calculation

- A unique prescription will be identified by the prescription number assigned by the pharmacy and included in the Part D claims data, and count in the compliance calculation
- Refills will not count as an additional prescription in the compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year

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## Example—Prescriptions for Compliance Calculation

<p>One prescription with four refills, written in March 2024.</p> 	<p>Mar 2024    Apr 2024    Jun 2024    Jul 2024    Aug 2024</p> 	<p>Prescription count in the 2024 compliance calculation</p> <p><b>1</b></p>
<p>Three prescriptions, each with no refills, written February 2024, April 2024, and July 2024.</p> 	<p>Feb 2024    Apr 2024    Jul 2024</p> 	<p>Prescription count in the 2024 compliance calculation</p> <p><b>3</b></p>
<p>One prescription with three refills, written in December 2023.</p> 	<p>Dec 2023    Jan 2024    Mar 2024    Apr 2024</p> 	<p>Prescription count in the 2024 compliance calculation</p> <p><b>1</b></p>

 = Counted in compliance calculation   
  = Not counted in compliance calculation

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## Updates to the National Council for Prescription Drug Programs (NCPDP) Standards

- The CMS EPCS Program will automatically adopt the electronic prescribing standards as they are updated through other Part D rulemaking\*

\*§ 423.160(b)

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## Small Prescriber Exception

**Prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year.**

- **\*NO CHANGES\***

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## Same Legal Entity Exception

**Prescriptions for Schedule II-V controlled substances issued when the prescriber and the dispensing pharmacy are the same entity.**

- **\*REMOVED\*** starting in the 2024 Measurement Year

### Rationale

- Prescribers in the same legal entities as the dispensing pharmacy have multiple methods\* to conduct internal electronic transmittals
- Identify electronic prescriptions using the Prescription Origin Code data element in the Part D claims
  - A value of 3 indicates electronic transmission

\* § 423.160(a)(3)(iii)

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## Recognized Emergency Exception

**Prescribers located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.**

- **\*UPDATED\*** starting the 2024 Measurement Year
  - CMS will identify which emergencies or disasters qualify for this exception
    - Communicated via normal CMS EPCS Program communication channels
  - Exception applied to prescribers for the entire measurement year

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## Exception for Circumstances Beyond the Prescriber's Control

**Prescribers who receive a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances due to circumstances beyond the prescriber's control.**

- **\*UPDATED\*** starting the 2024 Measurement Year
  - Removed “other than an emergency or disaster” from the definition of “extraordinary circumstance”
  - Waivers
    - Approved waivers for the CMS EPCS Program apply to the entire applicable measurement year
    - Waiver applications must be received by CMS within 60 days from the date of the notice of non-compliance

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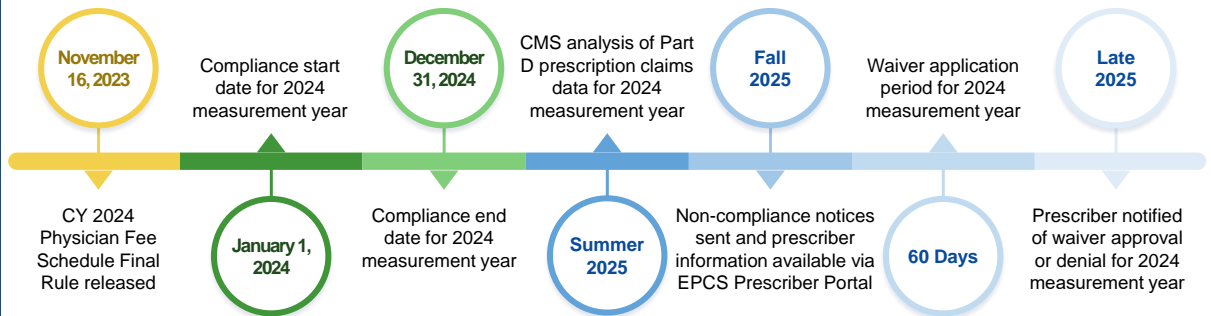
## Actions for Non-Compliance

- **\*UPDATED\***
  - The non-compliance action will continue to be a notice of non-compliance for subsequent measurement years
  - CMS may use CMS EPCS Program non-compliance information for assessing potential fraud, waste, and abuse

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## Timeline—2024 Measurement Year



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## CMS EPCS Program Resources



**Betty Seabrook, MPM, BSCS**  
Health Services Advisory Group  
(HSAG)

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## Educational Resources

- CMS EPCS Program website:  
[www.cms.gov/medicare/e-health/eprescribing/cms-eprescribing-for-controlled-substances-program](http://www.cms.gov/medicare/e-health/eprescribing/cms-eprescribing-for-controlled-substances-program)
- Join the [CMS EPCS Program Listserv](#) to receive the latest updates via email
- Available Educational Documents and Resources
  - Webinar recordings, transcripts, and handouts
  - Educational documents

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## CMS EPCS Service Center

The CMS EPCS Program [Service Center](#) will serve as the primary point of contact to help address program questions.

# CMS EPCS

### HOURS

Monday–Friday, 8 a.m. – 8 p.m. ET

*Non-peak hours are before 10 a.m. and after 2 p.m. ET*

### CONTACT US

-  1-866-288-8292
-  [EPCS-EPrescribe@cms.hhs.gov](mailto:EPCS-EPrescribe@cms.hhs.gov)
-  Hearing impaired dial 711 for TRS Communications Assistant
-  Online at CCSQ Support Central

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## Questions?



Please submit questions via  
the *Questions* box

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## PECOS, NPPEs, and HARP Logins

- Verify/update provider address and email in PECOS and NPPEs, as soon as possible
  - Medicare Provider Enrollment, Chain, and Ownership System (PECOS)
    - <https://pecos.cms.hhs.gov/pecos/login.do#headingLv1>
  - National Plan & Provider Enumeration System (NPPEs)
    - <https://nppes.cms.hhs.gov>
- Credentials will be required by Fall 2024 to access CMS EPCS Prescriber Portal
  - HCQIS Access Roles and Profile (HARP)
    - <https://harp.cms.gov/login>

HCQIS = Health Care Quality Information Systems

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**Thank you**