

## Streaming Audio

- Audio for this event is available via GoTo® Internet streaming.
- Use Chrome for the best event experience.
- No telephone line is required.
- Computer speakers or headphones are necessary to listen to streaming audio.
- Limited dial-in lines are available.
- Please request a dial-in line via the Ask the Staff a Question box.



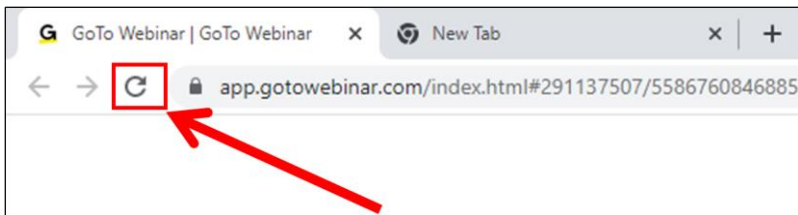
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## Troubleshooting Audio

Audio from computer speakers breaking up?  
Audio suddenly stop?  
Click Refresh or F5.



F5 Key  
Top Row of Keyboard



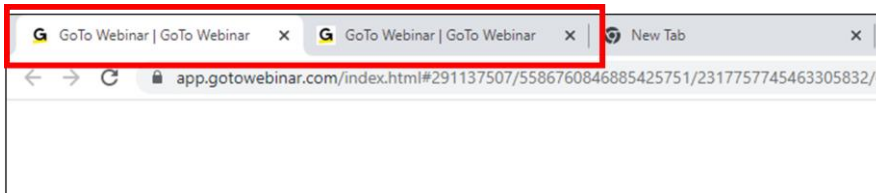
Refresh



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## Troubleshooting Echo

- Hear a bad echo on the call?
- Multiple browsers/tabs that are open to a single event (multiple audio feeds) usually cause the echo.
- Close all but one browser/tab to clear the echo.



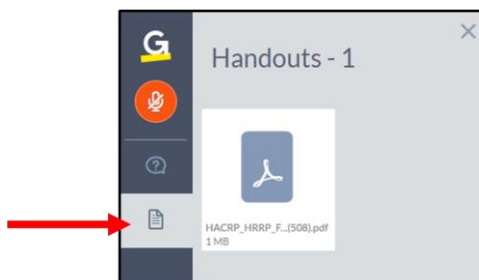
Example of Two Browsers/Tabs Open in Same Event



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## Downloading Slides/Handouts

Click the Handouts button to view any attached documents, such as slide decks and resource documents.



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## Acronyms

- **CCSQ**: Center for Clinical Standards and Quality
- **CY**: Calendar Year
- **DEA**: Drug Enforcement Administration
- **DPMS**: Division of Program and Measurement Support
- **EPCS**: Electronic Prescribing for Controlled Substances
- **HARP**: Health Care Quality Information Systems (HCQIS) Access Roles and Profile
- **LTC**: Long-Term Care
- **MA-PD**: Medicare Advantage prescription drug
- **MIPS**: Merit-Based Incentive Payment System
- **NCPDP**: National Council for Prescription Drug Programs
- **NPES**: National Plan and Provider Enumeration System
- **NPRM**: Notice of Proposed Rulemaking
- **PECOS**: Medicare Provider Enrollment, Chain, and Ownership System
- **PDE**: Prescription Drug Event
- **PFS**: Physician Fee Schedule
- **QMVG**: Quality Measurement and Value-Based Incentives Group
- **QPP**: Quality Payment Program
- **SUPPORT Act**: Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act



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# Centers for Medicare & Medicaid (CMS) Electronic Prescribing for Controlled Substances (EPCS)

## Program Update and CY2024 PFS Proposed Rule

July 27, 2023

CCSQ/QMVG/DPMS  
Program Lead: Mei Zhang

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## Disclaimers

- This presentation was prepared as a tool to assist providers and neither grants rights nor imposes obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for complying with legal requirements for the electronic prescription for controlled substances lies with the provider of services.
- This publication is a general summary that explains certain aspects of the Medicare Program but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference.
- The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this presentation.

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## Objectives

- Provide CMS EPCS Program Background
- Review 2023 CMS EPCS Program Rules
- Summarize CMS EPCS Proposed Program Rules for the 2024 Measurement Year
- Highlight EPCS Program Educational Information
- Review the EPCS Prescriber User Group Opportunity



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# CMS EPCS Program Background

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## Previous Regulatory Action

- Section 2003 of the 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
- Federal regulatory authority governing the CMS Electronic Prescribing for Controlled Substances (EPCS) Program is contained in 42 CFR 423.160(a)(5)
- The CMS EPCS Program rules have been addressed in the CY21, CY22, and CY23 Physician Fee Schedule Final Rules
- The CMS EPCS Program is separate from any other state or federal program electronic prescribing requirements

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# CMS EPCS Program Terminology

**CMS EPCS Program**—Official title. We will refer to the program requirements for EPCS at § 423.160(a)(5) as the “CMS EPCS Program.”

**Non-compliance action or Action for non-compliance**—Refers to a consequence for not meeting the CMS EPCS Program compliance threshold after exceptions have been applied.

**Measurement year**—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. In prior rules, we have used the term “current year” or “evaluated year,” but moving forward we will use the term “measurement year.”

**Compliance threshold**—The requirement that prescribers must conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, after exceptions, each measurement year.

**Compliance analysis period**—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.

**Notification period**—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.

**Measurement cycle**—Generally a period of 24 months, consisting of a measurement year, the compliance analysis period, and the notification period.



# CMS EPCS Program Regulatory Milestones

<b>CY2020</b>	<p><b>CMS published a Request for Information (RFI) for electronic prescribing of controlled substances under Medicare Part D</b></p> <ul style="list-style-type: none"> <li>• Sought input around implementation of Section 2003 of the SUPPORT Act.</li> </ul>
<b>CY2021</b>	<p><b>Physician Fee Schedule Final Rule</b></p> <ul style="list-style-type: none"> <li>• Established the requirement that prescribers use the NCPDP SCRIPT standard version 2017071 for EPCS transmissions.</li> </ul>
<b>CY2022</b>	<p><b>Physician Fee Schedule Final Rule</b></p> <ul style="list-style-type: none"> <li>• Established exceptions.</li> <li>• Mandated prescribers to conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, after exceptions.</li> <li>• Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025.</li> <li>• Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023.</li> <li>• Limited the 2023 compliance actions to a compliance letter.</li> </ul>
<b>CY2023</b>	<p><b>Physician Fee Schedule Final Rule</b></p> <ul style="list-style-type: none"> <li>• The small prescriber exception will be assessed using current measurement year data instead of prior year data.</li> <li>• Identified the 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.</li> <li>• Extended the existing compliance action of sending a non-compliance notice to the 2024 measurement year.</li> </ul>

Sources: <https://www.federalregister.gov/d/2020-16897>, <https://www.federalregister.gov/d/2020-26815>,  
<https://www.federalregister.gov/d/2021-23972>, <https://www.federalregister.gov/d/2022-23873>



# Controlled Substances

- Prescribers issuing electronic prescriptions for controlled substances must use a software application that meets all [Drug Enforcement Administration](#) (DEA) requirements
- Controlled substance: Drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of 21 U.S.C. §812

Schedule I	Schedule II	Schedule III, IV, and V
<ul style="list-style-type: none"> <li>• <b>NOT included in the CMS EPCS Program</b></li> <li>• These drugs have no currently accepted medical use and a high potential for abuse</li> <li>• Examples: heroin, marijuana, LSD, PCP, and crack cocaine</li> </ul>	<ul style="list-style-type: none"> <li>• Drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence</li> <li>• Examples: morphine, oxycodone, and methylphenidate</li> </ul>	<ul style="list-style-type: none"> <li>• Drugs with an abuse risk less than Schedule II</li> <li>• Examples: acetaminophen/codeine, diazepam, and alprazolam</li> </ul>

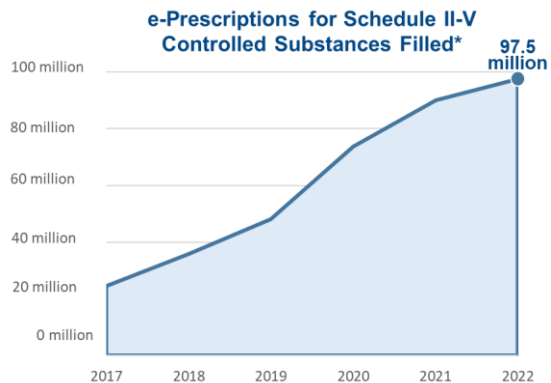
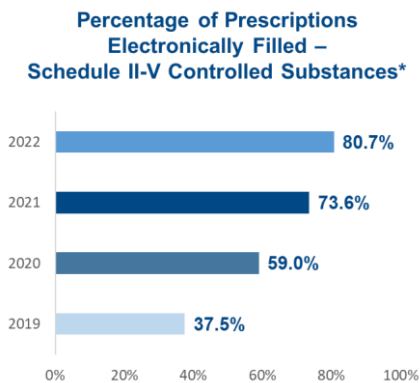
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Source: [https://deadiversion.usdoj.gov/ecomm/e\\_rx/](https://deadiversion.usdoj.gov/ecomm/e_rx/)  
<https://www.govinfo.gov/content/pkg/FR-2010-03-31/pdf/2010-6687.pdf>



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# Growth of EPCS



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Source: CMS  
 \*Data based on Part D final action Schedule II-V controlled substance claims, without CMS EPCS Program exceptions



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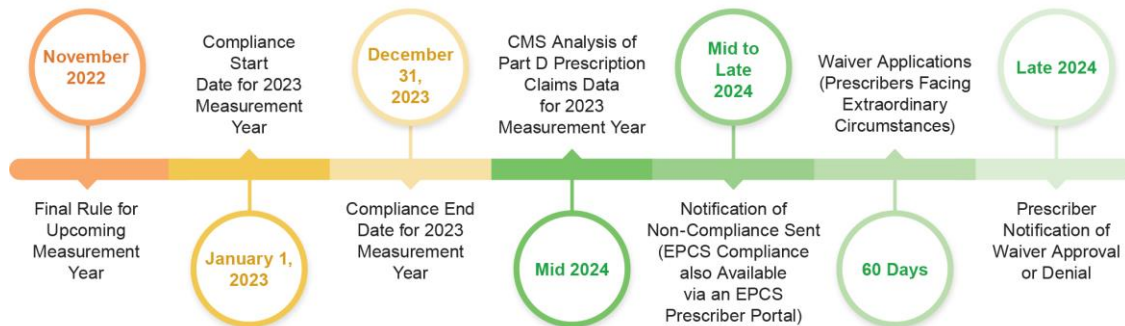
# CMS EPCS Program Rules for the 2023 Measurement Year

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## CMS EPCS Program Timeline 2023 Measurement Year



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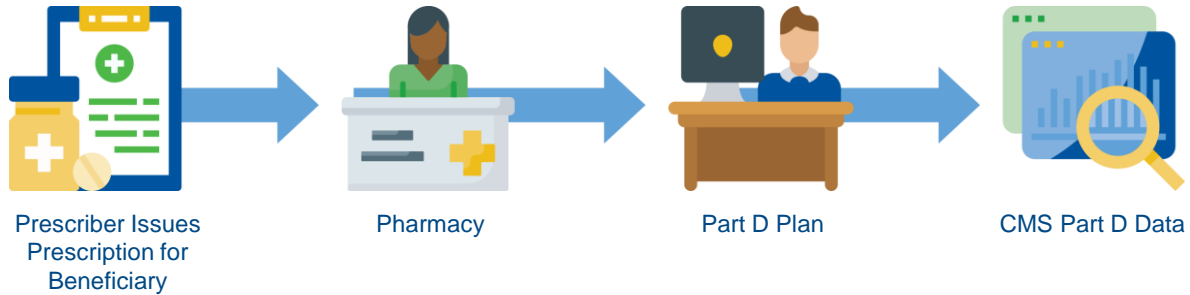


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## Included Prescription Claims

Medicare Part D prescription claims (including Medicare Advantage claims) for Schedule II, III, IV, and V controlled substances in the measurement year



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## Evaluation of Compliance

- CMS will analyze Medicare Part D claims and use the prescriber's National Provider Identifier (NPI) to measure compliance for all prescribing, regardless of the prescriber's practice location
- Compliance Threshold
  - **70%** of all eligible Medicare Part D Schedule II-V controlled substance prescriptions electronically prescribed
    - Excluding any prescriptions that fall within an exception
    - Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025

$$\text{EPCS Compliance Rate (\%)} = \frac{\text{\# of electronically prescribed Part D Schedule II-V controlled substance prescription claims from the prescriber, after exceptions}}{\text{\# of all Part D Schedule II-V controlled substance prescription claims from the prescriber, after exceptions}} \times 100\%$$

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## 2023 Measurement Year Exceptions

### Prescriptions

- Prescriptions for Schedule II-V controlled substances issued when the prescriber's PECOS or NPES location matches the geographic area of an emergency or disaster declared by a Federal, State, or local government entity
- Prescriptions for Schedule II-V controlled substances issued when the prescriber and dispensing pharmacy are the same entity

### Prescribers

- Prescribers who issue 100 or fewer qualifying Part D Schedule II-V controlled substance prescriptions in the measurement year will be exempt

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PECOS: Medicare Provider Enrollment, Chain, and Ownership System  
NPES: National Plan and Provider Enumeration System



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## Waiver

- Prescribers may request a waiver for the measurement year when circumstances beyond their control, other than disasters declared by a Federal, State, or local government entity, prevented them from electronically prescribing Schedule II-V controlled substances
- Prescribers will be able to access the waiver application from the EPCS Prescriber Portal in Fall of 2024, after the 2023 compliance analysis is complete

### Reasons to Apply for Waiver

- Technological limitations not within control of the prescriber
- Other circumstance outside of prescriber's control

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## Communication of Non-compliance

- Non-compliance notifications for the 2023 Measurement Year will be sent in the fall of 2024
- Prescribers or their authorized representative will be able to log into an EPCS Prescriber Portal via their HARP account to review their annual EPCS compliance status
  - EPCS Prescriber Portal will be available in Spring of 2024
  - Compliance information will be available via the EPCS Prescriber Portal in late 2024

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## CMS EPCS Program

## CY 2024 Physician Fee Schedule Proposed Rule

22 Link to the proposed rule:  
<https://www.federalregister.gov/d/2023-14624>



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# CMS EPCS Program in the CY 2024 Physician Fee Schedule Proposed Rule

1. Standard for CMS EPCS Program
2. Definition of Prescriptions for Compliance Calculation
3. Updates to Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances
4. Actions for Non-Compliance



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## 1.a. Updates to the NCPDP Standards

### Currently Established Standard

- Part D prescribers are required to use the NCPDP SCRIPT standard version 2017071 for EPCS prescription transmissions
- Under separate rulemaking\*, CMS has proposed to replace the NCPDP SCRIPT standard version 2017071 with the next version of the electronic prescribing standard, NCPDP SCRIPT standard version 2022011

### 2024 Notification Regarding the Standard

- In order to align with other CMS rulemaking, the CMS EPCS Program will automatically adopt the electronic prescribing standards as they are updated through other Part D rulemaking after a transition period

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[\\*CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule \(87 FR 79550\)](#)



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## 1.b. Standards for Same Legal Entity

### Currently Established Exception for Same Entity Prescribers

- An exception is granted for prescriptions issued where the prescriber and dispensing pharmacy are the same entity

### 2024 Proposed Changes to Policies for Same Legal Entity Prescribers

- Expand the available standards\* for prescribers that are within the same legal entity
- Remove the same entity exception
- Include all same legal entity prescriptions in the calculations by identifying electronic prescriptions using the Prescription Origin Code data element in the Part D claims, where a value of 3 indicates electronic transmission

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\* § 423.160(a)(3)(iii)



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## 2. Definition of Prescriptions for Compliance Calculation

### Currently Established Definition of Prescriptions

- The compliance threshold would be calculated based on examining Part D claims at the end of the measurement year
- Calculated dividing the number of Part D Schedule II-V controlled substances e-prescribed by the total number of Part D Schedule II-V controlled substance prescriptions prescribed (after exceptions)
- Did not define how prescriptions with multiple fills (refills) would be calculated

### 2024 Proposed Changes to the Definition of Prescriptions

- A unique prescription would be identified by the prescription number assigned by the pharmacy and included in the Part D claims data, and count in the compliance analysis
- Refills would 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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### 3. Updates to Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances

#### Currently Established Exception for Recognized Emergencies

- Prescribers practicing in the geographic location of a recognized emergency declared by a Federal, State, or local government entity when the dispensing date of the medication occurs during the declared disaster
- CMS uses the PECOS or NPPES address data to determine whether the exception is applicable

#### 2024 Proposed Changes to the Exception for Recognized Emergencies

- CMS would identify which events trigger the recognized emergency exception
- Intend to align declared emergencies with the MIPS automatic extreme and uncontrollable circumstances policy, in most cases
- Would apply the exception for the entire measurement year

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PECOS: Medicare Provider Enrollment, Chain, and Ownership System  
NPPES: National Plan and Provider Enumeration System



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### 3. Updates to Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances, cont.

#### Currently Established Extraordinary Circumstances Waiver Exception

- An exception may be granted in situations where the “prescriber has received a CMS approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber’s control”
- Waivers approved for a period of time, not to exceed one year
- Prescribers must provide documentation of the extraordinary circumstance

#### 2024 Proposed Changes to the Extraordinary Circumstances Waiver Exception

- Remove the restriction “other than an emergency or disaster” from the definition of “extraordinary circumstance”
- Approved waivers for the CMS EPCS Program would 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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## 4. Actions for Non-Compliance

### Currently Established Non-compliance Actions

- For the 2023 and 2024 CMS EPCS Measurement Years, CMS will send notice to non-compliant prescribers at the conclusion of each annual compliance analysis

### 2024 Proposed Changes for Non-compliance Actions

- Continue the practice of issuing a prescriber notice of non-compliance as a non-compliance action for subsequent measurement years
- May use non-compliance information for assessing potential fraud, waste, and abuse

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## How to Comment on the 2024 Proposed Rule

- Feedback during this presentation isn't considered as formal comments; please submit comments in writing using the formal process.
- Please refer to the Calendar Year (CY) 2024 Medicare Physician Fee Schedule (PFS) Notice of Proposed Rulemaking (NPRM) for complete information on proposed changes.
  - Link to the proposed rule: <https://www.federalregister.gov/d/2023-14624>
    - See proposed rule for information on submitting comments by close of the 60-day comment period, September 11, 2023 (when commenting refer to file code CMS-1784-P).
    - Instructions for submitting comments can be found in proposed rule; FAX transmissions will not be accepted.
    - You must officially submit your comments in one of following ways:
      - Electronically through Regulations.gov
      - By regular mail
      - By express or overnight mail

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# CMS EPCS Program

## Educational Resources

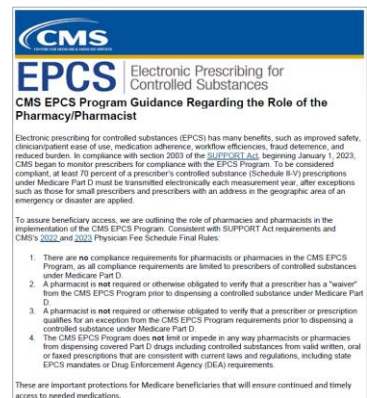
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### Do This First!

1. Join the [CMS EPCS Program Listserv](#) to receive the latest updates via email
2. Bookmark the [CMS EPCS Program Website](#)
3. Browse and download the educational documents:
  - Frequently Asked Questions
  - Getting Started Quick Reference Guide
  - Glossary
  - Regulatory Milestones
  - Previous webinar recordings



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The screenshot shows the CMS.gov website with the "E-Prescribing" page selected. The page title is "E-Prescribing". The main content area contains a paragraph explaining that E-Prescribing is a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care. Below this, there is a section titled "CMS Invites Comments on E-Prescribing and Related Standards in Proposed Rule CMS-4201-P" with a sub-header "The proposed rule 'Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare". A blue sidebar on the left lists "E-Prescribing", "Adopted Standard and Transactions", "Medicare Incentives", and "Resources and Materials". A blue footer contains the number "33" and the CMS logo.

Scroll to the bottom for downloads

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The screenshot shows the "Downloads" section of the website, indicated by a yellow download icon. It lists five documents with links: "EPCS Program Getting Started Quick Reference Guide (PDF)", "EPCS Frequently Asked Questions (PDF)", "EPCS Glossary (PDF)", "EPCS Regulatory Milestones (PDF)", and "Introduction to the CMS EPCS Program (originally presented on January 12, 2023) (ZIP)". Below the list is a blue button that says "Send CMS feedback about this document". An orange arrow points from the text "Provide feedback on selected documents by clicking the link at the bottom" to this button. A blue footer contains the number "34" and the CMS logo.

Provide feedback on selected documents by clicking the link at the bottom

Send CMS feedback about this document

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## Contact the Support Center

- [Create or Track a Service Center Ticket](#)
- Phone: 1-866-288-8292
  - Monday through Friday 8 am–8 pm Eastern Time
- Email: [EPCS-EPrescribe@cms.hhs.gov](mailto:EPCS-EPrescribe@cms.hhs.gov)



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# CMS EPCS Program

# Prescriber User Group

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## Importance of the User Group

- Help the EPCS Program understand the needs of prescribers who seek program information and who interact with the EPCS Prescriber Portal
- Provide end user feedback on selected EPCS Program educational products to enhance the user experience
- Participate in usability testing prior to the first release of the EPCS Prescriber Portal so that the final product meets the needs of prescribers measured by the EPCS Program



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## User Group Member Commitment

- Volunteer approximately 10 hours over a period of 12 months beginning in September 2023
- Proactively participate in group activities
- Attend virtual meetings (kickoff, pre-usability testing, and additional as needed)
- Provide input on selected program educational products
- Provide input on the end user experience and participate in testing of the EPCS Prescriber Portal

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## Call for Members

- Prescribers or prescriber staff representing:
  - Urban and rural practice settings
  - Low- and high-volume prescribers
  - Varied specialties – e.g., nurse practitioners, physician assistants, psychiatry, dentistry, urology, emergency medicine



**Interested?**

**[Apply for a seat on the EPCS Prescriber User Group](#)**

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## Questions or Comments

- Questions/comments on the EPCS CY24 PFS Proposed Rule:
  - Submit through CY 2024 PFS Notice of Proposed Rulemaking (NPRM)
    - Link: <https://www.federalregister.gov/d/2023-14624>
    - Comments due by September 11, 2023
    - Refer to file code CMS-1784-P
- Questions/comments on the CMS EPCS Program:
  - Contact the CMS EPCS Program Service Center
    - [Create or Track a Service Center Ticket](#)
    - Phone: 1-866-288-8292
      - Monday through Friday 8 am–8 pm Eastern Time
    - Email: [EPCS-EPrescribe@cms.hhs.gov](mailto:EPCS-EPrescribe@cms.hhs.gov)

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# Thank You

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