FREQUENTLY ASKED QUESTIONS

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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 and Medicare Advantage prescription drug (MA-PD) plans 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 Physician Fee Schedule Final Rule. 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 in the measurement year.
  - 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.
  - 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.
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. The Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan and Provider Enumeration System (NPPES) will be used as the data sources to identify the geographic location of prescribers for purposes of the emergency exception. CMS will 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 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 (excluding any prescriptions that fall within an exception).
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 Drug Enforcement Agency (DEA) requirements.

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 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:
    o Prescriptions for controlled substances issued when the prescriber and pharmacy are the same entity.
    o Prescribers who issue 100 or fewer qualifying Part D controlled substance prescriptions in the measurement year.
    o 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.
    o 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. 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 measurement year, Medicare Part D claims with a Date of Service between January 1, 2023 to December 31, 2023, with a submission date on or before the submission deadline for 2023 (that is, June 28, 2024) will be included in the compliance analysis.

How will I be notified if I am non-compliant?
- Prescribers found to be non-compliant for the 2023 measurement year will receive a non-compliance notice during the 2024 calendar year. Notices will be sent by e-mail when possible, to available e-mail 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 e-mail address in PECOS or NPPES. CMS strongly recommends that all prescribers keep their e-mail address accurate and up to date in both systems. 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 notices 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 notices and waiver applications. You can also find EPCS Program announcements at https://www.cms.gov/Medicare/E-Health/Eprescribing.

Are there compliance actions for not electronically prescribing controlled substances?
- Yes. For the 2023 and 2024 measurement years, CMS will send a non-compliance notice to prescribers violating the EPCS mandate. CMS is evaluating compliance actions for future measurement years, and those compliance actions will be identified in future 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. Such extraordinary circumstances may include: 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 document the existence of a circumstance beyond their control that prevented the prescriber from conducting EPCS for a designated measurement year.
  Please subscribe to the EPCS Program listserv (Click to subscribe) 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?
- Waiver will be issued for a period of up to the entire measurement year. Waivers for the 2023 measurement year will be granted in late 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 assistance for waiver request 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 (Click to subscribe) 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.