The Centers for Medicare & Medicaid Services Electronic Prescribing for Controlled Substances Program Q&A Document for the March 2025 Webinar:

Program Overview, Compliance Requirement, and LTC Facility Prescriptions

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Measurement Year 2025 Requirement

1. Q. Have there been any changes or updates to the program timeline?

A. No, nothing has changed with the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program timeline, also known as the measurement cycle. The only timing change is related to prescriptions written for a beneficiary in a long-term care facility to be included in determining prescriber compliance, which moved from starting January 1, 2025, to starting January 1, 2028.

As a reminder, the measurement cycle begins with the compliance start and end dates, which are January 1 and December 31, respectively, of the measurement year. Prescriptions filled during this time are used to calculate compliance for the year.

Next is the analysis compliance period, which begins August after the measurement year, and then the notification period, which begins mid-September. During this time, CMS reviews Medicare Part D prescription claims data to determine whether prescribers have met the compliance threshold for the CMS EPCS Program, after exceptions have been applied.

The notification period takes place in September after the measurement year and is when CMS notifies prescribers of their initial compliance status and any associated review or waiver process that may be available before CMS determines prescribers' final compliance statuses.

The waiver application submission period occurs from mid-September to mid-November after the measurement year, lasting 60 days. This period is when prescribers and their designated representatives can log in to the CMS EPCS Prescriber Portal to check prescriber compliance and submit waiver applications for circumstances beyond prescribers' control. CMS then determines each prescriber's final compliance status.

For more on the program's measurement cycle, visit the "CMS EPCS Program Timeline" section of the <u>CMS EPCS Program webpage</u>.

2. Q. What's the current program requirement?

- Q. What is the 2025 requirement?
- Q. What are the details on the compliance requirement for 2025?
- Q. What are the 2025 requirements?
- Q. What are the requirements for the program?
- Q. What are the requirement details?

A. First, it's important to note that all prescribers who issue Schedule II–V controlled substance prescriptions under Medicare Part D or Medicare Advantage prescription drug plans in the measurement year are federally mandated to meet the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement.

Second, the program requirement for measurement year 2025 remains unchanged: To be considered compliant, prescribers must electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D, after exceptions, in the measurement year.

Prescribers are exempt from the program if they qualify for the automatic small prescriber exception, for the automatic declared disaster exception, or for the CMS-approved waiver exception. Prescribers who are not yet compliant with the program for the measurement year, after automatic exceptions, will have the opportunity to submit a waiver application to be considered for the CMS-approved waiver exception if they experienced circumstances beyond their control that prevented them from meeting the program's requirement. Once approved, the waiver will be good for the entire measurement year.

- 3. Q. What's the biggest change from 2024 to 2025?
 - Q. What are the details on the extension of the compliance deadline for LTC facility prescriptions from 2025 to 2028?
 - Q. What are the 2025 changes for compliance requirements for measurement years?
 - Q. What are the changes for MY 2025?
 - Q. Has anything changed?
 - Q. What's new?
 - Q. Have there been any updates to the requirement?
 - Q. Is there anything new to support my client?
 - Q. Is there anything new? I'm curious about LTC requirements.
 - Q. Why are you extending the compliance deadlines?
 - Q. Are there any significant changes to the EPCS Program?

A. In the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (PFS) final rule, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Electronic Prescribing for Controlled Substances (EPCS) Program policy that prescriptions written for a beneficiary in a long-term care facility (FTC) facility will not be included in determining prescriber compliance until January 1, 2028.

CMS also finalized that compliance actions against prescribers who don't meet the compliance threshold based on prescriptions written for a beneficiary in an LTC facility will start measurement year 2028.

Before the CY 2025 Medicare PFS final rule, prescriptions written for a beneficiary in an LTC facility were supposed to be included in determining prescriber compliance starting January 1, 2025, which was only a few months ago.

The June 2024 Part D and Health IT Standards final rule finalized requiring the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 as the e-prescribing standard for transmitting prescriptions for all covered Part D drugs starting January 1, 2028. NCPDP SCRIPT standard version 2023011

permits 3-way communication that would better facilitate LTC workflows in a way that NCPDP SCRIPT standard version 2017071 does not.

CMS acknowledged that even though prescribers could use NCPDP SCRIPT standard version 2023011 as of July 17, 2024, it might not be feasible for LTCs to have their e-prescribing software programs configured to the new standard by January 1, 2025.

CMS moved the date so that it aligns with when NCPDP SCRIPT standard version 2017071 retires and when the new NCPDP SCRIPT standard version is required for all Part D prescriptions.

CMS believes that the new date now gives prescribers and pharmacies enough time to adopt the new standard.

Long-Term Care Facilities

4. Q. What are the requirements for LTC prescribing?

Q. How do you plan on holding LTCs responsible to receive our prescriptions?

A. The Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program analyzes prescriptions under Medicare and Medicare Advantage prescription drug plans at the prescriber level. Currently, claims received for prescriptions filled in long-term care facilities are excluded from the prescriber's analysis. Beginning January 1, 2028, these claims will be included in the prescriber's total number of prescriptions for the measurement year.

5. Q. How will this affect LTC facilities?

A. In the Calendar Year 2025 Medicare Physician Fee Schedule final rule, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Electronic Prescribing for Controlled Substances (EPCS) Program policy that prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in

determining compliance until January 1, 2028. CMS also finalized that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in an LTC facility will start measurement year 2028.

6. Q. What is the nurses' role in long-term care settings when it comes to assisting providers with e-prescribing controlled meds?

A. In the Calendar Year 2025 Medicare Physician Fee Schedule final rule, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Electronic Prescribing for Controlled Substances (EPCS) Program policy that prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in determining prescriber compliance until January 1, 2028.

National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 permits 3-way communication that would better facilitate LTC workflows in a way that NCPDP SCRIPT standard version 2017071 does not. In NCPDP SCRIPT standard version 2023011, through use of a MessageIndicatorFlag, an RxFill transaction may be sent as a copy to inform or synchronize systems. Through use of this functionality, a prescriber can electronically send a controlled substance prescription, including for a covered Part D drug, to a pharmacy, and the pharmacy can use the MessageIndicatorFlag in an RxFill transaction when dispensing the prescription to inform the LTC facility of the medication order. This function streamlines prescribers' workflows and ensures that the LTC facility responsible for providing the controlled substance to the patient is aware of the order.

CMS acknowledged that even though prescribers could use NCPDP SCRIPT standard version 2023011 as of July 17, 2024, it might not be feasible for LTCs to have their e-prescribing software programs configured to the new standard by January 1, 2025.

CMS moved the date so that it aligns with when NCPDP SCRIPT standard version 2017071 retires and when the new NCPDP SCRIPT standard version is required.

CMS believes that the new date now gives prescribers and pharmacies enough time to adopt the new standard.

7. Q. Will there be a new NCPDP change message created?

A. The following is our current messaging about the new National Council for Prescription Drug Programs (NCPDP) change: In the Calendar Year 2025 Medicare Physician Fee Schedule final rule, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Electronic Prescribing for Controlled Substances (EPCS) Program policy that prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in determining prescriber compliance until January 1, 2028.

NCPDP SCRIPT standard version 2023011 permits 3-way communication that would better facilitate LTC workflows in a way that NCPDP SCRIPT standard version 2017071 does not. In NCPDP SCRIPT standard version 2023011, through use of a MessageIndicatorFlag, an RxFill transaction may be sent as a copy to inform or synchronize systems. Through use of this functionality, a prescriber can electronically send a controlled substance prescription, including for a covered Part D drug, to a pharmacy, and the pharmacy can use the MessageIndicatorFlag in an RxFill transaction when dispensing the prescription to inform the LTC facility of the medication order. This function streamlines prescribers' workflows and ensures that the LTC facility responsible for providing the controlled substance to the patient is aware of the order.

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CMS believes that the new date now gives prescribers and pharmacies enough time to adopt the new standard.

EPCS Prescriber Portal

8. Q. How can you check a compliance status?

A. On the <u>Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing</u>
<u>for Controlled Substances (EPCS) Prescriber Portal</u>, a prescriber of Medicare Part D
Schedule II–V controlled substances and their designated representatives can check the prescriber's compliance status.

Users can log in to the EPCS Prescriber Portal with their Health Care Quality Information Systems (HCQIS) Access Roles and Profile (HARP) account user ID and password.

Once in the EPCS Prescriber Portal, users can:

- Review the prescriber's compliance status for the measurement year, including any automatic exceptions.
- Submit a waiver application for the measurement year, if needed, based on circumstances beyond the prescriber's control.
- Check the prescriber's waiver application status.

For more information, see the "CMS EPCS Prescriber Portal" section on the <u>CMS</u>
<u>EPCS Program webpage</u> and the <u>CMS EPCS Prescriber Portal & Waiver Application</u>
User Guide.

9. Q. How can I navigate the system for this process?

A. To review a prescriber's compliance status and submit a waiver application, if needed, users need to log in to the <u>Centers for Medicare & Medicaid Services</u>

(CMS) Electronic Prescribing for Controlled Substances (EPCS) Prescriber Portal with a Health Care Quality Information Systems (HCQIS) Access Roles and Profile (HARP) account using their user ID and password, which 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 <u>HARP Create an Account webpage</u>. You can find step-by-step instructions in the <u>Centers for Medicare & Medicaid Services</u>

(CMS) EPCS Prescriber Portal & Waiver Application User Guide.

10. Q. Are we ever going to be able to see our data so we can identify patients that didn't meet the requirements?

A. The prescriber can request their compliance data after further identity verification, but the Centers for Medicare & Medicaid Services (CMS) doesn't share patient data. In general, prescribers can use reports from their electronic health record and e-prescribing systems to track their patients' e-prescribing metrics. This can assist prescribers in tracking the CMS Electronic Prescribing for Controlled Substances (EPCS) Program requirement and any separate State requirements that may apply to their situation. Separate State requirements vary regarding which patients are included and which exceptions may apply. Once a prescriber's annual compliance information is available on CMS EPCS Prescriber Portal and if they believe there's a discrepancy with their compliance results, they can call, email, or submit an online ticket to Center for Clinical Standards and Quality Support Central to receive help from its experts.

11. Q. How can I gain access to the portal as a staff member?

A. Prescribers and their designated representatives can access the <u>Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Prescriber Portal if they have their own Health Care Quality Information Systems (HCQIS) Access Roles and Profile (HARP) account user ID</u>

and password, which are the same login credentials for accessing the Quality Payment Program Portal. If a user doesn't have a HARP account, they can apply for one on the HARP Create an Account webpage.

12. Q. Will there be an option to begin viewing the status of the providers EPCS throughout the year?

A. Currently, the <u>Centers for Medicare & Medicaid Services (CMS) Electronic</u>

<u>Prescribing for Controlled Substances (EPCS) Prescriber Portal</u> has been developed to show only final compliance results and allow for a measurement year waiver application, if needed, after the close of the year. At this time, CMS isn't planning to provide viewing status throughout the year.

13. Q. Is there any stopgap or planned enhancement to prevent providers from searching for another provider on the Prescriber Portal?

A. A user can view a prescriber's compliance status by searching for the prescriber's National Provider Identifier (NPI). A user can also submit a waiver application on behalf of a prescriber or add their email address to a submitted waiver application to receive updates. The Centers for Medicare & Medicaid Services (CMS) uses the CMS Electronic Prescribing for Controlled Substances (EPCS) Prescriber Portal analytics to monitor Health Care Quality Information Systems (HCQIS) Access Roles and Profile (HARP) account activity specific to actions performed on the EPCS Prescriber Portal.

Waivers

14. Q. How do I submit a waiver application?

A. Each fall after the measurement year, for 60 days typically from mid-September to mid-November, each non-compliant prescriber or their designated representative may submit a waiver application, as needed, to request a CMS-approved waiver exception when circumstances beyond their control prevented the prescriber from meeting the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement for the measurement year.

Prescribers and their designated representatives can submit waiver applications through the CMS EPCS Prescriber Portal.

To log in to the EPCS Prescriber Portal, users:

- Need a Health Care Quality Information Systems (HCQIS) Access, Roles, and Profile (HARP) account user ID and password
- Use the same login credentials for accessing the Quality Payment Program
 Portal
- Can apply for a HARP account on the <u>HARP Create an Account webpage</u>

For more detailed instructions on how to submit a waiver application, refer to the CMS EPCS Prescriber Portal & Waiver Application User Guide on the CMS EPCS Prescriber Program webpage in the "Downloads" section.

15. Q. What information will be needed to submit a waiver application?

A. A prescriber or their designated representative should have any digitized supporting documentation readily available that supports the prescriber's Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program waiver application's description of the circumstances beyond the prescriber's control that prevented them from e-prescribing controlled substances in the measurement year. The supporting documentation may be

uploaded to the CMS EPCS Prescriber Portal when the prescriber's waiver application is being filled out.

Examples of supporting documentation include:

- Documentation showing speed and bandwidth limitations from available internet service providers
- Correspondence from the prescriber's e-prescribing for controlled substances software program vendor or a pharmacy supporting a continued technical issue
- Documentation that serves as evidence of a local disaster or emergency that
 affected the prescriber's ability to e-prescribe controlled substances during
 the measurement year (for example, a news article, a local disaster
 declaration, and communication with the prescriber's insurance agency)

For more information on what to submit with a waiver application, refer to the CMS EPCS Prescriber Portal & Waiver Application User Guide on the CMS EPCS Prescriber Program webpage in the "Downloads" section.

16. Q. What wavier information do you have for small practices?

A. Prescribers who receive the small prescriber exception don't need to submit a waiver application for the measurement year. The Centers for Medicare & Medicaid Services (CMS) automatically grants this exception to prescribers who issue 100 or fewer qualifying Schedule II–V controlled substance prescriptions under Medicare Part D, both electronic and non-electronic, in the measurement year. However, we still encourage these prescribers to check their compliance status on the CMS
Electronic Prescribing for Controlled Substances (EPCS) Prescriber Portal. If your practice doesn't meet the small prescriber exception, but there are technical or other circumstances beyond the prescribers' control that prevents them from meeting the requirement, they may each submit a waiver application for the measurement year.

Exceptions

17. Q. What about the providers that do not prescribe Schedule II medications or prescribe very little?

A: Prescribers who don't prescribe Schedule II controlled substances or prescribe them infrequently may still be subject to the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement if they write any qualifying prescriptions for Schedule II–V controlled substances under Medicare Part D.

CMS automatically grants an exception to prescribers who issue 100 or fewer qualifying Schedule II–V controlled substance prescriptions under Medicare Part D, both electronic and non-electronic, in the measurement year.

Regulatory and Compliance

18. Q. What is the CMS EPCS Prescriber Program?

A. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018 (Public Law 115-271) was enacted to address the opioid crisis. Section 2003 of the SUPPORT Act mandates e-prescribing for controlled substances under Medicare Part D and Medicare Advantage prescription drug plans. Through rulemaking, the Centers for Medicare & Medicaid Services (CMS) established the CMS Electronic Prescribing for Controlled Substances (EPCS) Program requirement with exceptions and set the first date of compliance actions to begin January 1, 2023. Compliance results for the 2023 measurement year were made available on the CMS EPCS Prescriber Portal on September 18, 2024.

- 19. Q. What is the program's compliance requirement?
 - Q. What are the specific requirements of the rule?
 - Q. What are the regulatory requirements?
 - Q. What are the regulations?
 - Q. What are the regulations?
 - Q. What are the requirement specifics to meet standards?
 - Q. What are the EPCS requirements from CMS?
 - Q. What are the compliance regulations?
 - Q. What are the requirement details?
 - Q. How will compliance be reported and measured?
 - Q. What are the requirements for compliance?
 - Q. What are the compliance requirements?

A. All prescribers who issue controlled substance prescriptions under Medicare Part D are required to be compliant with the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program each measurement year. Note that prescribers don't need to report anything to CMS. They need only e-prescribe at least 70% of the qualifying Medicare Part D controlled substance prescriptions they issue in the measurement year, after exceptions.

To measure a prescriber's compliance with the EPCS Program each year, CMS analyzes the Medicare Part D Schedule II–V controlled substance prescription claims attributed to the prescriber's National Provider Identifier (NPI).

Each year, non-compliant prescribers receive non-compliance notices informing them that they are violating the EPCS Program requirement and including information about how they can come into compliance, the benefits of e-prescribing controlled substances, and a link to the CMS EPCS Prescriber Portal.

20. Q. How can I apply for the program?

Q. How can you apply for the program?

A. Prescribers don't have to register for the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program or report any data to CMS for the EPCS Program. CMS analyzes Medicare Part D claims data to determine prescriber compliance.

21.Q. Who is this measure intended for?

A. All prescribers who issue Schedule II–V controlled substance prescriptions under Medicare Part D or Medicare Advantage prescription drug plans in the measurement year are federally mandated to meet the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement.

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

22. Q. What's the importance of compliance?

A. The Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program enhances patient safety through patient identity checks, medication recommendations, and timely and accurate transmission of time-sensitive prescriptions. It also reduces prescriber burden by detecting and preventing prescription fraud and irregularities, improving workflow efficiencies, avoiding data errors, and reducing pharmacy calls for clarifying written prescriptions.

Starting in measurement year 2023, each prescriber identified by CMS as non-compliant with the CMS EPCS Program requirement for the measurement year receives the non-compliance notice during the notification period. The notice includes information to a prescriber that they are violating the CMS EPCS Program requirement, information about how they may come into compliance, information on the information on the benefits of e-prescribing for controlled substances, and a link

to the <u>CMS EPCS Prescriber Portal</u> where they can check their compliance status and may submit a waiver application for circumstances beyond their control.

Note that a prescriber's final 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.

23. Q. Is this a mandate?

A. Yes, the Centers for Medicare & Medicaid Services (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) mandates prescribers to electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug plans, after exceptions, each measurement year.

24. Q. What recommended steps can providers and organizations take to ensure compliance?

A. To get started with the Centers for Medicare & Medicaid Services (CMS)

Electronic Prescribing for Controlled Substances (EPCS) Program, prescribers can:

- 1. Set up an e-prescribing software program that meets all <u>U.S. Drug</u> Enforcement Agency requirements.
- Verify their contact information in the <u>Medicare Provider Enrollment, Chain,</u> and Ownership System (PECOS) and in the <u>National Plan and Provider</u> <u>Enumeration System (NPPES)</u>.
- 3. Set up a <u>Health Care Quality Information Systems (HCQIS) Access Roles and Profile (HARP) account.</u>
- 4. E-prescribe Schedule II–V controlled substances.
- 5. Review their compliance status on the CMS EPCS Prescriber Portal.

6. Submit a waiver application through the EPCS Prescriber Portal, if appropriate.

25. Q. How are the metrics calculated?

Q. How can I calculate my compliance rate?

A. The Centers for Medicare & Medicaid Services (CMS) will analyze Medicare Part D claims and use the prescriber's National Provider Identifier (NPI) associated with the claim. CMS will begin the analysis by identifying Medicare Part D Schedule II–V controlled substance prescriptions filled January 1–December 31 of the measurement year and remove prescriptions written for beneficiaries in long-term care facilities.

In claims data, a prescription, including its refills, is given a unique prescription number by the pharmacy. CMS will use only 1 instance of the prescription number for the compliance calculation. Therefore, refills won't count as an additional prescription in the compliance threshold calculation unless the result is the first occurrence of the unique prescription in the measurement year.

CMS calculates the compliance rate by dividing the prescriber's number of Medicare Part D controlled substance prescriptions eligible to be e-prescribed by the prescriber's overall number of qualifying Medicare Part D controlled substance prescriptions. For prescribers without an exception, if the rate is 70% or higher, the prescriber is considered compliant with the CMS Electronic Prescribing for Controlled Substances (EPCS) Program.

26. Q. What is the passing compliance metric?

A. 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.

27. Q. What are the consequences of violating the program?

A. Starting in measurement year 2023, the non-compliance action is the non-compliance notice. The notice includes information to prescribers that they are violating the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement, information about how they may come into compliance, information on the benefits of e-prescribing controlled substances, 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 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 the non-compliance notice and submitting waiver applications, subscribe to the <u>CMS EPCS Program Listserv</u>. You can also find more information about them on the <u>CMS EPCS Program webpage</u>.

28. Q. What are the psychiatry regulations for the EPCS Program?

Q. Do outpatient behavioral health providers need to follow this rule?

A. All prescribers, including those in psychiatry and other behavioral health fields, who issue Schedule II–V controlled substance prescriptions under Medicare Part D or Medicare Advantage prescription drug plans in the measurement year are federally mandated to meet the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement.

To be considered compliant, prescribers must electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D, after exceptions, in the measurement year. Providers who receive the small prescriber exception don't need to submit a waiver application for the measurement

year. Centers for Medicare & Medicaid Services (CMS) automatically grants this exception to prescribers who issue 100 or fewer qualifying Schedule II–V controlled substance prescriptions under Medicare Part D, both electronic and non-electronic, in the measurement year.

Prescribers are exempt from the program if they qualify for the automatic small prescriber exception, for the automatic declared disaster exception, or for the CMS-approved waiver exception. However, we still encourage these prescribers to check their compliance status on the CMS EPCS Prescriber Portal. Prescribers who are not yet compliant with the program for the measurement year, after automatic exceptions, will have the opportunity to submit a waiver application to be considered for the CMS-approved waiver exception if they experienced circumstances beyond their control that prevented them from meeting the program's requirement. Once approved, the waiver will be good for the entire measurement year.

29. Q. Is the responsibility on the provider, facility, or pharmacy?

A. The Centers for Medicare & Medicaid Services (CMS) measures compliance with the CMS Electronic Prescribing for Controlled Substances (EPCS) Program at the prescriber National Provider Identifier (NPI) level, not the facility level. It is prescribers' responsibility to ensure their compliance with the program's requirement for e-prescribing controlled substances, and the non-compliance action is applied to the individual prescriber.

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.

30. Q. Are telemedicine providers allowed to e-prescribe?

A. As of the date of this webinar and until at least December 31, 2025, authorized prescribers can prescribe controlled substances through telehealth if they meet certain criteria. Specifically, a U.S. Drug Enforcement Agency-registered practitioner can prescribe a Schedule II–V controlled substance to a patient using telemedicine without having conducted an in-person medical evaluation if required conditions are met. For more on required criteria and conditions, refer to the <u>U.S. Department of Health and Human Services "Prescribing controlled substances via telehealth" webpage</u>.

31. Q. In what areas can misinterpretation or non-compliance occur?

A. Misinterpretation or non-compliance can occur in several areas, such as State and Federal mandates for e-prescribing for controlled substances.

A common misunderstanding is not recognizing that the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program applies to Medicare Part D only.

It's also important to note that the CMS EPCS Program's compliance requirement is for prescribers, not for practices, organizations, or hospitals.

Confusion may also surround the measurement year associated with waiver applications. For the CMS EPCS Program, prescribers submit a waiver application for the previous, not the current, measurement year. This means that in September 2025, they'll submit a waiver application for measurement year 2024 if they didn't meet the compliance requirement and believe there were circumstances beyond their control that prevented them from prescribing electronically.

Another point of confusion is related to electronic health records (EHRs) and the CMS EPCS Prescriber Portal. A user's EHR doesn't need to be integrated with the EPCS Prescriber Portal, because the EPCS Program automatically calculates

prescriber compliance using Medicare Part D claims. A prescriber issuing electronic prescriptions must use a software program that meets all U.S. Drug Enforcement Agency (DEA) requirements. No additional e-prescribing software program is needed to meet the EPCS Program requirement.

For more information on DEA requirements for e-prescribing software programs, visit the DEA Electronic Prescribing for Controlled Substances (EPCS) webpage.

32. Q. What's one thing facilities should focus on to ensure stronger and more effective compliance in this area?

A. One key area for facilities to focus on is ensuring that prescribers are compliant with the e-prescribing requirements for controlled substances, as compliance is at the prescriber level, not the facility level. To support prescriber compliance, facilities should implement U.S. Drug Enforcement Agency-approved e-prescribing software. For more information on compliance, visit the <u>Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program webpage.</u>

33. Q. What process and qualifications are required?

A. Prescribers issuing electronic prescriptions for controlled substances must use a software application that meets all <u>U.S. Drug Enforcement Agency requirements</u>. No additional e-prescribing software system is needed to meet the requirement for the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program.

34. Q. Are the requirements going to change in subsequent years?

A. It's unlikely. However, any future changes to the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program requirement that do occur will be made through rulemaking and sub-regulatory guidance.

35. Q. When will this become mandatory? Provider cost to implement is hindering adoption.

A. On October 24, 2018, Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018 became public law (Public Law 115-271), requiring that prescriptions under a Medicare Part D or Medicare Advantage prescription drug plan be transmitted in accordance with an electronic prescription drug program.

The Calendar Year 2022 Medicare Physician Fee Schedule final rule, which appeared in the November 19, 2021, issue of the Federal Register, established the first measurement year for the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program, which was January 1–December 31, 2023.

Prescribers who aren't yet compliant with the program for the measurement year, after automatic exceptions, will have the opportunity to submit a waiver application to be considered for the CMS-approved waiver exception if they experienced circumstances beyond their control that prevented them from meeting the program's requirement. Once approved, the waiver exception will be good for the entire measurement year.

The cost of implementing e-prescribing is generally affordable, depending on the software provider. And while CMS can't recommend specific vendors, we will note that systems are available for as low as \$75 annually per prescriber with a \$90 setup fee, and many electronic health record systems now include e-prescribing for controlled substances in their ongoing annual software update cost.

36. Q. We have 3 areas DC, Maryland, and Virginia. How can we support any differences between the states for our facility?

A. The Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program is a Federal program mandated under 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). Individual U.S. states may have their own e-prescribing for controlled substances program requirements separate from the CMS EPCS Program. The CMS EPCS Program uses a prescriber's National Provider Identifier (NPI) on Medicare Part D claims to identify how many qualifying prescriptions were attributed to the prescriber's NPI, regardless of the prescriber's practice location.

37. Q. Is this applicable to Critical Access Hospitals?

A. The Centers for Medicare & Medicaid Services (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), requires prescribers to electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug plans, after exceptions, each measurement year.

38.Q. When are physicians in SNF expected to be compliant by?

Q. How does this affect SNFs?

A. The Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program looks at Medicare Part D claims only. Most skilled nursing facility (SNF) claims fall under Medicare Part A.

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

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

39. Q. What ASAP standard is going to be required?

A. Addictions and Substance Abuse Program (ASAP) requirements are outside the scope of the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program. All prescribers who issue controlled substance prescriptions under Medicare Part D are required to be compliant with the CMS EPCS Program each measurement year. Note that prescribers don't need to report anything to CMS. They need only e-prescribe at least 70% of the qualifying Medicare Part D Schedule II–V controlled substance prescriptions they issue in the measurement year, after exceptions.

40. Q. If a provider is not using an EHR, do they still need to e-prescribe controlled substances?

A. A prescriber issuing electronic prescriptions for controlled substances must use a software program that meets all <u>U.S. Drug Enforcement Agency (DEA) e-prescribing requirements</u>. No additional e-prescribing software system is needed to meet the requirement for the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program.

If the prescriber is new to electronically prescribing controlled substances, they need to:

- Contact e-prescribing software vendors and confirm that their software meets all DEA e-prescribing requirements. Some e-prescribing software can integrate with electronic health records (EHRs), while others run as standalone software.
- Complete identity-proofing requirements.
- Obtain a two-factor authentication device or adopt a process.

Configure logical access control.

A prescriber experiencing technical issues when electronically prescribing controlled substances should contact their in-house IT support or their e-prescribing software vendor. Examples of technical issues include login issues related to their username or password, multi-factor authentication codes, and prescription transmission errors.

41. Q. How should the compliance department monitor compliance?

A. In general, facilities can use reports from their electronic health record and e-prescribing systems to track their e-prescribing metrics for all their prescribers. This can assist with tracking the program requirement and any separate State requirements that may apply to their situation. Separate State requirements vary regarding which patients are included and which exceptions may apply. A prescriber and their designated representatives can check the prescriber's compliance status using their National Provider Identifier (NPI) on the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Prescriber Portal.

42. Q. What audit mechanisms are in place to ensure e-prescribing for controlled substances compliance?

 for circumstances beyond their control. The waiver application submission period is open from mid-September to mid-November after the measurement year.

A prescriber's final 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.

43. Q. How does this affect credentialing, or is it relevant to credentialing?

A. Prescribers must be registered with the U.S. Drug Enforcement Administration (DEA) to prescribe controlled substances electronically. For information on DEA registration requirements, visit the <u>DEA Registration Q&A webpage</u>.

Pharmacy

44. Q. What are the pharmacy requirements?

A. To ensure beneficiary access, the Centers for Medicare & Medicaid Services (CMS) has provided guidance regarding the role of pharmacies and pharmacists in the implementation of the CMS Electronic Prescribing for Controlled Substances (EPCS) Program:

- Pharmacists and pharmacies don't have to be in compliance with the CMS EPCS Program requirement. The compliance requirement is limited to prescribers of Schedule II–V controlled substances under Medicare Part D.
- A pharmacist isn't required or otherwise obligated to verify that a prescriber has a CMS-accepted waiver exception from the CMS EPCS Program before they fill a Schedule II–V controlled substance prescription under Medicare Part D.
- A pharmacist isn't required or otherwise obligated to verify that a prescriber or prescription qualified for an exception to the CMS EPCS Program requirements before they fill dispensing a Schedule II–V controlled substance prescription under Medicare Part D.

The CMS EPCS Program doesn't limit or prevent pharmacists or pharmacies
from filling covered Part D prescriptions—including Schedule II–V controlled
substances—from valid written, oral, and faxed prescriptions consistent with
current laws and regulations, including State e-prescribing for controlled
substance mandates and U.S. Drug Enforcement Agency requirements.

These are important protections for Medicare patients that will ensure their continued and timely access to the medications they need.

45. Q. How will this program affect me and my prescriptions that I take being a medical professional?

A. For prescribers, the benefit of the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program is that it reduces prescriber burden by deterring and detecting prescription fraud and irregularities, improving workflow efficiency, and avoiding data-entry errors and pharmacy calls to clarify paper prescriptions.

For beneficiaries, the benefit of the program is that it enhances patient safety by allowing for patient identity checks, reducing prescription tampering, allowing for medication recommendations that lower the risk of errors and potentially harmful interactions, ensuring timely and accurate transmission of time-sensitive prescriptions, and reducing patient trips.

The 70% compliance threshold was finalized in the Calendar Year 2022 Medicare Physician Fee Schedule final rule. The compliance threshold was finalized to implement the mandate effectively in a manner that balances the mandate with helping ensure that prescribers are not overly burdened and are able to issue prescriptions for their patients during the rare occurrences when e-prescribing for controlled substances isn't feasible, such as cases of temporary technological failures and cases where it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such

delay would adversely impact the patient's medical condition. Based on feedback from interested parties and their review of prescription drug event data—also known as the Part D claims data—e-prescribing for controlled substances isn't feasible in no more than an estimated 30% of instances due to circumstances such as the ones mentioned in the paragraph. Part D prescribers should be able to conduct e-prescribing for controlled substances on 70% of their Part D controlled-substance prescriptions without being overly burdened or burdening patients.

46. Q. Are closed-door pharmacies subject to this?

A. If by "closed-door pharmacies" you're referring to a long-term care (LTC) pharmacy, then the requirements don't go into effect until January 1, 2028.

In the Calendar Year 2025 Medicare Physician Fee Schedule final rule, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Electronic Prescribing for Controlled Substances (EPCS) Program policy that prescriptions written for a beneficiary in an LTC facility won't be included in determining compliance until January 1, 2028. CMS also finalized that compliance actions against prescribers who don't meet the compliance threshold based on prescriptions written for a beneficiary in an LTC facility will start measurement year 2028.

47. Q. What should we do about patients that use local pharmacies that are closed on Sundays?

A. The Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program recognized, through rulemaking, that there may be instances when a prescriber can't successfully transmit a controlled substance prescription to a pharmacy such as in cases of temporary technological failures or cases where it would be impractical for the patient to obtain medications prescribed by e-prescriptions in a timely manner and such delay would adversely impact the patient's medical condition. For this reason, the program set a threshold of electronically transmitting at least 70% of Part D controlled substance prescriptions annually as the program requirement.

48. Q. What role does the pharmacy or do the pharmacists play regarding the EPCS LTC changes?

A. In the Calendar Year 2025 Medicare Physician Fee Schedule final rule, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Electronic Prescribing for Controlled Substances (EPCS) Program policy that prescriptions written for a beneficiary in a long-term care (LTC) facility won't be included in determining compliance until January 1, 2028. CMS also finalized that compliance actions against prescribers who don't meet the compliance threshold based on prescriptions written for a beneficiary in an LTC facility will start measurement year 2028.

49. Q. What major changes or updates will impact retail pharmacies?

A. To ensure beneficiary access, the Centers for Medicare & Medicaid Services (CMS) has provided guidance regarding the role of pharmacies and pharmacists in the implementation of the CMS Electronic Prescribing for Controlled Substances (EPCS) Program:

- Pharmacists and pharmacies don't have to be in compliance with the CMS EPCS Program requirement. The compliance requirement is limited to prescribers of Schedule II–V controlled substances under Medicare Part D.
- A pharmacist isn't required or otherwise obligated to verify that a prescriber has a CMS-accepted waiver exception from the CMS EPCS Program before they fill a Schedule II–V controlled substance prescription under Medicare Part D.
- A pharmacist isn't required or otherwise obligated to verify that a prescriber or prescription qualified for an exception to the CMS EPCS Program requirements before they fill dispensing a Schedule II–V controlled substance prescription under Medicare Part D.
- The CMS EPCS Program doesn't limit or prevent pharmacists or pharmacies from filling covered Part D prescriptions—including Schedule II–V controlled substances—from valid written, oral, and faxed prescriptions consistent with

current laws and regulations, including State e-prescribing for controlled substance mandates and U.S. Drug Enforcement Agency requirements.

These are important protections for Medicare patients that will ensure their continued and timely access to the medications they need.

50. Q. How does this affect reimbursement or paying pharmacy?

A. The Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program promotes electronic transmission of prescriptions from the point of care to the pharmacy. The program doesn't affect Medicare Part D pharmacy payment rules.

51. Q. Are the meds on tiers?

A. The Centers for Medicare & Medicaid Services (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), requires prescribers to electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription plans, after exceptions, each measurement year. The "tiers" for medications in the CMS EMCS Program would be the Schedule II–V controlled substances. Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into 5 schedules. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Schedule I controlled substances have no accepted medical use in the United States currently and aren't included in the CMS EPCS Program.

The alphabetical list of drugs and their schedule, according to Title 21, Section 202, of the CSA, is available in the CSA Controlled Substances Alphabetical Order PDF.

52. Q. Will our IRF be required to submit controlled substance prescriptions via e-prescribing?

A. Typically, Medicare Part A covers inpatient rehabilitation facility (IRF) services and Part A claims aren't used in the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program analysis. However, any Schedule II–V controlled substance covered under Part D while the patient is in an IRF will be included in the EPCS Program analysis and should be e-prescribed. When calculating prescriber compliance for the 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 records for Part D claims data. Prescriptions written for a beneficiary in a long-term care facility will be included in determining compliance no earlier than January 1, 2028.

Program Resources

53. Q. What should LTC providers and facilities be doing today to prepare for 2028?

Q. What is the NCPDP update plan?

A. Long-term care prescribers and facilities should work to implement the National Council for Prescription Drug Programs (NCPDP) standards finalized through the Centers for Medicare & Medicaid Service's (CMS's) final rule published in the June 17, 2024, Federal Register, titled "Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications."

54. Q. Since this is my first exposure, I'm not sure what questions I may have. How should I get started?

A. Those who are new to the program should review the <u>Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS)</u>

Program webpage, notably the resources available in the "Downloads" section.

To receive important program communications, they should also subscribe to the CMS EPCS Program Listsery.

55. Q. How can providers proactively prepare to meet the requirements?

- Q. How can I best be prepared for the future?
- Q. What resources are available for this program?
- Q. What resources are available to help with this?

A. For more guidance on the Centers for Medicare & Medicaid Services (CMS)

Electronic Prescribing for Controlled Substances (EPCS) Program, users should review the CMS EPCS Program webpage and subscribe to the CMS EPCS Program updates.

Listserv for program updates.

56. Q. How can I better understand the program requirements so that I can help my clients understand them?

A. The Centers for Medicare & Medicaid Services (CMS) has posted several educational documents available for downloading from the CMS Electronic
Prescribing for Controlled Substances (EPCS) Program webpage, including the CMS EPCS Program Getting Started Quick Reference Guide.

57. Q. What education can a consultant provide on an ongoing basis to better support medical directors in the hospice realm?

A. Note that the Centers for Medicare & Medicaid Services (CMS) Electronic

Prescribing for Controlled Substances (EPCS) Program looks at Medicare Part D

claims only. Hospice claims generally fall under Medicare Part A. However, if a

hospice patient has a controlled substance prescription covered under Part D rather

than the hospice benefit claim, the prescription will be counted. Promoting the use of e-prescribing in the hospice setting can reduce errors and streamline communication between the prescriber and the pharmacist for enhancement of patient care.

58. Q. Where can I get more waiver information?

A. You can find the CMS EPCS Prescriber Portal & Waiver Application User Guide on the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Prescriber Program webpage in the "Downloads" section. CMS is planning a webinar this summer that will focus on the 2024 measurement year compliance results and submitting a waiver application. Be sure to subscribe to the CMS EPCS Program Listsery to receive future event announcements.

59. Q. Where can you find any analytics that have been done regarding the data collected?

Currently, the Centers for Medicare & Medicaid Services (CMS) doesn't plan to publicly release analytics on e-prescribing for controlled substances.

60. Q. Can the information covered in this webinar be sent in an email with a link to educate others?

A. After this webinar, we'll prepare a video of this presentation, including a transcript, and a Q&A doc where we'll answer all submitted questions. We'll publish these materials on the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program webpage as soon as possible. To be notified of when these materials are available, subscribe to the CMS EPCS Program Listsery.

- 61. Q. How can we gain access to reporting schedules and protocols for the measurement years?
 - Q. Where can I access reporting schedules and protocols for the measurement years?

A. For information on the measurement cycle schedule and milestones, visit the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program webpage and review the "CMS EPCS Program Timeline" section.

62. Q. What education is there to help with implementation?

A. For more guidance on the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program, users should review the CMS EPCS Program webpage and join the CMS EPCS Program Listserv to receive important program updates.

Other

63. Q. What direction would you like to see the EPCS Program go in the next 1–5 years?

A. The Centers for Medicare & Medicaid Services (CMS) would like to see all prescribers of controlled substances meet the program requirement for e-prescribing.

Unrelated to the EPCS Program

- 64.Q. What is the likelihood of controlled substances becoming legal?
 - Q. What's the legality of using telemedicine for night admissions for limited quantities to care for the patient until the patient can be seen?
 - Q. How are other organizations monitoring e-prescribing for controlled substances compliance?

- Q. What's the most viable way to join the network of health plans?
- Q. Does e-prescribing mean that the physician will have to enter the order individually? Or can the nurse enter the order for e-sign?
- Q. Who oversees all Rx prescribed (many MDs)? If pat can't remember Rx(s); ex EMR RxPage remains empty even after providing written Rx.
- Q. How does this tie into the electronic medical record Prescription Drug Monitoring Program?
- Q. With the new change in administration, HHS specifically, does CMS foresee major changes being implemented with the EPCS Program?
- Q. Will this program be impacted by the new administration? Q. What happens if your facility transitions from one EMR to another in the reporting year?
- Q. Do you have any information about transitioning from one EMR to another in the reporting year?
- Q. When will the VA be able to electronically receive eRX for controlled substance?
- Q. What are the rules for the patient and doctors for refusing medication and palliative care?
- Q. What is required to call in a narcotic in the middle of the night? Are verbal orders allowed?

A. This question is outside the scope of the Centers for Medicare & Medicaid Services (CMS) Electronic Prescribing for Controlled Substances (EPCS) Program.