

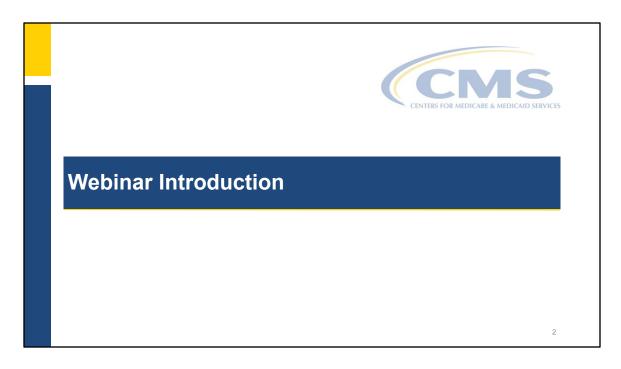
CMS Electronic Prescribing for Controlled Substances Program



March 2025 Webinar: Program Overview, Compliance Requirement, and LTC Facility Prescriptions

March 27, 2025

Hello, and good afternoon, everyone. My name is Morgan Garguilo, and I'm your producer for today's webinar. Welcome to the Centers for Medicare & Medicaid Services, or CMS, Electronic Prescribing for Controlled Substances, or EPCS, Program's March 2025 webinar: Program Overview, Compliance Requirement, and LTC Facility Prescriptions. Let's get started.



Before we dive into today's topics, we have a few housekeeping items to go through.

Presentation Download

To download a PDF of today's presentation:

- · Select the "Chat" button in Zoom.
- · Locate the file in the chat.
- · Select the file name to download it.

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Feel free to download and save a PDF of today's presentation, available now in the chat.

Now we'll kick things off starting with Courtney Rose.

Jerome Bukstein, PharmD	Compliance and Support Specialist	
	Rainmakers Strategic Solutions	
Courtney Rose	Education and Outreach Workstream Lead	
	Rainmakers Strategic Solutions	
Wendy Weber, PharmD, MBA, BCPS, FAPhA	EPCS Workstream Lead	
	Rainmakers Strategic Solutions	

Thank you, Morgan. Welcome, everyone, and thank you for taking the time to attend today's EPCS Program webinar.

The purpose of the CMS EPCS Program is to improve patient safety and reduce prescriber burden.

We have three presenters today.

Jerome Bukstein is a doctor of pharmacy and works as a compliance and support specialist at Rainmakers Strategic Solutions. He'll present the second half of Section 1.

I'm Courtney Rose, the CMS EPCS education and outreach lead at Rainmakers, and I'm also presenting today. I'll handle some of the webinar's introduction, the first half of Section 1, Section 4, and the webinar's conclusion.

Wendy Weber is also a doctor of pharmacy, has an MBA, is a board-certified pharmacotherapy specialist, and is a fellow of The American Pharmacists Association. She works as the EPCS workstream lead at Rainmakers. She's covering sections 2 and 3.

Agenda

Webinar Introduction

Section 1: CMS EPCS Program Overview

Section 2: Review of Measurement Year 2024 Program Requirement

Section 3: Calendar Year 2025 Medicare Physician Fee Schedule Final Rule and 2025 Program Requirement

Section 4: FAQ From September 2024 Webinar

Conclusion

Q&A Session

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Here's our agenda for this afternoon:

- Right now, we're going over the webinar introduction;
- Next is Section 1, which is an overview of the CMS EPCS Program;
- Section 2 is a review of the 2024 measurement year program requirement;
- For Section 3, we talk about the Calendar Year 2025 Medicare Physician Fee Schedule final rule and 2025 Program Requirement;
- In Section 4, we go over some frequently asked questions from the EPCS Program's September 2024 webinar;
- · Next is the conclusion; and
- Finally, the Q&A session.

Disclaimer

This presentation is for prescribers and related health care staff to help them:

- Understand the CMS EPCS Program requirement
- Learn about the changes for the 2024 and 2025 measurement years

This presentation doesn't grant prescribers and related health care staff rights or impose obligations, and it isn't a legal document.

Every attempt has been made to ensure the accuracy of this presentation's information. It is the prescriber's responsibility to correctly prescribe Schedule II–V controlled substances under Medicare Part D.

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There are a few things to note for this presentation. First, the presentation is for prescribers who issue Schedule II through V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug, or MA-PD, plans and related health care staff to help them understand the requirement of the CMS EPCS Program and learn about the changes for the 2024 and 2025 measurement years. Second, this presentation doesn't grant prescribers and related health care staff rights or impose obligations, and it isn't a legal document.

Third, every attempt has been made to ensure the accuracy of this presentation's information. However, it's ultimately the prescriber's responsibility to correctly prescribe Schedule II through V controlled substances under Medicare Part D.

Webinar Questions

- · Submit questions through Q&A feature.
- After the presentation, submit related questions to the <u>Center for Clinical Standards and Quality (CCSQ) Support Central.</u>
- For unrelated questions, first search for answers on the <u>CMS EPCS</u> Program webpage.
- If you can't find answers, submit questions to <u>CCSQ Support Central</u>.

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If you have questions related to the webinar during today's presentation, we ask that you submit them through Zoom's Q&A feature. We'll answer them at the end of the webinar as time permits. If we don't get to your question during the Q&A session, we'll answer it in a Q&A document, which we'll publish on the CMS EPCS Program webpage as soon as possible.

After the presentation, we ask that you submit any remaining related questions, including the webinar name, to the Center for Clinical Standards and Quality, or CCSQ, Support Central.

For a question unrelated to the webinar topic, we recommend that you first search for an answer on the CMS EPCS Program webpage. If you still can't find an answer, submit your question to CCSQ Support Central.

Objectives

After this webinar, attendees should be able to:

- Describe the regulation and benefits of the CMS EPCS Program
- · Identify who must meet the program requirement
- Understand the importance of maintaining current prescriber addresses and email information in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan and Provider Enumeration System (NPPES)
- Recognize how to use the CMS EPCS Prescriber Portal, including when to submit a waiver application
- Summarize the non-compliance action and what to do with the non-compliance notice
- Understand the program requirement for the 2024 and 2025 measurement years

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After this webinar, attendees should be able to:

- Describe the regulation and benefits of the CMS EPCS Program;
- Identify who must meet the EPCS Program requirement;
- Understand the importance of maintaining current prescriber addresses and email information in the Medicare Provider Enrollment, Chain, and Ownership System, or PECOS, and the National Plan and Provider Enumeration System, or NPPES;
- Recognize how to use the CMS EPCS Prescriber Portal, including when to submit a waiver application;
- Summarize the non-compliance action and what to do with the noncompliance notice; and
- Understand the EPCS Program requirement for the 2024 and 2025 measurement years, including the compliance requirement update starting in measurement year 2025, per the Physician Fee Schedule final rule for the calendar year.

Opening Poll

How often do you electronically prescribe controlled substances?

- A. Never
- B. Sometimes
- C. Always
- D. I'm not a prescriber
- E. Other

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Before we get into today's topics, let's do a quick opening poll to take a pulse on how many of us electronically prescribe regularly.

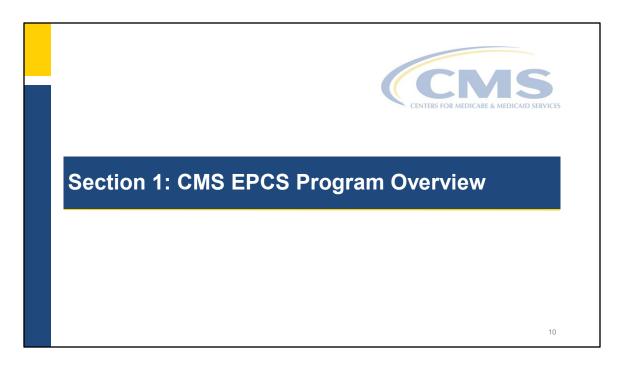
You should now see a pop-up window showing a question and different answers.

So how often do you electronically prescribe controlled substances? Choose the answer that best represents your experience and then select Submit to lock in your answer.

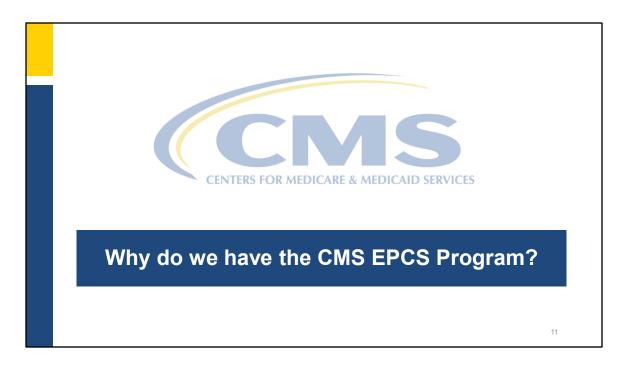
- A. Never,
- B. Sometimes,
- C. Always,
- D. I'm not a prescriber, or
- E. Other.

Be as honest as you can. Your response is anonymous.

All right, let's look at the results.



Our first section is a refresher on some of the main details of the CMS EPCS Program.



Some of you may be wondering, why do we have the CMS EPCS Program?

Electronic Prescribing for Controlled Substances

Electronic prescribing for controlled substances (EPCS) is the electronic transmission of an error-free and understandable prescription for controlled substances from the issuing prescriber's point of care to a pharmacy.

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First, let's define what electronic prescribing for controlled substances, or EPCS, is. EPCS is the electronic transmission of an error-free and understandable prescription for controlled substances from the issuing prescriber's point of care to a pharmacy.

Program Background, Purpose, and Regulations

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018 was enacted to address the opioid crisis. Section 2003 of the SUPPORT Act mandates the CMS EPCS Program.

Compliance threshold:

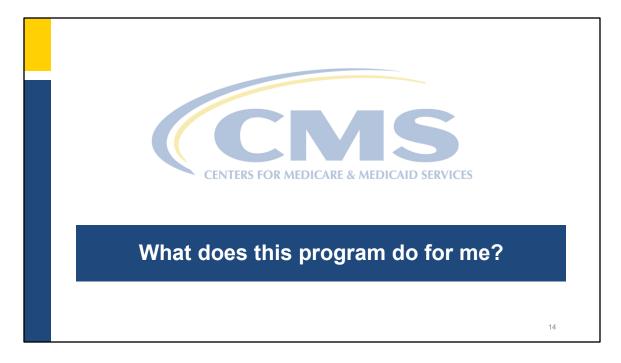
Prescribers must electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug (MA-PD) plans, after exceptions, for the measurement year.

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With an understanding of what EPCS is, we can now talk about the CMS EPCS Program's background, purpose, and regulations.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities, or SUPPORT, Act of 2018 was enacted to address the opioid crisis. Section 2003 of the SUPPORT Act mandates the CMS EPCS Program.

Through rulemaking, CMS established the program's compliance threshold, which is that prescribers must electronically prescribe at least 70% of their qualifying Schedule II through V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug, or MA-PD, plans, after exceptions, for the measurement year.



Now we're going to talk about the different program benefits for both prescribers and beneficiaries.

After hearing about what the CMS EPCS Program is, why it exists, and its compliance requirement, some of you may still be wondering what the program does for you, as prescribers, and what it does for the Medicare beneficiaries you serve.

Beneficiary and Prescriber Benefits

Beneficiaries

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
- · Reducing patient trips

Prescribers

Reduces prescriber burden by:

- · Deterring and detecting prescription fraud and irregularities
- · Improving workflow efficiency
- · Avoiding data-entry errors and pharmacy calls to clarify paper prescriptions

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For beneficiaries, the benefit of the CMS EPCS 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.

For prescribers, the benefit of the program is that it reduces prescriber burden by:

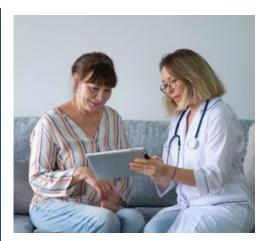
- · Deterring and detecting prescription fraud and irregularities,
- · Improving workflow efficiency, and
- Avoiding data-entry errors and pharmacy calls to clarify paper prescriptions.



Now let's talk about the CMS EPCS Program requirement and the exceptions to that requirement, including the small prescriber exception, the declared disaster exception, and the CMS-approved waiver exception.

So who's affected by the program and required to be compliant with it, what's the program requirement?

Who Must Meet the Requirement



All prescribers who issue Schedule II–V controlled substance prescriptions under Medicare Part D or MA-PD plans.

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All prescribers who issue Schedule II through V controlled substance prescriptions under Medicare Part D or MA-PD plans in the measurement year are federally mandated to meet the CMS EPCS Program requirement.

Program Compliance

To be considered compliant, prescribers must electronically prescribe at least 70% of their qualifying Schedule II–V controlled substances prescriptions under Medicare Part D, after exceptions, in the measurement year.

Prescribers are exempt from the program requirement in the following situations.

- Small prescriber exception: CMS automatically grants 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 grants this exception to prescribers in the geographic area of
 an emergency or disaster as determined by CMS. CMS posts a list of the qualifying emergencies and disasters
 for each measurement year on its EPCS Program webpage.
- CMS-approved waiver exception: CMS grants this exception to each prescriber who submits a waiver
 application and then receives a CMS-approved waiver because they were unable to meet the CMS EPCS
 Program requirement due to circumstances beyond their control.

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

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To be considered compliant, prescribers must electronically prescribe at least 70% of their qualifying Schedule II through V controlled substance prescriptions under Medicare Part D, after exceptions, in the measurement year.

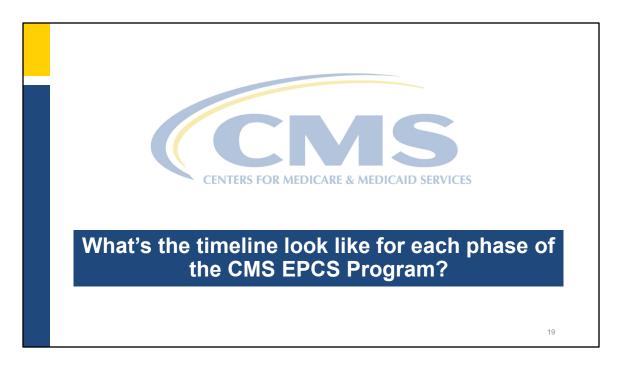
However, there are exceptions to the CMS EPCS Program requirement. Per Section 2003 of the SUPPORT Act, the U.S. Department of Health and Human Services, or HHS, Secretary has discretion on whether to grant exceptions to the CMS EPCS Program requirement. The secretary also has the authority, through rulemaking, to enforce and specify appropriate penalties for final non-compliance with the program requirement.

Prescribers are automatically exempt in the following situations.

- For the small prescriber exception, CMS automatically grants this exception to prescribers
 who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the
 measurement year.
- With the declared disaster exception, CMS automatically grants this exception to prescribers in the geographic area of an emergency or disaster as declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS identifies which emergencies and disasters qualify for this exception and posts a list of the qualifying emergencies and disasters for each measurement year on its EPCS Program webpage.
- The CMS-approved waiver exception: CMS grants this exception to each prescriber who

submits a waiver application and then receives a CMS-approved waiver because they were unable to meet the CMS EPCS Program requirement due to circumstances beyond their control.

Note that for prescriptions written for a beneficiary in a long-term care, or LTC, facility will be included in determining compliance no earlier than January 1, 2028.

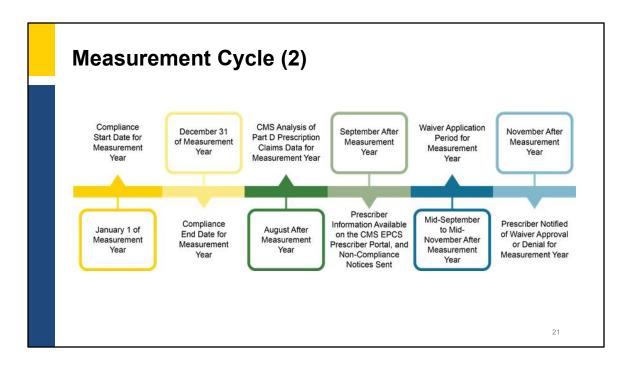


A lot of people ask us, what's the timeline look like for each phase of the CMS EPCS Program?

Measurement Cycle (1) Takes place over 24 months and consists of: • Measurement year • Notification period • Waiver application submission period

In general, the measurement cycle takes place over 24 months and consists of:

- The measurement year,
- The notification period, and
- The waiver application submission period.



On screen is the CMS EPCS Program timeline, which represents 1 measurement cycle.

The timeline begins with the compliance start and end dates, which are January 1 and December 31, respectively, of the measurement year.

The timeline then shows that the analysis compliance period begins August after the measurement year and then the notification period begins in mid-September. The waiver application submission period starts mid-September, lasting for 60 days, and ends mid-November. To receive notifications about the waiver application submission period, be sure to sign up for the CMS EPCS Program Listserv.

The timeline also shows CMS will notify prescribers their application approval status starting in November after the measurement year.

Measurement Year The measurement year takes place January 1–December 31, 2025, for the 2025 measurement year. Prescriptions filled during this time will be used to calculate compliance for the year. Begins January 1 Ends December 31

The measurement year begins January 1 and ends December 31 each calendar year.

Prescriptions filled during this time will be used to calculate compliance for the year.

CMS begins its compliance calculation in August, when it has received most of the Medicare Part D claims.

Note that the 2025 measurement year for the EPCS Program is January 1 to December 31, 2025, which is happening right now.

Compliance Analysis, Notification, and Waiver **Application Submission Periods** · Begins in August after the Takes place in September after the Occurs from mid-September to midmeasurement year measurement year November after the measurement year • Is when CMS reviews Medicare Part Is when CMS notifies prescribers of D prescription claims their initial compliance status • 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 CMS to determine each prescriber's final compliance status Waiver Compliance Notification application analysis period period submission period

The compliance analysis period begins in August after the measurement year. 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 compliance analysis period for the 2025 measurement year is in August and September 2026.

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 notification period for measurement year 2025 takes place September 2026.

The waiver application submission period occurs from mid-September to mid-November after the measurement year. 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.

The waiver application submission period for measurement year 2025 takes place from mid-September to mid-November 2026.

Now I'll pass the presentation over to Dr. Jerome Bukstein for the second half of this section.



So what's the non-compliance action for the CMS EPCS Program?

Non-Compliance Action

The non-compliance action is the non-compliance notice from CMS.

Each non-compliant prescriber receives the non-compliance notice during the notification period (September after measurement year).

The non-compliance notice includes information to a prescriber that they are violating the program requirement, about how they can come into compliance, and on the benefits of EPCS.

The notice also includes a link to the CMS EPCS Prescriber Portal where each prescriber may:

- Check their compliance status
- · Submit a waiver application

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The CMS EPCS Program's non-compliance action is the non-compliance notice.

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, which takes place in September after the measurement year.

Starting in measurement year 2023, the non-compliance action is the notice of non-compliance. The notice includes information to a prescriber that they are violating the CMS EPCS Program requirement, information about how they can come into compliance, information on the benefits of EPCS, 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.

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.

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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.

Getting the Non-Compliance Notice

CMS:

- Emails the notices through <u>CMSLists@subscriptions.cms.hhs.gov</u> or <u>EPCSProgramSupport@rainmakerssolutions.com</u> when possible
- Sends the notices as a physical letter if there's no email address for the prescriber in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) or in the National Plan and Provider Enumeration System (NPPES)

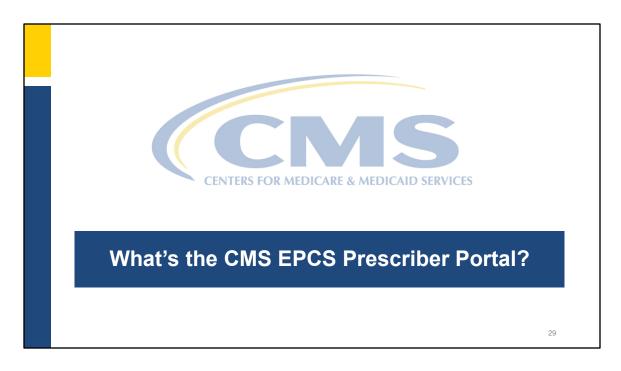
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Note that CMS emails the non-compliance notices through the CMS lists or CMS EPCS Program Support team's email addresses, as seen on screen, when possible and as a physical letter if there's no email address for the prescriber in the Medicare Provider Enrollment, Chain, and Ownership System, or PECOS, or in the National Plan and Provider Enumeration System, or NPPES.

Reminder: Update Your Addresses in PECO and NPPES CMS encourages prescribers to update their email and mailing addresses in PECOS and NPPES.* * CMS also uses these addresses and PECOS and NPPES as the data sources for identifying which prescribers qualify for the automatic declared disaster exception.

CMS encourages prescribers to update their email and mailing addresses in PECOS and NPPES.

By making sure their email and mailing addresses are up to date in these systems, prescribers ensure their timely receipt of the notices and, therefore, the opportunity to submit a waiver application to become compliant. Note that CMS also uses these addresses and PECOS and NPPES as the data sources for identifying which prescribers qualify for the automatic declared disaster exception.



So what's the CMS EPCS Prescriber Portal?

CMS EPCS Prescriber Portal

The <u>CMS EPCS Prescriber Portal</u> is a web platform that a prescriber of Schedule II–V controlled substances under Medicare Part D and their designated representatives can access to:

- View the prescriber's compliance status for the measurement year
- Submit a waiver application for the measurement year, if needed
- Check the prescriber's waiver application status

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 (QPP) Portal
- Can apply for a HARP account on the <u>HARP Create an Account webpage</u>

The waiver application submission period is open on the EPCS Prescriber Portal for 60 days from mid-September to mid-November after the measurement year.

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The CMS EPCS Prescriber Portal is a web platform that a prescriber of Schedule II through V controlled substances under Medicare Part D and their designated representatives can access:

- To view the prescriber's compliance status for the measurement year;
- To submit a waiver application for the measurement year, if needed, explaining any circumstances beyond the prescriber's control that prevented them from meeting the program requirement; and
- To check the prescriber's waiver application status.

To log in to the EPCS Prescriber Portal, users need a Health Care Quality Information Systems, or HCQIS, Access, Roles, and Profile, or HARP, account user ID and password. Note that these are the same login credentials for accessing the Quality Payment Program, or QPP, Portal. If a user doesn't have a HARP account, they can apply for one on the HARP Create an Account webpage.

Note that the waiver application submission period is open on the EPCS Prescriber Portal for 60 days from mid-September to mid-November after the measurement year.

To receive announcements with exact dates for when the waiver application submission period is open, subscribe to the CMS EPCS Program Listserv.

Submitting a Waiver Application

Each fall after the measurement year, for 60 days typically from mid-September to mid-November, each prescriber and their designated representative may submit a waiver application, as needed, to receive a CMS-approved waiver exception when circumstances beyond their control prevented the prescriber from meeting the EPCS Program requirement.

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

For approved applications, CMS issues waivers to prescribers for the entire measurement year.

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One of things users can do on the CMS EPCS Prescriber Portal is submit a waiver application. Each fall after the measurement year, for 60 days typically from mid-September to mid-November, each prescriber and their designated representative may submit a waiver application, as needed, to receive a CMS-approved waiver exception when circumstances beyond their control prevented the prescriber from meeting the EPCS Program requirement.

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

Note that for applications that CMS approves, it then issues waivers to prescribers for the entire measurement year.



If my State already requires me to electronically prescribe controlled substances, am I automatically compliant for this program?

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Next, let's discuss what prescribers need to get started with the CMS EPCS Program.

One misconception we see is prescribers think that if their state already requires them to electronically prescribe controlled substances, they're automatically compliant with the CMS EPCS Program.

Check State's Requirements for e-Prescribing Controlled Substances

The CMS EPCS Program is:

- A Federal program
- Mandated under Section 2003 of the SUPPORT Act

Individual U.S. states may have their own requirements for e-prescribing controlled substances.

Prescribers should check their specific State's laws and requirements for eprescribing controlled substances

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But before getting started with the CMS EPCS Program, prescribers need to check their specific state's laws and requirements for e-prescribing controlled substances to see if they need to do anything else other than what's required through the Federal program. The CMS EPCS Program is a Federal program mandated under Section 2003 of the SUPPORT Act.

Individual U.S. states may have their own requirements for e-prescribing controlled substances separate from the CMS EPCS Program that prescribers need to follow.

Prescribers should check their specific State's laws and requirements for eprescribing controlled substances.

Set Up e-Prescribing Software Program

Prescribers of controlled substances:

- · Must follow DEA guidance
- Must use DEA-approved eprescribing software program
- May need additional registration for controlled substance prescriptions
- May be subject to State-specific e-prescribing requirements

Prescribers should work with their eprescribing software program vendor to:

- Complete identity-proofing requirements
- Get 2-factor authentication
- · Configure logical access control
- Contact vendor for tech issues related to e-prescribing software program

3

Prescribers of controlled substances must follow DEA guidance and select one of the DEA-approved e-prescribing software programs and get it set up. They may also need additional registration for controlled substance prescriptions or be subject to State-specific e-prescribing requirements.

After a prescriber selects a DEA-approved e-prescribing software program, they should work with the software program's vendor to:

- · Complete identity-proofing requirements,
- · Get 2-factor authentication, and
- · Configure logical access control.

Prescribers should also contact the vendor when they experience tech issues related to their e-prescribing software program.

Program Resources

- CMS EPCS Program webpage:
 - o 2024 Declared Disaster Exception Fact Sheet
 - Regulatory Milestones
 - o Getting Started Quick Reference Guide
 - Glossary
 - Frequently Asked Questions
- CMS EPCS Program Listserv
- CCSQ Support Central
- HARP Contact Help Desk webpage

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The following is a list of some CMS EPCS Program resources for getting started and staying up to date with the program.

The first is the CMS EPCS Program webpage, which is the centralized location for program updates. Visitors can also find webinar recordings, transcripts, and handouts as well as other education documents on the webpage. Some of the education documents include the:

- · 2024 Declared Disaster Exception Fact Sheet,
- · Regulatory Milestones document,
- · Getting Started Quick Reference Guide,
- Glossarv, and
- · Frequently Asked Questions document.

The CMS EPCS Program Listserv informs its subscribers of program updates and upcoming deadlines through periodic announcements. CMS recommends subscribing to the Listserv to receive these announcements.

CCSQ Support Central is the primary point of contact for questions on the CMS EPCS Program.

And the HARP Contact Help Desk webpage is where HARP users can select a topic and subtopic that they need help with, including HARP password and account recovery, manual identity-proofing issues, and user research feedback.

Resources are linked on screen for your conveience.



Section 1: Check Your Knowledge

Select the best answer for each question. We'll review responses together.

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Let's see what you've learned so far with our first knowledge check.

You should see a pop-up window with the first question and different answers. Choose the best answer for the question and then select Submit to lock in your answer. We'll review responses together.

Who must comply with the CMS EPCS Program requirement?

- A. Prescribers who issue only non-controlled substance prescriptions
- B. Prescribers who issue Schedule II through V controlled substance prescriptions under Medicare Part D and Medicare Advantage drug plans

Let's see what you said.

The correct answer is B. Prescribers who issue Schedule II through V controlled substance prescriptions under Medicare Part D and Medicare Advantage prescription drug plans must meet the CMS EPCS Program requirement.

What are the consequences for each prescriber who has not yet met the CMS EPCS Program requirement for the measurement year?

A. Each prescriber will receive the non-compliance notice from CMS, which includes a link to the CMS EPCS Prescriber Portal where they can check their compliance status and

- submit a waiver application for circumstances beyond their control.
- B. Each prescriber must attend mandatory training to be retrained on the CMS EPCS Program requirement.

What did people say?

The correct answer is A. Each prescriber who has not yet met the CMS EPCS Program requirement for the measurement year receives the non-compliance notice from CMS. The notice includes information to the prescriber that they are violating the CMS EPCS Program requirement, information about how they can come into compliance, information on the benefits of EPCS, 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. After CMS has reviewed all waiver application submissions for a measurement year, each non-compliant prescriber's non-compliance status is considered final. Note that their final non-compliance 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, in the event that evidence of fraud, waste, or abuse is present.

Why is it important for prescribers to update their mailing and email addresses in PECOS and NPPES?

A. For each non-compliant prescriber to receive the non-compliance notice and for CMS to determine who gets an automatic declared disaster exception

B. To ensure that CMS approves prescriptions faster

Here are the results.

We touched on this briefly earlier. The correct answer is A, for each non-compliant prescriber to receive the non-compliance notice and for CMS to determine who gets an automatic disaster exception. CMS relies on the mailing and email addresses in PECOS and NPPES to send each non-compliant prescriber the non-compliance notice and to decide which prescribers get an automatic declared disaster exception. Keeping this information up to date ensures that prescribers can act on critical program updates and maintain their compliance.

Next up, Dr. Wendy Weber will present for Section 2.



Section 2: Review of Measurement Year 2024 Program Requirement

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Now it's time for Section 2, which is a review of the measurement year 2024 program requirement.



In this part, we discuss the measurement year 2024 requirement, including a summary of the requirement, noting what changed for MY 2024.

We've received questions asking us to explain what changed for the 2024 measurement year, so we're reviewing the changes again as a reminder as we wrap up measurement year 2024 and prepare for the rest of its measurement cycle.

Measurement Year 2024 Updates

CY 2024 Medicare PFS final rule appeared in the November 16, 2023, issue of the Federal Register:

- Finalized removal of the same legal entity exception while clarifying that EPCS Program would auto align with Part D e-prescribing standards
- · Finalized counting unique prescriptions by prescription number
- Allowed CMS to identify which emergencies qualify for the emergency exception and that emergency exception would apply for the measurement year
- Continued practice of issuing each prescriber the non-compliance notice as the non-compliance action
- Recognized that a prescriber's final non-compliance under EPCS Program may be considered in CMS processes for assessing potential fraud, waste, and abuse

3

The following are updates and clarifications for measurement year 2024. CY 2024 Medicare PFS final rule appeared in the November 16, 2023, issue of the Federal Register and finalized the removal of the same legal entity exception while clarifying that the CMS EPCS Program would automatically align with Part D e-prescribing standards.

It also finalized counting unique prescriptions in the measurement year by prescription number.

It updated the exception for emergencies to allow CMS to identify which emergencies qualify for the exception and that the duration of the emergency exception would apply for the measurement year.

The final rule also continued the practice of issuing each prescriber the non-compliance notice as the non-compliance action for subsequent measurement years.

And it recognized 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.

Measurement Year 2024 Requirement Summary

To be considered compliant for measurement year 2024, prescribers must electronically prescribe at least 70% of their qualifying Schedule II–V controlled substance prescriptions under Medicare Part D, after exceptions.

Prescribers are exempt from the program requirement in the following situations.

- Small prescriber exception: CMS automatically grants 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 grants this exception to prescribers in the geographic area of an emergency or disaster as determined by CMS. CMS posts a list of the qualifying emergencies and disasters for each measurement year on its EPCS Program webpage.
- CMS-approved waiver exception: CMS grants this exception to each prescriber who submitted
 a waiver application and then received a CMS-approved waiver because they were unable to
 meet the CMS EPCS Program requirement due to circumstances beyond their control.

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The following is a summary of the measurement year 2024 requirement for the CMS EPCS Program.

To be considered compliant for measurement year 2024, prescribers must electronically prescribe at least 70% of their qualifying Schedule II through V controlled substance prescriptions under Medicare Part D, after exceptions.

However, there are exceptions to the CMS EPCS Program requirement. Per Section 2003 of the SUPPORT Act, the U.S. Department of Health and Human Services, or HHS, Secretary has discretion on whether to grant exceptions to the CMS EPCS Program requirement. The secretary also has the authority, through rulemaking, to enforce and specify appropriate penalties for non-compliance with the program requirement.

Prescribers are exempt from the program requirement in the following situations.

- For the small prescriber exception, CMS automatically grants this exception to prescribers
 who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the
 measurement year.
- With the declared disaster exception, CMS automatically grants this exception to
 prescribers in the geographic area of an emergency or disaster as declared by a Federal,
 State, or local government entity. Starting in the 2024 measurement year, CMS identifies
 which emergencies and disasters qualify for this exception and posts a list of qualifying

emergencies and disasters for each measurement year on its EPCS Program webpage.

• CMS grants the CMS-approved waiver exception to each prescriber who submitted a waiver application and then received a CMS-approved waiver because they were unable to meet the CMS EPCS Program requirement due to circumstances beyond their control.

Check NPI Compliance Status / Sub	omit Waiver Application		
Enter the prescriber's NPI below to check compliance str control will be able to submit a waiver application for the		perienced extraordinary circumstance(s)	beyond their
NPI			
1000001028 X Check Status			C Reset
TEST PRESCRIBER 102 INTERNAL MEDICINE		*CMS has automatically calculal your prescribing data and excep	
	76 Declared Disaster Excep	your prescribing data and excep	
INTERNAL MEDICINE	76 Declared Disaster Except 36 Small Prescriber Except 100 First Towns	your prescribing data and exception No	

Each prescriber can check which exceptions they qualify for through their compliance status on the CMS EPCS Prescriber Portal.

After entering their NPI and selecting the "Check Status" button, the prescriber can see the details of their compliance status for the measurement year, including their total number of Part D prescriptions, total number of e-prescribed prescriptions, their percentage of prescriptions that they e-prescribed, and whether they qualify for any automatic exceptions, such as the declared disaster exception and small prescriber exception. Note that each prescriber can also review the list of CMS-determined emergencies and disasters that CMS posts on its EPCS Program webpage to see if they qualify for the declared disaster exception for the measurement year.



Section 2: Check Your Knowledge

Select the best answer for each question. We'll review responses together.

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Let's take a few minutes for the second knowledge check.

You should see the pop-up window again. Choose the option that best answers the question and then select Submit to lock in your answer. We'll review responses together.

Where can a prescriber see whether they qualify for the automatic declared disaster exception?

- A. Through the list of CMS-determined emergencies and disasters that CMS posts on its EPCS Program webpage
- B. Through their compliance status on the CMS EPCS Prescriber Portal.
- C. Both A and B

So what are the results?

The correct answer is C, both A and B. A prescriber can see whether they qualify for the automatic declared disaster exception by checking both the list of CMS-determined emergencies and disasters that CMS posts on its EPCS Program webpage and their compliance status on the CMS EPCS Prescriber Portal. To download the CMS EPCS declared disasters fact sheet, go to the "Downloads" section on the CMS EPCS Program webpage. You can also visit the "CMS EPCS Prescriber Portal" section on the webpage to learn more about a prescriber's compliance status.



Section 3: Calendar Year 2025 Medicare Physician Fee Schedule Final Rule and Program Requirement

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Now let's go over Section 3, the Calendar Year 2025 Medicare Physician Fee Schedule final rule and program requirement.

2025 Change

In the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (PFS) final rule, CMS finalized that:

- Prescriptions written for a beneficiary in a long-term care (LTC) facility included in determining prescriber compliance starting January 1, 2028.
- Compliance actions against prescribers who don't meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility will start measurement year 2028.
 - The June 2024 Part D and Health IT Standards final rule finalized requiring the 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 doesn't.

4

Note that in the Calendar Year, or CY, 2025 Medicare Physician Fee Schedule, or PFS, final rule, CMS finalized the CMS EPCS Program policy that prescriptions written for a beneficiary in a long-term care, or LTC, 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 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 believed 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.



Section 3: Check Your Knowledge

Select the best answer for each question. We'll review responses together.

45

Now that we're at the end of Section 3, it's time for our third knowledge check.

Again, you should see a pop-up window with the question and answers to choose from. Choose the best answer for the question and then select Submit to lock in your answer. We'll review responses together.

For the EPCS Program in the CY 2025 PFS final rule, what change went into effect for prescriptions issued to beneficiaries in a long-term care, or LTC, facility?

- A. Included in determining prescriber compliance beginning in 2025
- B. Included in determining prescriber compliance beginning in 2028

So what did we say?

Yes, B is the correct answer. As we just mentioned, CMS finalized the CMS EPCS Program policy that prescriptions written for a beneficiary in a long-term care, or LTC, facility won't be included in determining prescriber compliance until January 1, 2028.

Handing the presentation back to Courtney for Section 4 and the webinar conclusion.



Section 4: FAQ From September 2024 Webinar

Review of some FAQ from the previous webinar

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OK, before we end our presentation and move on to the Q&A session, let's go over some frequently asked questions from the September 2024 webinar, which is available in full on the EPCS Program webpage.

Do I need to report prescription data to CMS? When?



- Prescribers don't need to report any prescription data to CMS.
- CMS automatically calculates prescriber compliance.
- Prescribers must electronically prescribe at least 70% of the qualifying Schedule II–V controlled substance prescriptions under Medicare Part D and MA-PD plans each year, after exceptions.
- CMS doesn't consider a prescription sent through fax to be an electronic prescription.

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One of the things we saw people asking frequently during the September 2024 webinar, as well as after in help desk tickets, was whether and when prescribers needed to report any prescription data to CMS for the program to calculate compliance.

To be clear, no one needs to report anything to the CMS EPCS Program. CMS automatically calculates prescriber compliance with the program using Medicare Part D claims. To be considered compliant with the program requirement, prescribers must electronically prescribe at least 70% of the qualifying Schedule II through V controlled substance prescriptions each year under Medicare Part D and Medicare Advantage prescription drug plans, after exceptions.

Note that for the EPCS Program, CMS doesn't consider a prescription sent through fax to be an electronic prescription.

For more on program compliance, visit the "Compliance Overview" section on the CMS EPCS Program webpage.

How will each facility address compliance with prescribers?



CMS:

- Measures compliance at the prescriber's National Provider Identifier (NPI) level, not the facility level
- Uses Medicare Part D claims to identify how many qualifying prescriptions were attributed to the prescriber's NPI, regardless of practice location
- Applies the non-compliance action to individual prescribers, not to facilities

Prescribers:

Ensure their compliance with the CMS EPCS Program requirement

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Another question we saw a lot was how facilities should ensure that prescribers were compliant with the CMS EPCS Program.

The answer is that CMS measures compliance for the EPCS Program at the prescriber National Provider Identifier, or NPI, level, not the facility level, so facilities don't have to do anything to ensure a prescriber's compliance. CMS uses a prescriber's 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. It's prescribers' responsibility to ensure their compliance with the program's requirement for electronically prescribing controlled substances, and the non-compliance action is applied to individual prescribers, not to facilities.

Does the CMS EPCS Prescriber Portal integrate with my existing EHR?



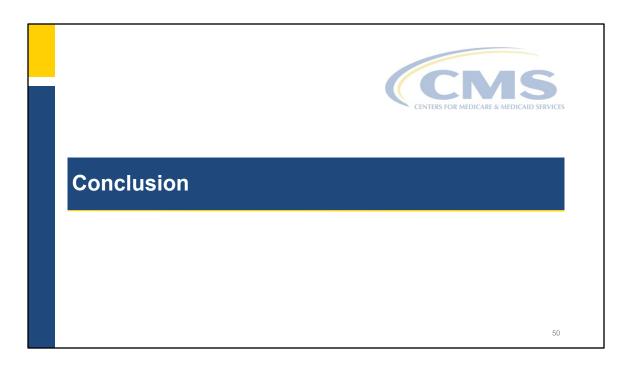
- User's electronic health record (EHR) doesn't need to be integrated with the CMS EPCS Prescriber Portal
 - The CMS EPCS Prescriber Portal is not an e-prescribing software program
 - The CMS EPCS Prescriber Portal is for prescriber to check their compliance status and submit a waiver application
- CMS automatically calculates prescriber compliance using Medicare Part D claims.
- A prescriber issuing electronic prescriptions must use a software program that meets the Drug Enforcement Administration (DEA) requirement.
- No additional e-prescribing software program needed to meet the requirement.

4

The last question from the September webinar we want to highlight is, does the CMS EPCS Prescriber Portal integrate with an existing EHR?

No, a user's electronic health record, or EHR, doesn't need to be integrated with the CMS EPCS Prescriber Portal, because the CMS EPCS Program and the CMS EPCS Prescriber Portal aren't e-prescribing software programs and don't need to connect to any external program. The CMS EPCS Prescriber Portal is for prescribers to check their compliance status and submit a waiver application. CMS automatically calculates prescriber compliance using Medicare Part D claims.

However, a prescriber issuing electronic prescriptions must use a software program that meets the Drug Enforcement Administration, or DEA, requirement. Other than the e-prescribing software program, prescribers don't need any additional software to meet the CMS EPCS Program requirement.



We've reached the final section of our main presentation, where we'll take a closing poll, do a quick recap, review the program resources, and a see reminder of where to send your remaining questions.

Closing Poll

How prepared do you now feel to fulfill the 2025 measurement year CMS EPCS Program requirement?

- A. Not at all prepared
- B. Not prepared
- C. Somewhat prepared
- D. Prepared
- E. Extremely prepared

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So here's our closing poll to help us get a general sense of how effective this webinar was in preparing you.

You should now see a pop-up window showing a question and different answers. Choose the answer that best represents your experience and then select Submit to lock in your answer.

How prepared do you now feel to fulfill the 2025 measurement year CMS EPCS Program requirement?

- A. Not at all prepared
- B. Not prepared
- C. Somewhat prepared
- D. Prepared
- E. Extremely prepared

Be as honest as you can. Your response is anonymous.

All right, thank you for taking the time to fill that out.

Recap

Webinar attendees should now be able to:

- Identify who must meet the EPCS Program requirement
- Recognize how to use the CMS EPCS Prescriber Portal, including when to submit a waiver application
- Summarize the non-compliance action and what to do with the non-compliance notice
- Recall the EPCS Program requirement for the 2024 and 2025 measurement years

5

Now that we've finished the presentation, webinar attendees should now be able to:

- Identify who must meet the EPCS Program requirement;
- Recognize how to use the CMS EPCS Prescriber Portal, including when to submit a waiver application;
- Understand the importance of maintaining current prescriber addresses and email information in PECOS and NPPES:
- Summarize the non-compliance action and what to do with the noncompliance notice; and
- Recall the EPCS Program requirement for the 2024 and 2025 measurement years, including the compliance requirement update starting in measurement year 2025, per the Physician Fee Schedule final rule for the calendar year.

Important Terms

- CMS-approved waiver exception
- CMS EPCS Prescriber Portal
 CMS EPCS Program
- Compliance analysis period
- Compliance threshold
- Declared disaster exception
- Electronic prescribing for controlled substances (EPCS)
- HARP
- Long-term care facility (LTC)
- Measurement cycle
- Measurement year
- Medicare Advantage prescription drug (MA-PD) plans

- Medicare Part D
- National Provider Identifier (NPI)
- Non-compliance action
- Non-compliance notice
- Notification period
- Small prescriber exception
- Schedule II–V controlled substances
- Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act
- Waiver

On screen are some important terms you should have seen in this webinar and when otherwise learning or talking about the CMS EPCS Program.

If you download the PDF of this presentation, available now in the chat, you can select the link corresponding with each term, and it'll take you to the presentation slide where the term is first defined or discussed. You can also find each of these terms and their definitions in the CMS EPCS Program Glossary, available in the "Downloads" section on the CMS EPCS Program webpage.

We Want Your Feedback

- Who: Users of the CMS EPCS Prescriber Portal
- What: Feedback sessions
- Why: To learn what works, what doesn't work, and what CMS could improve with the EPCS Prescriber Portal
- When: Opportunities coming soon

If you're interested in participating in or staying informed about future feedback opportunities, email EPCSProgramSupport@rainmakerssolutions.com.

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CMS will soon have feedback session opportunities for users of the CMS EPCS Prescriber Portal to share their thoughts.

To understand these users' firsthand experiences, CMS will host sessions with selected users to learn their opinions on the EPCS Prescriber Portal—what works, what doesn't work, and what CMS could improve.

Learning about individual's firsthand experience navigating the CMS EPCS Program is invaluable, and insights from these sessions will help inform potential future improvements to the EPCS Prescriber Portal.

Opportunities are coming soon, and spaces will be limited. If you're interested in participating in or staying informed about future feedback opportunities, contact the EPCS Program Support team through the email address linked on screen.

Closing

CMS EPCS | Electronic Prescribing for Controlled Substances

After the event:

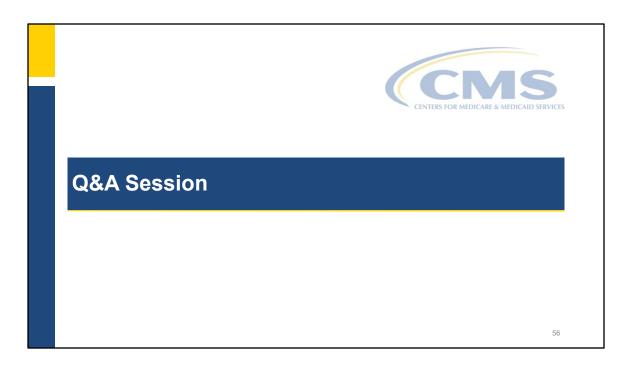
- Submit any remaining related questions to CCSQ Support Central and include webinar's name.
- For questions unrelated to the webinar topic, first search for answers on the CMS EPCS Program webpage.
- If you still can't find answers, submit your questions to CCSQ Support Central.

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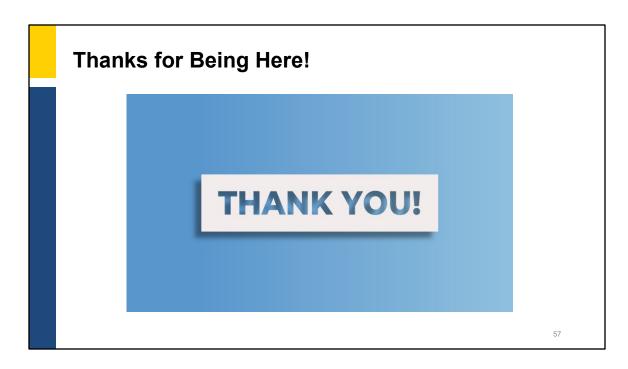
We've reached the end of our main presentation.

Next, we'll start our Q&A session. If after the session you have any remaining questions related to the webinar topic, submit them to CCSQ Support Central, including the webinar's name in your message.

For any questions unrelated to the webinar topic, we recommend first searching for answers on the CMS EPCS Program webpage. If you still can't find what you're looking for, submit your questions to CCSQ Support Central.



Before today's presentation, we received questions from participants when they registered. We'll start our Q&A session with those. We'll then move on to the questions that attendees asked in the Q&A feature during the presentation. So what's our first question?



And that's the end of our presentation and Q&A session. Thanks for being here and taking part!

In a few weeks, we'll post the webinar recording, transcript, and final Q&A document in the "Downloads" section on the CMS EPCS Program webpage. So be on the lookout for those.