

Acronyms

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General Questions

What is the CMS EPCS Program?

• The 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 (Public Law 115-271), which mobilized federal efforts to improve safety and quality of health care, requires that Schedule II, III, IV, and V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug (MA-PD) plans be prescribed electronically, 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. The compliance requirement 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 Drug Enforcement
Administration (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, each measurement year.



Are there exceptions to the CMS EPCS Program?

- Prescribers must electronically prescribe at least 70 percent of their Schedule II, III, IV, and 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 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. CMS posts a list of the qualifying emergencies or disasters for each measurement year on the CMS EPCS website.
 - CMS-Approved Waiver: 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, 2025.

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

• When calculating prescriber compliance, CMS will exclude 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.

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 the CMS EPCS Program requirement 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. Medicare
Part D claims data will be analyzed to determine compliance for the program. A Health Care Quality
Information Systems (HCQIS) Access, Roles and Profile (HARP) account will be needed to access
the CMS EPCS Prescriber Portal to review compliance status and submit a waiver application, if
needed.



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 Drug Enforcement Administration (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 state specific 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 in-house Information Technology (IT) support, electronic prescribing (eRX) or electronic health record (EHR)/electronic medical record (EMR) 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 EHR, EMR, or e-prescribing system, and 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 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 as well as for sending out non-compliance notices. 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 that prescribers must electronically prescribe at least 70 percent of their Schedule II, III, IV,
and V controlled substances prescriptions under Medicare Part D, after exceptions, each
measurement year.

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

 Under Section 2003 of the SUPPORT Act (<u>Public Law 115-271</u>), 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 (with qualified exceptions) only to prescribers who issue controlled substance prescriptions under Medicare Part D. Consistent with section 2003 of the SUPPORT Act (section 1860D-4(e)(7) of the Social Security Act) and the CY 2022 and CY 2023 Physician Fee Schedule final rules:
 - 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 is the criterion for compliance?

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

How will compliance be measured?

- CMS will analyze 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 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 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. CMS posts a list of the qualifying emergencies or disasters for each measurement year on the CMS EPCS website.
 - CMS-Approved Waiver: 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 facility will be included in determining compliance no earlier than January 1, 2025.

After exceptions, a prescriber is considered compliant if at least 70 percent of the prescriber's Schedule II, III, IV, and V controlled substance prescriptions under Medicare Part D are electronically prescribed 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 after each 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 compliance analysis for the 2023 compliance measurement year will begin in August 2024 and include Medicare Part D claims with a Date of Service or fill date from January 1, 2023, to December 31, 2023, submitted on or before 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 fall of 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 or their representatives 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 or their representatives may apply for a waiver if they were unable to meet the CMS EPCS Program requirement due to circumstances beyond the prescribers' control. 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 information at https://www.cms.gov/medicare/e-health/eprescribing/cms-eprescribing-for-controlled-substances-program.

What happens if I am non-compliant?

Starting in the 2023 measurement year, the non-compliance action will be a notice of non-compliance. The notice will include information to prescribers that they are violating the CMS EPCS Program requirement, information about how they can come into a compliance, benefits of EPCS, and a link to the CMS EPCS Prescriber Portal where they can check compliance status and may request a waiver for circumstances beyond the prescriber's control. A prescriber's non-compliance under the CMS EPCS Program may be considered in CMS processes for assessing potential fraud, waste, and abuse.



Waiver Questions

Who is eligible for the CMS EPCS Program waiver?

Prescribers unable to meet the CMS EPCS Program requirement to electronically prescribe at least
70 percent of the qualifying Part D Schedule II-V controlled substance prescriptions, due to
circumstances beyond the prescribers' control, 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 or their representatives with a HARP account
may securely access the CMS EPCS Prescriber Portal (https://cqr.cms.gov/epcs/landing) during the
fall of the following calendar year to check their compliance status and request a waiver. Noncompliant prescribers applying for a waiver must provide an explanation/documentation of
circumstances beyond their control that prevented them from meeting the CMS EPCS Program
requirement. 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?

 A prescriber who receives a CMS-approved waiver because the prescriber is unable to meet the CMS EPCS Program requirement due to circumstances beyond the prescriber's control will be exempt for the entire measurement year. For example, a prescriber who receives a waiver for the 2023 measurement year will be exempt for measurement year 2023.

Do I need to apply for a waiver 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 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 CMS 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 requirement for this program?

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

Acronym List

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	Healthcare Quality Information System (HCQIS) Access, Roles and Profile
HCQIS	Health Care Quality Information Systems
HHS	Department of Health and Human Services
LTC	Long-Term Care
MA-PD	Medicare Advantage Prescription Drug Plan
NCPDP	National Council for Prescription Drug Programs
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
PDPs	Prescription Drug Plans
SUPPORT Act	The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act