

Webinar Questions

- 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 at a later date.
 - NOTE: As a reminder, we do not use the raised-hand feature in the Chat tool during webinars.
- After this event, submit any additional questions through the [CMS EPCS Program Service Center](#). Include the webinar name, slide number, and speaker name.
- 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](#).
- We will respond to questions as soon as possible.

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Introduction to the CMS EPCS Program

January 12, 2023

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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.
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Electronic Prescribing for Controlled Substances (EPCS)

Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Centers for Medicare & Medicaid Services (CMS)

Center for Clinical Standards and Quality (CCSQ)

Quality Measurement and Value-Based Incentives Group (QMVIG)

Division of Program and Measurement Support (DPMS)

Program Leads: Mei Zhang and Kimberly Go

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Welcome!

The purpose of this presentation is to promote national awareness of the CMS EPCS Program



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Objectives

- Review CMS EPCS Program Background
- Summarize CMS EPCS Program Rules for the 2023 Measurement Year
- Point to additional information

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CMS EPCS Program Background

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Statutory and Regulatory Authority

- 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 EPCS Program is contained in 42 CFR 423.160(a)(5)
- The CMS EPCS Program rules have been addressed in the Physician Fee Schedule
- The CMS EPCS Program is separate from any other state or federal program requirements

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Schedule II, III, IV, and V Controlled Substances

Controlled substance: Drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of part B of 21 U.S.C. §802(32)(A)

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

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Source: <https://www.dea.gov/drug-information/drug-scheduling>



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CMS EPCS Program Regulatory Milestones

2020	<p>CMS published a Request for Information (RFI) for electronic prescribing of controlled substances under Medicare Part D</p> <ul style="list-style-type: none"> • Sought input around implementation of Section 2003 of the SUPPORT Act
2021	<p>Physician Fee Schedule Final Rule</p> <ul style="list-style-type: none"> • Established the requirement that prescribers use the NCPDP SCRIPT standard version 2017071 for EPCS transmissions
2022	<p>Physician Fee Schedule Final Rule</p> <ul style="list-style-type: none"> • 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 compliance actions to no earlier than January 1, 2023 • 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 long-term care facility will not be included in determining compliance until that date. • Established exceptions • Finalized a policy to limit 2023 compliance actions to a compliance letter
2023	<p>Physician Fee Schedule Final Rule</p> <ul style="list-style-type: none"> • Finalized a policy that the small prescriber exception for 2023 EPCS compliance would be assessed using 2023 data • 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 • Extended the existing compliance action of sending a compliance letter to the 2024 measurement year (evaluated year)

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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>



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DEA Regulations

Prescribers issuing electronic prescriptions for controlled substances must use a software application that meets all [Drug Enforcement Administration](#) (DEA) requirements

Remember to check your state laws—you may need additional registration for controlled substance prescriptions and/or have state-specific EPCS requirements

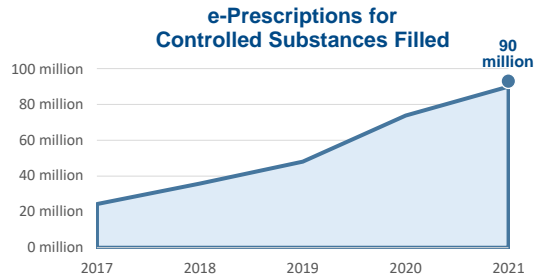
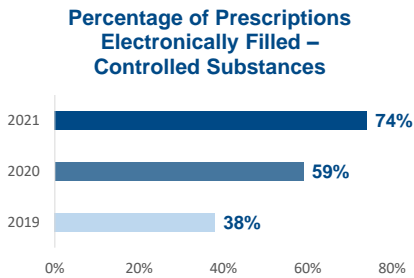
Benefits of EPCS



Growth of EPCS

EPCS utilization continues to rise

- The percentage of Medicare Part D (including Medicare Advantage) controlled substance prescriptions filled electronically increased from 38% in 2019 to 74% in 2021
- In 2021, 90 million electronic prescriptions for controlled substances were filled under Medicare Part D (including Medicare Advantage)



13 Source: CMS



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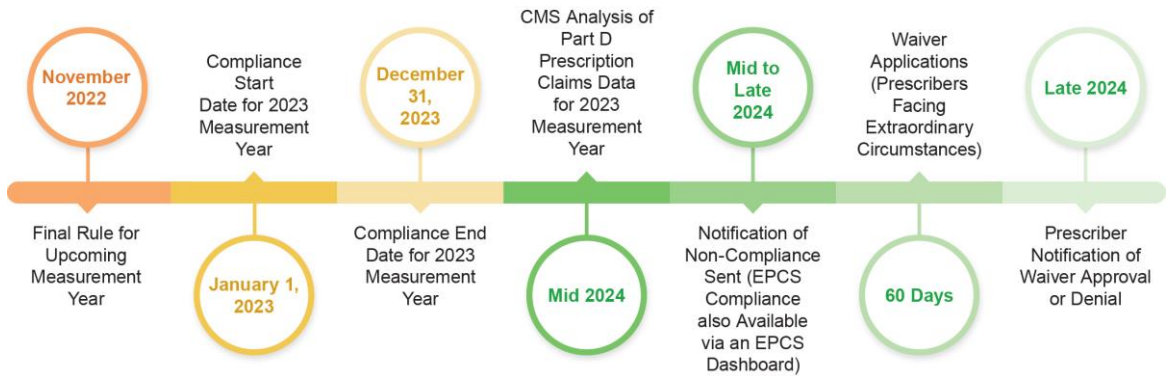
CMS EPCS Program Rules for the 2023 Measurement Year

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CMS EPCS Program Timeline— 2023 Measurement Year



Timeframe for EPCS Adoption

- The first measurement year for compliance with requirements of the CMS EPCS Program is January 1, 2023–December 31, 2023
 - All Schedule II-V controlled substance prescriptions that are Part D drugs between these dates will be included, after exceptions
 - Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025
- All prescribers who issue controlled substance prescriptions under Medicare Part D are included in the CMS EPCS Program, after exceptions

Compliance Threshold Calculation

- 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 calculations will begin after the PDE submission deadline of June 2024
- Compliance Threshold
 - **70%** of all 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

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

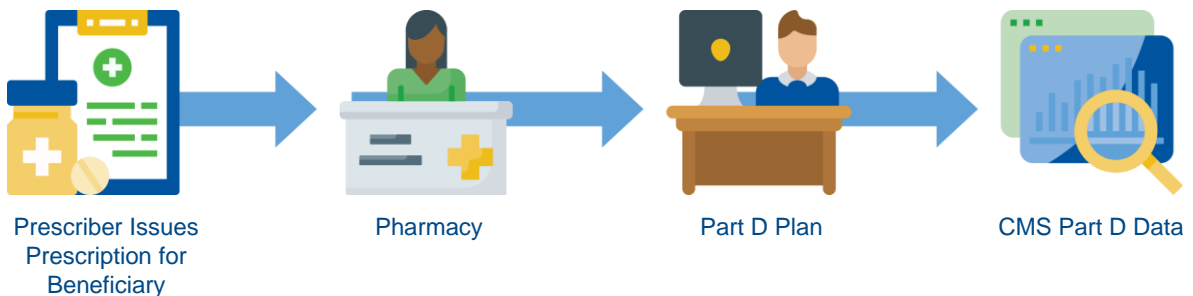
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Included Prescription Claims

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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2023 Measurement Year Exceptions— Prescriptions

- Prescriptions will not be considered for purposes of determining CMS EPCS Program compliance in the following situations:
 - Prescriptions for controlled substances issued when the prescriber and dispensing pharmacy are the same entity
 - Prescriptions for controlled substances issued when the prescriber is located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity

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2023 Measurement Year— LTC Prescriptions

- Prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in determining compliance until January 1, 2025

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2023 Measurement Year Exceptions— Prescribers

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

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Waiver

- Prescribers may request a waiver for the measurement year when circumstances beyond their control prevented them from electronically prescribing controlled substances
 - Waiver requests will be accepted for 60 days after the notifications of non-compliance are delivered
 - Waiver for the 2023 Measurement Year will be granted in late 2024
 - Waiver requests shall include documentation showing the existence of a circumstance beyond prescriber control that prevented the prescriber from conducting EPCS
 - Waiver will be issued for a period of up to the entire 2023 Measurement Year
- Prescribers will be able to access the waiver application from the EPCS Dashboard in 2024, after the 2023 compliance analysis is complete

Extraordinary Circumstances

- Economic hardship prevents acquisition of system necessary to conduct EPCS
- 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 Dashboard via their Health Care Quality Information Systems (HCQIS) Access Roles and Profile (HARP) account to review their annual EPCS compliance status
 - EPCS Dashboard will be available by end of January 2024
 - Compliance information will be available via the EPCS Dashboard in late 2024

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What happens if you are not compliant?

- For the 2023 EPCS Measurement Year, CMS will send a notification of non-compliance to prescribers violating the EPCS mandate

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Additional Information

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Help and Support

- [CMS EPCS Program Website](#)
 - Available for download:
 - FAQ
 - Getting Started Quick Reference Guide
 - Glossary
 - Regulatory Milestones
- [CMS EPCS Program Listserv](#)
- 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



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Q&A Session

- You may submit questions via the Q&A panel
- Speakers will answer as many questions as time allows

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Thank You

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