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## General Questions

### What is the CMS EPCS Program?

The Centers for Medicare & Medicaid (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program, established and authorized by Section 2003 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018 ([Public Law 115-271](#)), which mobilized federal efforts to improve safety and quality of health care, requires that Schedule II–V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug (MA-PD) plans be prescribed electronically, subject to any exceptions that the U.S. Department of Health and Human Services (HHS) may specify.

The CMS EPCS Program rules are addressed in the Physician Fee Schedule (PFS) final rule for calendar years (CYs) [2021](#), [2022](#), [2023](#), [2024](#), and [2025](#). The compliance requirement became effective with the first measurement year, CY 2023. Each subsequent measurement year begins January 1 and ends December 31.

### What is electronic prescribing for controlled substances?

Electronic prescribing for controlled substances (EPCS) is the electronic transmission of an accurate, error-free, and understandable prescription for controlled substances directly to a pharmacy from the point of care. There are Drug Enforcement Administration (DEA) EPCS requirements.

### Is the CMS EPCS Program voluntary?

No. All prescribers who issue Schedule II–V controlled substance prescriptions under Medicare Part D are included in the CMS EPCS Program, after exceptions, each measurement year.

### Are there exceptions to the CMS EPCS Program?

Prescribers must electronically prescribe at least 70% of their Schedule II–V controlled substance prescriptions under Medicare Part D, after exceptions, each measurement year. Prescribers will be exempt from this requirement in the following situations:

- **Small Prescriber Exception:** CMS automatically provides this exception to prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year.
- **Declared Disaster Exception:** CMS automatically provides this exception to prescribers located in the geographic area of a disaster or an emergency declared by a Federal, State, or local government entity. Starting in measurement year 2024, CMS identifies which disasters and emergencies qualify for this exception. CMS posts a list of the qualifying disasters and emergencies for each measurement year on the [CMS EPCS Program webpage](#).

- **CMS-Approved Waiver Exception:** CMS provides this exception to prescribers who submit and receive a CMS-approved waiver because the prescriber is unable to meet the CMS EPCS Program requirement due to circumstances beyond the prescriber's control.

Prescriptions written for a beneficiary in a long-term care (LTC) facility will be included in determining compliance no earlier than January 1, 2028.

### **How are prescriptions written for a beneficiary in a long-term care facility identified within the CMS EPCS Program?**

When calculating prescriber compliance for the CMS EPCS Program, CMS excludes Patient Residence Code values of 03 (Nursing facility [long-term care facility]) and 09 (intermediate care facility/Individuals with Intellectual Disabilities [ICF/IID]) from the prescription drug event (PDE) records for Part D claims data.

Prescriptions written for a beneficiary in an LTC facility will be included in determining compliance no earlier than January 1, 2028.

### **My state already requires me to electronically prescribe controlled substances. Am I automatically compliant with the CMS EPCS Program?**

No. The CMS EPCS Program is separate from State e-prescribing for controlled substance requirements. Compliance with the CMS EPCS Program requirement will be determined based on Medicare Part D claims data.

### **Do I need to register for the CMS EPCS Program or report any data to CMS for the EPCS Program?**

No. Prescribers don't have to register for the CMS EPCS Program or report any data to CMS for the EPCS Program. CMS analyzes Medicare Part D claims data to determine prescriber compliance. To review a prescriber's compliance status and submit a waiver application, if needed, users need to log in to the CMS EPCS Prescriber Portal with a [Health Care Quality Information Systems \(HCQIS\) Access, Roles, and Profile \(HARP\)](#) account user ID and password. These are the same credentials for accessing the Quality Payment Program Portal. If a user doesn't have an account, they can apply for one on the [HARP Create an Account webpage](#).

**I electronically prescribe non-controlled substances. What additional steps do I need to complete to electronically prescribe controlled substances?**

Prescribers of controlled substances must follow [Drug Enforcement Administration guidance](#). Remember to check your specific State's laws and requirements for EPCS. You may need additional registration for controlled substance prescriptions or be subject to State-specific EPCS requirements.

**I'm having trouble logging in to electronically prescribe controlled substances. What should I do?**

Technical issues related to logging in to your e-prescribing system, multifactor authentication errors, and prescription transmission errors should be handled through your in-house information technology support and your e-prescribing system, electronic health record, or electronic medical record vendor.

**Is a fax of a prescription considered an electronic prescription under the CMS EPCS Program?**

No. For the purposes of the CMS EPCS Program, CMS doesn't consider a prescription generated by an electronic system—such as an electronic health record, electronic medical record, or e-prescribing system—and transmitted through fax to be an electronic prescription.

**I practice at various locations. How will my controlled substance prescriptions be measured?**

CMS uses a prescriber's National Provider Identifier (NPI) on Medicare Part D claims to identify how many qualifying controlled substance prescriptions were attributed to the NPI during the measurement year, regardless of the prescriber's practice location.

**What if I can't electronically prescribe for a while due to a disaster?**

To reduce burden, CMS monitors emergencies and disasters during the measurement year to identify when circumstances arise in which an exception to the CMS EPCS Program requirement might apply. CMS then grants affected prescribers a declared disaster exception for the entire measurement year. The [Medicare Provider Enrollment, Chain, and Ownership System](#) (PECOS) and the [National Plan and Provider Enumeration System](#) (NPPES) are the data sources CMS uses to identify the geographic location of prescribers for the declared disaster exception. CMS also uses PECOS and NPPES data sources for sending non-compliance notices. CMS strongly recommends that all prescribers keep their addresses accurate and up to date in both systems.

**I participate in the Medicare Promoting Interoperability Program. Will I automatically receive credit for the CMS EPCS Program?**

No. Although the Medicare Promoting Interoperability (PI) Program and the PI category under the Quality Payment Program include e-prescribing measures, the CMS EPCS Program is a separate

Federal program. The EPCS Program is specific to controlled substance prescribing and requires prescribers to electronically prescribe at least 70% of their Schedule II–V controlled substances prescriptions under Medicare Part D, after exceptions, each measurement year.

### **Are prescribers who don't participate in Medicare included in the CMS EPCS Program?**

Under Section 2003 of the SUPPORT Act ([Public Law 115-271](#)), all prescribers—regardless of their Medicare participation status or specialty taxonomy—must meet the CMS EPCS Program requirement for prescriptions filled under Medicare Part D and Medicare Advantage prescription drug (MA-PD) plans.

### **Are pharmacies required to enforce the rules of the CMS EPCS Program?**

The CMS EPCS Program applies only to prescribers who issue Schedule II–V controlled substance prescriptions under Medicare Part D. Consistent with Section 2003 of the SUPPORT Act ([Public Law 115-271](#)).

There is no compliance requirement for pharmacists or pharmacies in the CMS EPCS Program, as the compliance requirement is limited to prescribers of controlled substances under Medicare Part D.

- A pharmacist is not required to verify that a prescriber has a waiver from the CMS EPCS Program prior to dispensing a controlled substance under Medicare Part D.
- A pharmacist is not required to verify that a prescriber or prescription qualifies for an exception from the CMS EPCS Program requirement prior to dispensing a controlled substance under Medicare Part D.

The CMS EPCS Program does not limit or impede in any way pharmacists or pharmacies from dispensing covered Part D drugs, including controlled substances from valid written, oral, or faxed prescriptions that are consistent with current laws and regulations, including state EPCS mandates or Drug Enforcement Administration (DEA) requirements.

## **Compliance Questions**

### **What's the compliance requirement?**

To be considered compliant, prescribers must electronically prescribe at least 70% of their Schedule II–V controlled substance prescriptions under Medicare Part D, after exceptions, each measurement year.

### **How is compliance measured?**

CMS analyzes Medicare Part D claims for controlled substance prescriptions in the measurement year using prescriber NPIs to identify how many prescriptions were attributed to an NPI regardless of practice location.

Prescribers will be exempt from the requirement in the following situations:

- **Small Prescriber Exception:** CMS automatically provides this exception to prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year.
- **Declared Disaster Exception:** CMS automatically provides this exception to prescribers located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting measurement year 2024, CMS identifies which emergencies and disasters qualify for this exception. CMS posts a list of the qualifying emergencies and disasters for each measurement year on the [CMS EPCS Program webpage](#).
- **CMS-Approved Waiver Exception:** CMS provides this exception to prescribers who submit and receive a CMS-approved waiver because the prescriber was unable to meet the CMS EPCS Program requirement due to circumstances beyond the prescriber's control.

CMS considers a prescriber compliant if they electronically prescribe at least 70% of their Schedule II–V controlled substance prescriptions under Medicare Part D, after exceptions, in the measurement year. The calculation will be completed by dividing the number of Medicare Part D controlled substances the prescriber e-prescribed by the total number of Medicare Part D controlled substance prescriptions the prescriber issued, as reflected in the Medicare Part D claims data. Claims for prescription 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.

### **When does CMS begin assessing my EPCS Program compliance?**

CMS assesses a prescriber's compliance with the EPCS Program after each measurement year. Medicare Part D claims with a date of service or fill date of January 1–December 31 and a submission date on or before the submission deadline for the measurement year (that is, June 30 the following year) are included in the compliance analysis. For example, the compliance analysis period for the 2024 measurement year will begin August 2025 and include Medicare Part D claims with a date of service or fill date of January 1–December 31, 2024, submitted on or before June 30 2025.



## **How am I notified if I'm found non-compliant with the CMS EPCS Program?**

Prescribers identified by CMS as non-compliant for the measurement year receive a non-compliance notice during the notification period, which takes place in the fall after the measurement year.

The notices include information to prescribers that they are violating the CMS EPCS Program requirement, information about how they can come into compliance, information on the benefits of EPCS, and a link to the CMS EPCS Prescriber Portal where they can check their compliance status and may submit a waiver application for circumstances beyond their control.

CMS sends the notices through email when possible and as a physical letter if there was no email address for the prescriber in the [Medicare Provider Enrollment, Chain, and Ownership System](#) (PECOS) and the [National Plan and Provider Enumeration System](#) (NPES). CMS encourages prescribers to update their email and mailing addresses in PECOS and NPES to ensure timely receipt of the notices and, therefore, the opportunity to submit a waiver application to become compliant. Prescriber location addresses are also used to determine who qualifies for the automatic declared disaster exception.

Note that a prescriber's non-compliance under the EPCS Program may be considered in CMS processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present.

Prescribers and their designated representatives can also log in to the [CMS EPCS Prescriber Portal](#) to check the prescriber's compliance status and submit a waiver application, if necessary, for the measurement year. Non-compliant prescribers and their representatives may submit a waiver application if the prescriber was unable to meet the EPCS Program requirement due to circumstances beyond the prescriber's control.

For updates about non-compliance notices and submitting waiver applications, subscribe to the [CMS EPCS Program Listserv](#). You can also find more information about them on the [CMS EPCS Program webpage](#).

## **What happens if I'm found non-compliant with the CMS EPCS Program?**

Starting in measurement year 2023, the non-compliance action is the notice of non-compliance. The notices include information to prescribers that they are violating the CMS EPCS Program requirement, information about how they can come into compliance, information on the benefits of EPCS, and a link to the CMS EPCS Prescriber Portal where they can check their compliance status and may submit a waiver application for circumstances beyond their control.

A prescriber's final non-compliance under the CMS EPCS Program may be considered in CMS processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present.

For updates about non-compliance notices and submitting waiver applications, subscribe to the [CMS EPCS Program Listserv](#). You can also find more information about them on the [CMS EPCS Program webpage](#).



## Waiver Questions

### Who's eligible to submit a waiver application for the CMS EPCS Program?

Prescribers who were unable to meet the CMS EPCS Program requirement to electronically prescribe at least 70% of their qualifying Medicare Part D Schedule II–V controlled substance prescriptions in the measurement year due to circumstances beyond the prescribers' control are eligible to request a waiver. These circumstances may include technological limitations—such as prescribers having technical difficulties with pharmacies receiving their prescriptions—and other circumstances outside the prescriber's control.

### What's the process for submitting a waiver application for the CMS EPCS Program?

Prescribers and their designated representatives with a HARP account may log in to the [CMS EPCS Prescriber Portal](#) to check their compliance status and submit a waiver application, as needed, for the measurement year during the 60-day waiver application submission period from mid-September to mid-November after the measurement year. Non-compliant prescribers submitting a waiver application must provide an explanation/documentation of circumstances beyond their control that prevented them from meeting the CMS EPCS Program requirement.

For program updates about the EPCS Prescriber Portal, subscribe to the [CMS EPCS Program Listserv](#).

### Is there a limit to how many waivers applications I can submit for the CMS EPCS Program?

Only one waiver application can be submitted for a prescriber each measurement year. However, a prescriber's designated representative may submit waiver applications on behalf of multiple prescribers.

### How long does an approved waiver last for the CMS EPCS Program?

A prescriber who receives a CMS-approved waiver because prescribers are unable to meet the CMS EPCS Program requirement due to circumstances beyond their control is exempt for the entire measurement year. For example, a prescriber who received a CMS-approved waiver for the 2024 measurement year is exempt for measurement year 2024.

### Do I need to submit a waiver application for each of my practice locations?

No. Since a waiver is granted based on a prescriber's NPI, if you are granted a waiver, it applies to all locations where you prescribe controlled substances.

### I'm unable to submit a waiver application online. Is there another way to submit one?

Yes. During the waiver application submission period, CMS provides technical assistance for waiver requests over the telephone to prescribers who can't apply for their waiver online. During the period, prescribers may call the Center for Clinical Standards and Quality Support Central for the CMS EPCS Program at 1-866-288-8292 for help.

Prescribers and their designated representatives may submit a waiver application through the CMS EPCS Prescriber Portal during the 60-day waiver application submission period from mid-September to mid-November after the measurement year.

For program updates on when prescribers can submit a waiver application, subscribe to the [CMS EPCS Program Listserv](#). You can also find CMS EPCS Program announcements on the [CMS EPCS Program webpage](#).

### **I have a waiver from my State's EPCS program. Does that waiver cover the requirement for the CMS EPCS Program?**

No. The CMS EPCS Program is a Federal program that's separate from State EPCS requirements, including waiver application submissions and approvals.

## **Acronym List**

<b>Acronym</b>	<b>Definition</b>
CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
EHR	Electronic Health Record
EMR	Electronic Medical Record
EPCS	Electronic Prescribing for Controlled Substances
HARP	Health Care Quality Information Systems (HCQIS) Access, Roles, and Profile
HCQIS	Health Care Quality Information Systems
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
ICF/IID	Intermediate Care Facility/Individuals with Intellectual Disabilities
LTC	Long-Term Care
MA-PD	Medicare Advantage Prescription Drug
NCPDP	National Council for Prescription Drug Programs
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
PDP	Prescription Drug Plan
PECOS	Medicare Provider Enrollment, Chain, and Ownership System
QPP	Quality Payment Program
SUPPORT Act	The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

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