EPCS Electronic Prescribing for Controlled Substances

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General Questions

What is Section 2003 of the SUPPORT Act and how does it impact my controlled substance prescribing?

Section 2003 of the SUPPORT Act mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D prescription drug plans (Medicare Part D) be done electronically in accordance with an electronic prescription drug program. Electronic prescribing for controlled substances (EPCS) has many benefits such as improved patient safety, medication adherence, and workflow efficiencies, fraud deterrence, and reduced burden.

What is the EPCS Program?

 CMS is administering the electronic prescribing requirement mandated in Section 2003 of the SUPPORT Act through the EPCS Program. The EPCS Program rules have been addressed in the <u>Physician Fee Schedule Final Rule</u>. The first measurement year for compliance with the requirements of the EPCS Program begins January 1, 2023 and ends December 31, 2023.

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 EPCS Program voluntary?

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

Are there exceptions to the EPCS Program?

- Prescribers will be exempt from, or particular prescriptions will not be considered for purposes of determining compliance with, this requirement in the following situations:
 - Prescriptions for controlled substances issued when the prescriber and dispensing pharmacy are the same entity.
 - Prescribers who issue 100 or fewer qualifying Part D controlled substance prescriptions per calendar year.
 - Prescribers who CMS determines are in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.
 - Prescribers who have received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances due to circumstances beyond the prescriber's control.

Compliance actions for prescriptions for beneficiaries in a long-term care (LTC) facility will begin January 1, 2025.



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 any 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 EPCS Program?

No. Prescribers do not have to register or report data to CMS for the 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 Drug Enforcement Agency (DEA) guidance, which is summarized at https://deadiversion.usdoj.gov/ecomm/e_rx/.

Is a fax of a prescription considered an electronic prescription?

 No. A prescription generated by an electronic system, such as an electronic health record (EHR) or e-prescribing system, and printed or transmitted through fax is not considered an electronic prescription for purposes of the 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 declared by a Federal, State, or local government entity during the measurement year to identify when circumstances arise in which an exception to the EPCS requirement might apply.

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

 No. While the Promoting Interoperability (PI) programs and the PI category under the Quality Payment Program (QPP) include e-prescribing measures, the EPCS Program is a separate federal program. The 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.



Compliance Questions

What are the criteria for compliance?

To be considered compliant, at least 70 percent of controlled substance (Schedule II-V)
prescriptions under Medicare Part D must be transmitted electronically each measurement year,
after exceptions are applied.

How will compliance be measured?

- CMS will analyze Medicare Part D claims for the first fill of 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, or particular prescriptions will not be considered for purposes
 of determining compliance with, this requirement in the following situations: Prescriptions for
 controlled substances issued when the prescriber and pharmacy are the same entity.
 - Prescribers who issue 100 or fewer qualifying Part D controlled substance prescriptions per calendar year.
 - Prescribers who CMS determines are in a geographic area of an emergency or disaster declared by a Federal, State, or local government entity.
 - Prescribers who have received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances due to circumstances beyond the prescriber's control.

Compliance actions for prescriptions for beneficiaries in a long-term care (LTC) facility will begin January 1, 2025.

After exceptions, a prescriber is considered compliant when at least 70 percent of prescribing for Schedule II, III, IV, and V controlled substances under Medicare Part D are done electronically 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.

When will CMS begin assessing my EPCS compliance?

The first EPCS compliance measurement year is January 1, 2023 through December 31, 2023.
 After the end of the calendar year, allowing time for claims submission and processing, CMS will analyze the Medicare Part D claims to measure compliance.



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

• Prescribers found to be non-compliant in the 2023 measurement year will receive a notification of non-compliance during the 2024 calendar year. Prescribers will also be able to log into the CMS EPCS Program website to review their annual compliance. CMS will announce more information regarding non-compliance notifications once it is available. Non-compliant prescribers may apply for a waiver if they experienced extraordinary circumstances that prevented them from electronically prescribing controlled substances. Please subscribe to the EPCS Program listserv to receive announcements regarding non-compliance notifications and waiver applications. You can also find EPCS Program announcements at https://www.cms.gov/Medicare/E-Health/Eprescribing.

Is there a penalty for not electronically prescribing controlled substances?

 Yes. For the 2023 measurement year, the penalty for non-compliant prescribers will be a CMS notification of EPCS Program non-compliance. CMS will propose penalties for future EPCS measurement years through rulemaking.

Waiver Questions

Who is eligible for an EPCS Program waiver?

Prescribers who experienced extraordinary circumstances that prevented them from electronically
prescribing controlled substances to Medicare Part D beneficiaries are eligible to request a waiver.
CMS defines "extraordinary circumstances" as situations such as economic hardships,
technological limitations, or other circumstances outside of the prescriber's control.

What is the process for submitting an EPCS Program waiver application?

 After the measurement year is complete, prescribers with a Healthcare Quality Information System (HCQIS) Access, Roles and Profile (HARP) account may securely access the EPCS Dashboard to check their compliance status and request a waiver. Prescribers must provide rationale and attest there were circumstances beyond their control which prevented them from electronically prescribing controlled substances for a designated compliance measurement year.

Please subscribe to the EPCS Program listserv (<u>Click to subscribe</u>) to receive program updates which will announce when the waiver application is available. You can also find EPCS Program announcements at https://www.cms.gov/Medicare/E-Health/Eprescribing.

How long does a waiver last?

• Waivers for the EPCS Program are applicable for up to one measurement year. Waivers for the 2023 measurement year will be granted in calendar year 2024.

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 waiver request assistance via telephone for prescribers who cannot apply for their waiver online. CMS will announce waiver assistance once it is available.
 Please subscribe to the EPCS Program listserv (<u>Click to subscribe</u>) to receive program updates which will announce when the waiver application is available. You can also find EPCS Program announcements at https://www.cms.gov/Medicare/E-Health/Eprescribing.

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 any state EPCS program requirements, including waiver application and approval.

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