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Acronyms

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General Questions

What is the CMS EPCS Program?

• The program, established and authorized by Section 2003 of the SUPPORT Act, which mobilized federal efforts to improve safety and quality of health care, requires that Schedule II, III, IV, or V controlled substance prescriptions under Medicare Part D be electronically transmitted, subject to any exceptions the Department of Health and Human Services (HHS) may specify. The CMS EPCS Program rules are addressed in the CY 2021, CY 2022, CY 2023, and CY 2024. Physician Fee Schedule Final Rules. Compliance requirements became effective with the first measurement year (CY 2023). Each subsequent measurement year begins on January 1 and ends on December 31.

What is electronic prescribing for controlled substances?

 Electronic prescribing for controlled substances (EPCS) refers to the prescriber's ability to electronically transmit an accurate, error-free, and understandable prescription for controlled substances directly to a pharmacy from the point-of-care. There are DEA requirements for electronic prescribing for controlled substances.

Is the CMS EPCS Program voluntary?

 No. All prescribers who issue controlled substance prescriptions under Medicare Part D are included in the CMS EPCS Program, after exceptions.

Are there exceptions to the CMS EPCS Program?

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

- Prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year.
- Prescribers located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.
- 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.

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

How are prescriptions written for a beneficiary in a long-term care facility identified within the CMS EPCS Program so as to not be included in determining compliance until January 1, 2025?

 When calculating prescriber compliance, we will exclude Patient Residence Code values of 03 (Nursing facility (long-term care facility)) and 09 (intermediate care facility for the mentally retarded (ICF/MR)) from the prescription drug event (PDE) records for Part D claims data.

My state already requires me to electronically prescribe controlled substances. Am I automatically compliant for this program?

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

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

No. Prescribers do not have to register or report data to CMS for the CMS EPCS Program.



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

 Prescribers of controlled substances must follow DEA guidance, which is summarized at https://www.deadiversion.usdoj.gov/ecomm/ecomm.html. Remember to check your state laws—you may need additional registration for controlled substance prescriptions and/or be subject to statespecific EPCS requirements.

I am having trouble logging in to electronically prescribe controlled substances. What should I do?

 Technical issues related to logging in to your e-prescribing system, multi-factor authentication errors, or prescription transmission errors would be handled through your electronic prescribing system or EHR vendor.

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

No. A prescription generated by an electronic system, such as an electronic health record (EHR) or eprescribing system and printed or transmitted through fax is not considered an electronic prescription for
purposes of the CMS EPCS Program.

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

• CMS will use the prescriber NPI on Medicare Part D claims to identify how many qualifying prescriptions were attributed to the NPI, regardless of practice location.

What if I cannot electronically prescribe for a period of time due to a disaster?

• To reduce prescriber burden, CMS will monitor emergencies and disasters during the measurement year to identify when circumstances arise in which an exception to the EPCS requirement might apply. CMS will grant prescribers an emergency exception for the entire measurement year. The Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan and Provider Enumeration System (NPPES) will be the data sources used to identify the geographic location of prescribers for the emergency exception. CMS will use these data sources to automatically apply disaster exceptions during the compliance analysis. CMS strongly recommends that all prescribers keep their addresses accurate and up to date in both systems.

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

 No. While the Promoting Interoperability (PI) programs and the PI category under the Quality Payment Program (QPP) include e-prescribing measures, the CMS EPCS Program is a separate federal program. The CMS EPCS Program is specific to controlled substance prescribing and requires a minimum EPCS compliance rate of 70 percent for Schedule II, III, IV, or V controlled substances under Medicare Part D, after exceptions.

Are prescribers who do not participate in Medicare included in the CMS EPCS Program?

• Under Section 2003 of the SUPPORT Act, all prescribers, regardless of their Medicare participation status or specialty taxonomy, must meet the CMS EPCS Program requirements for prescriptions filled under the patient's Medicare Part D or Medicare Advantage prescription drug plan.

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

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
DEA requirements.



Compliance Questions

What are the criteria for compliance?

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

How will compliance be measured?

- CMS will analyze Medicare Part D claims for controlled substance prescriptions in the measurement year, using the prescriber NPI to identify how many prescriptions were attributed to the NPI regardless of practice location.
 - Prescribers will be exempt from this requirement in the following situations:
 - Prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year.
 - Prescribers located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.
 - 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.

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

After exceptions, a prescriber is considered compliant when at least 70 percent of prescribing for Schedule II, III, IV, or V controlled substances under Medicare Part D are electronically transmitted within 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 will CMS begin assessing my EPCS compliance?

 A prescriber's EPCS compliance will be assessed by the measurement year that is, January 1 through December 31 of the calendar year. After the end of the measurement year, Medicare Part D claims with a Date of Service between January 1 to December 31 and a submission date on or before the submission deadline for the measurement year (that is, June 28 of the following year) will be included in the compliance analysis. For example, the first EPCS compliance measurement year 2023 was January 1, 2023, through December 31, 2023. The submission deadline for 2023 measurement year is June 28, 2024.



How will I be notified if I am non-compliant?

• Prescribers found to be non-compliant for the measurement year will receive a non-compliance notice during the following calendar year. Notices will be sent by email when possible, to available email addresses in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan and Provider Enumeration System (NPPES), and by regular mail if there is no email address in PECOS or NPPES. CMS strongly recommends that all prescribers keep their email address accurate and up to date in both systems. Prescribers will also be able to log into the CMS EPCS Prescriber Portal to review their annual compliance information. CMS will announce more information regarding non-compliance notices once it is available. Non-compliant prescribers may apply for a waiver if they experienced circumstances beyond their control that prevented them from electronically prescribing controlled substances. Please subscribe to the CMS EPCS Program listsery to receive announcements regarding non-compliance notices and waiver applications. You can also find CMS EPCS Program announcements at https://www.cms.gov/medicare/e-health/eprescribing/cms-eprescribing-for-controlled-substances-program.

What happens if I am non-compliant?

For the 2023, 2024, and subsequent measurement years, CMS will send a non-compliance notice to
prescribers violating the CMS EPCS Program mandate. CMS continues to evaluate prescriber
compliance and may address additional non-compliance actions through rulemaking.

Waiver Questions

Who is eligible for a CMS EPCS Program waiver?

Prescribers who experienced circumstances beyond the prescriber's control that prevented them from
electronically prescribing controlled substances to Medicare Part D beneficiaries are eligible to request a
waiver. The reasons to apply for a waiver may include technological limitations (e.g., providers having
technical difficulties with pharmacies receiving their prescriptions) or other circumstances outside of the
prescriber's control.

What is the process for submitting a CMS EPCS Program waiver application?

After the measurement year is complete, prescribers with a Health Care Quality Information Systems
(HCQIS) Access, Roles and Profile (HARP) account may securely access the CMS EPCS Prescriber
Portal to check their compliance status and request a waiver. Non-compliant prescribers applying for a
waiver must provide documentation of circumstances beyond their control that prevented them from
conducting EPCS for a designated measurement year. A waiver application must be received by CMS
within 60 days from the date of the notice of non-compliance.

Please subscribe to the CMS EPCS Program listserv (<u>click to subscribe</u>) to receive program updates regarding the CMS EPCS Prescriber Portal.

How long does a waiver last?

 Waivers will be issued for the entire measurement year. Waivers for the 2024 measurement year will be granted in late 2025.

Do I need to apply for a waiver for each of my practice locations?

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



I am unable to apply for a waiver online. Is there another way to request a waiver?

- Yes. CMS will provide technical assistance for waiver requests via telephone for prescribers who cannot
 apply for their waiver online. CMS will announce waiver assistance once it is available.
- Please subscribe to the CMS EPCS Program listserv (<u>click to subscribe</u>) to receive program updates
 that will announce when the waiver application is available. You can also find EPCS Program
 announcements at https://www.cms.gov/medicare/e-health/eprescribing/cms-eprescribing-for-controlled-substances-program.

I have a waiver from my state's EPCS program. Does that waiver cover the requirements for this program?

 No. The CMS EPCS Program is separate from state EPCS program requirements, including waiver application and approval.

ACRONYMS LIST

CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
EHR	Electronic Health Record
EPCS	Electronic Prescribing for Controlled Substances
HARP	Healthcare Quality Information System Access, Roles and Profile
HCQIS	Healthcare Quality Information System
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
PECOS	Provider Enrollment, Chain, and Ownership System
PI	Promoting Interoperability
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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