

CMS EPCS Program Updates and CY2024 Medicare PFS Final Rule

Presentation Transcript

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Mei Zhang: Slide 2: Welcome everyone and I'm Mei, the Program lead. We appreciate your attention and for taking the time to get to know about the CMS Electronic Prescribing for Controlled Substances Program, or EPCS. The EPCS program is under a section of the SUPPORT Act, which targets the opioid epidemic; mandating electronic prescribing for controlled substances, aims to reduce fraud, reduce prescriber burden, and ultimately increase patient safety. In this webinar, we'll discuss why we have the program, what the program measures, who may need to comply, how to be compliant, where to find the EPCS Program information, and program updates in the calendar year 2024 Physician Fee Schedule Final Rule. I hope this will be a valuable time spent for all. Now, I'll turn this over to our webinar team starting with Betty.

Betty Seabrook: Slide 3: Thank you, Mei. Good afternoon, everyone. My name is Betty Seabrook with HSAG. Before we get started with our agenda, let's go over a few housekeeping items concerning the webinar.

Slide 4: First off, please submit questions that you have regarding the webinar topic through the Q and A panel. We will monitor questions received throughout the webinar and we'll answer questions at the end of the presentation, as time permits. All questions will be addressed in a Q and A document to be published on the CMS EPCS website at a later date. After this event, submit any additional questions through the CMS EPCS Service Center. If possible, we ask that you include the webinar name and slide number when contacting the Service Center. For questions, unrelated to the webinar topic, we recommend first searching the CMS EPCS program website. If you do not find the answer there, please submit your questions through the CMS EPCS Program Service Center.

Slide 5: This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages. However, the ultimate responsibility for correctly prescribing for controlled substances lies with the provider of service.

Slide 6: Today's agenda, includes a brief overview of the CMS EPCS program background, followed by a review and close-out of the 2023 CMS EPCS Program measurement year. Next, we will cover the calendar year 2024 Physician Fee Schedule Final Rule, and what to expect for the 2024 for CMS EPCS Program measurement year. Next, we will provide information on the available CMS EPCS Program resources. And, lastly, we will close out with a Q&A session, time permitting.

Now I will turn it over to Mariana Grass to get started. Mariana.

Marianna Grass: Slide 7: Thank you, Betty. My name is Mariana Grass, with HSAG, and I will start by reviewing the CMS EPCS Program background.

Slide 8: This slide contains terms and definitions that will provide consistency and clarity going forward. First, the official name of our program is the CMS EPCS Program. The compliance threshold for this program is defined as the requirement that prescribers must electronically prescribe at least 70% of their Schedule II, III, IV, or V controlled substances for patients with Medicare Part D after exceptions each measurement year. Non-compliance action refers to a consequence for not meeting the CMS EPCS program compliance threshold, after exceptions have been applied.

There are several time periods that you should be aware of. Overall, we refer to each iteration of compliance measurement as the Measurement Cycle. This is generally a 24-month period that consists of a measurement year, the compliance analysis period, and the notification period. The measurement year is the time period beginning on January 1st and ending on December 31st of each calendar year.

Following the measurement year is a period known as the compliance analysis period. This is the time when the data are analyzed to determine whether prescribers have met the compliance threshold for the CMS EPCS Program.

After compliance analysis, we entered the notification period. During this time, a prescriber is notified of the prescriber's initial compliance or non-compliance status and any associated review or waiver process that may be available prior to CMS determining the prescriber's final compliance status.

Slide 9: Section 2003, of the SUPPORT Act, Public Law 115-271, mandates that the prescribing of Schedule II through V controlled substances under Medicare Part D, Prescription Drug Plans, and Medicare Advantage Prescription Drug Plans be done electronically, in accordance with the Electronic Prescription Drug Program.

Slide 10: The advantages of electronic prescribing compared to paper prescriptions, are that electronic prescriptions enhance patient safety and reduce prescriber burden. Electronic prescribing of controlled substances enhances patient safety through patient identity checks, which reduce prescription tampering; medication recommendations that lower the risk of errors and potentially harmful interactions; and timely and accurate transmission of time sensitive prescriptions, which reduces patient trips.

EPCS reduces prescriber burden by deterring and detecting prescription fraud and irregularities, improving workflow efficiencies, and avoiding data errors or pharmacy calls to clarify written prescriptions.

Slide 11: This slide displays the CMS EPCS program regulatory milestones. For calendar year 2020, CMS published an RFI for electronic

prescribing of controlled substances under Medicare Part D. The CMS EPCS Program rules have been addressed in the Physician Fee Schedule Final Rule since the 2021 rule. The calendar year 2021 PFS Final Rule established requirements for EPCS transmissions. The subsequent final rules, established requirements, exceptions, and non-compliance actions for the CMS EPCS Program.

Slide 12: The calendar year 2023 Final Rule adjusted the exception requirements, identified PECOS and NPPES as the data source for prescribers affected by a recognized emergency, and extended the non-compliance action to the 2024 measurement year. The last part of this slide shows a summary of the calendar year 2024 final rule, which is discussed in detail later in this presentation.

Slide 13: At this point, you might be asking yourself, what do I need to do to get started? Practitioners issuing electronic prescriptions for controlled substances must use a software application that meets all DEA requirements. No additional e-prescribing software system is needed to meet the requirement for the CMS EPCS Program.

If you are new to electronic prescribing of controlled substances, you will need to contact e-prescribing software vendors and confirm their software application satisfy the DEA requirements for EPCS. There are e-prescribing software options that can integrate with EHRs or run as standalone software. E-prescribing vendors are a key source of information and will help you with the following items: complete identity proofing requirements, obtain a dual or two-factor authentication device or process, and configure logical access control.

If you have any technical issues related to your e-prescribing software, please contact your software vendor.

We would like to remind you to check your state laws, as you will need additional registration for controlled substances prescriptions and or need to meet state specific EPCS requirements.

If you have any questions about this section, or any other section in the presentation, please submit your questions in the question panel.

Slide 14: Next, we will look at a summary of the 2023 CMS EPCS program measurement year, including the evaluation of compliance, and the timeline for the measurement cycle.

Slide 15: For measurement year 2023, prescribers are required to prescribe at least 70% of their Schedule II-V controlled substances under Medicare Part D after exceptions. The program exceptions applied to the measurement year 2023 include prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year; prescriptions for controlled substances when the

prescriber and dispensing pharmacy are the same entity; prescribers located in the geographical area of an emergency or disaster as declared by the Federal, State, or local government entity, and prescribers who receive a CMS approved waiver.

Speaking of waivers, prescribers may apply for and receive a CMS-approved waiver because the prescriber is unable to meet the CMS EPCS requirement. due to circumstances beyond the prescriber's control.

Non-compliance notices will be sent to non-compliant prescribers in the 2023 measurement year. The notice will include information to prescribers that they are violating the CMS EPCS Program requirements, information about how they can come into a compliance, benefits of EPCS, and a link to the CMS EPCS Prescriber Portal where they make request a waiver. Notices will be set by email, when possible, to available email addresses in PECOS and NPPES and by regular mail if no email address is available. CMS strongly recommends that all providers keep their email address accurate and up to date in both PECOS and NPPES. At the same time, the CMS EPCS Prescriber Portal will be populated with compliance information for the 2023 measurement year, allowing prescribers an opportunity to view the prescription information used in the compliance calculation. Please see the final rules for program requirements by measurement year.

Slide 16: This slide describes the measurement cycle for the 2023 measurement year. From left to right, you will see that in November of 2022, the calendar year 2023 Physician Fee Schedule Final Rule was released. Next, the 2023 measurement year began on January 1st, and ended on December 31st of 2023.

In the summer of 2024, CMS analysis of Part D prescription claims data for the 2023 measurement year will begin after the Medicare Part D reconciliation period. In the fall, prescribers will be able to check their CMS EPCS Program compliance, available via the CMS EPCS Prescriber Portal, and non-compliance notices will be sent out. After that, the CMS EPCS waiver application period for the 2023 measurement year will open for 60 days.

By late 2024, prescriber notifications of waiver approval or denial for the 2023 measurement year will be available.

I will now pass the presentation over to Valerie.

Valerie Mayorga:

Slide 17: Thank you, Mariana. Hello everyone, I am Valerie Mayorga with HSAG and I will now walk through the calendar year 2024 PFS Rule and the 2024 CMS Program Measurement Year. We will cover updates from the 2024 Physician Fee Schedule, the exceptions for the 2024 CMS EPCS Program measurement year, and the 2024 actions for non-compliance.

Slide 18: Just as in the 2023 measurement year, for the 2024 compliance analysis CMS will analyze Medicare Part D claims and use the prescriber's National Provider Identifier, or NPI. We will begin the analysis by identifying Medicare Part D Schedule II through V controlled substance prescription filled between January 1st and December 31st of 2024 to remove prescriptions written for a beneficiary in a long-term care facility. We will exclude claims with patient resident code values of three, indicating Nursing Facility Long-Term Care Facility, and nine, intermediate care facility. After removing prescriptions written for a beneficiary in a long-term care facility, we will have the eligible Medicare Part D Schedule II through V controlled substance prescriptions for the compliance calculation.

The small prescriber, and recognized emergency and extraordinary circumstances exceptions that we will discuss in the upcoming slides are prescriber level exceptions applied by CMS and do not impact the compliance rate calculation.

CMS calculates the EPCS compliance rate by dividing the prescriber's number of electronically prescribed eligible Medicare Part D controlled substance prescription by the prescriber's overall number of eligible 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 EPCS Program.

The 70% threshold remains unchanged for the 2024 measurement year.

Slide 19: The 2024 Physician Fee Schedule Final Rule specified when a prescription will be counted in the CMS EPCS Program compliance calculation. When a prescription is written, the number of refills is documented for the original prescription, and refills are filled by the pharmacy based on the original prescription. Generally, a prescription is communicated to the pharmacy once, whether via electronic transmission, fax, paper or telephone.

In claims data, a prescription, including its refills, is given a unique prescription number by the pharmacy. As confirmed in the 2024 physician fee schedule, CMS will use only one instance of the prescription number for the compliance calculation. Therefore, refills will not 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.

Slide 20: This slide provides a visual representation of the definition of prescriptions for the combined calculation. In the top example, the prescriber provides the patient with a prescription with four refills in March of 2024. As you can see, all five times this prescription was filled

were in 2024. Thus, only the initial fill in March 2024 is counted in the 2024 compliance calculation since the other four fills were refills.

In the second example, the prescriber provides the patient with three separate prescriptions for the same medication. None of these prescriptions have refills. Thus, when the individual prescriptions are filled in February, April and July 2024, each of those prescriptions are counted in the 2024 compliance calculation.

In the final example, the prescriber provides a patient with a prescription with three refills in December 2023. As you can see, the first time this prescription was filled was in the prior measurement year, 2023. Thus, the initial fill in December of 2023 is not counted in the 2024 compliance calculation. However, the fill in January 2024 is the first occurrence of the prescription in the measurement year and is counted in the 2024 compliance calculation. Subsequent refills are not counted in 2024 compliance calculation.

We hope this visual representation helps clarify how the CMS EPCS program handles refills in the compliance calculation.

Slide 21: As confirmed in 2024 Physician Fee Schedule rulemaking under the CMS EPCS Program, prescribers will use the same version of standards that are required for prescribers, dispensers, and Part D sponsors transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals. To reduce burden, the CMS EPCS Program will automatically adopt the electronic prescribing standards in 423.160(b), including any changes to the applicable NCPDP SCRIPT Standard, as they're adopted through other CMS rulemaking, based on current regulations. Thus, if new standards are adopted, for prescribers of Part D drugs, the CMS EPCS Program will require the new standards on the date set forth in the relevant rulemaking.

Slide 22: We are now going to cover the exceptions for the 2024 CMS EPCS Program measurement year, starting with the small prescriber exception. There was no update to the small prescriber exception in the calendar year 2024 PFS Final Rule. As in the 2023 measurement year, prescribers who issued 100 or fewer qualifying Part D controlled substance prescriptions in the measurement year will be granted an exception.

Slide 23: Starting in the 2024 measurement year, the same legal entity exemption has been removed. We previously finalized an exception for prescriptions issued where the prescriber and the dispensing pharmacy are the same entity, stating our belief that a requirement to use the NCPDP SCRIPT standard version 2017071 within a closed system could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when a

unified database is split into a transactional system that relays information to and from the same entity.

Since that time, we realized that we could provide some flexibility to prescribers and dispensing pharmacies that are the same entity without excluding these prescriptions completely from the CMS EPCS Program. Specifically, prescribers in the same legal entities as the dispensing pharmacy may use Part D approved standards to conduct internal electronic transmittals. Additionally, Medicare Part D claims indicate prescribers are using an electronic system for prescribing. Therefore, we will identify electronic prescriptions using the prescription origin code data element in the Part D claim, where a value of 3 indicates an electronic transmission.

Slide 24: Next, we are going to discuss the established exception for recognized emergencies. Starting in the 2024 measurement year, we will identify which emergencies or disasters qualify for this exception. We will review each emergency situation on a case-by-case basis, but will generally look to events designated as a FEMA major disaster or public health emergency declared by the Secretary. We also intend to align the determination of emergency exception with the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program's (QPP) automatic extreme and uncontrollable circumstances policy and expect alignment deviations to be rare.

Prescribers will be informed of which emergencies qualify for the exception in the CMS EPCS Program through normal communication channels, such as listservs and the CMS EPCS Program website. In an effort to continue aligning the CMS EPCS program with the Quality Payment Program, prescribers impacted by the CMS EPCS Program recognized emergency exception will be excepted for the entire measurement year, and not just for the duration of the emergency. As a reminder, CMS uses the PECOS or NPPES address data to determine whether the exception for recognized emergencies is applicable. So, it is important for prescribers to keep their information current in these systems.

Slide 25: Now, let's discuss the waiver exception for circumstances beyond the prescriber's control, starting in the 2024 measurement year. To ensure a smooth transition to a process where CMS identifies the events that trigger the recognized emergency exception in the 2024 Physician Fee Schedule Rule, we removed the restriction "other than emergency or disaster" from the definition of an "extraordinary circumstance" for the waiver. This allows prescribers to submit a waiver for emergencies outside of those identified for the EPCS Program.

As of the 2023 measurement year, prescribers will be able to access the waiver application from the CMS EPCS Prescriber Portal in the fall, after the end of the measurement year.

Also updated in 2024 Physician Fee Schedule Rule, we established that approved waivers starting in 2024 measurement year will apply to the entire year. Prescribers who receive a waiver and continue to experience circumstances beyond the prescriber's control that extend beyond December 31, 2024, will be required to complete a new waiver application for the 2025 measurement year. Waiver requests must be received by CMS within 60 days from the date of the notice of non-compliance.

Slide 26: For the 2024 CMS EPCS measurement year, CMS will continue the action of sending notices to non-compliant prescribers after the annual compliance analysis is completed in mid- to late-2025. Additionally, the calendar year 2024 Physician Fee Schedule rule continued the practice of issuing a prescriber a notice of non-compliance as a non-compliance action for subsequent measurement years. Notices will be sent by e-mail, when possible, to available e-mail addresses in PECOS and NPPES, and by regular mail if there is no email address in PECOS or NPPES. CMS strongly recommends that all prescribers keep their e-mail address accurate and up to date in both systems.

These notices will consist of a notice to prescribers that they are violating the CMS EPCS Program requirements, information about how they can come into compliance, the benefits of EPCS, and a link to the CMS EPCS Prescriber Portal, where they may request a waiver. At the same time, the CMS EPCS Prescriber Portal will be populated with compliance information for the 2024 measurement year, allowing prescribers an opportunity to view the prescription information used in the compliance calculation. We believe that continuing to send non-compliance notices will support increased EPCS adherence and encourage increased EPCS adoption rates.

A prescriber's non-compliance information may also be used in the assessment for potential fraud, waste, and abuse. We recognize that non-compliance alone is not a definitive indicator of fraud, waste, or abuse. However, we maintain that one risk to public safety is potential fraud, waste, and abuse and intend that a prescriber's non-compliance may be considered in our processes for assessing for potential fraud, waste, and abuse.

Slide 27: As an overview of the 2024 CMS EPCS Program measurement year, we're now going to cover the important milestones in the Measurement Cycle. Generally, the milestones for the 2024 measurement year are similar to those in the 2023 measurement year. The first milestone took place in the fall of 2023 when the calendar year 2024 Physician Fee Schedule Final Rule was released in November 2023. Next, the

compliance start date for the 2024 measurement year was January 1, 2024. The compliance end date is December 31, 2024.

In the summer of 2025, CMS will begin the Part D prescription claims data analysis for the 2024 measurement year. In the fall of 2025, EPCS compliance results will be available for all prescribers via the CMS EPCS Prescriber Portal and the non-compliance notices for the 2024 measurement year, will be sent. Also, in the fall of 2025, the EPCS waiver application period will open for the 2024 measurement year. As a reminder, waiver applications must be received by CMS within 60 days from the date of the notice of non-compliance. Finally, in late 2025, prescribers will be notified of their waiver approval or denial for the 2024 measurement year.

Please remember to enter your questions about the 2024 measurement year in the questions pane. Now, I will pass the presentation over to Betty to cover CMS EPCS Program resources.

Betty Seabrook:

Slide 28: Thanks, Valerie. Hello, again, everyone. As Valerie just stated, I will be going over the CMS program educational resources and downloads that are available to clinicians, their authorized representative, or the general public at large.

First, the CMS EPCS Program website is the go-to place to learn more about the program. The website includes information about the CMS EPCS Program background, milestones, and a link to sign up for the listserv. We encourage you to provide feedback on materials available on the website using the links that are available on selected documents.

Please note that the CMS EPCS listserv is the primary communication channel for the program. We encourage you to sign up, if you haven't already done so, and also encourage others to join, as well. This program is relatively new, and spreading the word about the listserv can be very helpful for your colleagues.

A few of the resources that we have available on the website include past webinar recordings, transcripts, and handouts. We also have educational documents, such as the program Getting Started Quick Reference Guide, a Frequently Asked Questions document, glossary, and regulatory milestones.

Lastly, we have the CMS EPCS Service Center for those that would like to speak with someone regarding program questions they may have. CCSQ Support Central is a website where you can submit your questions or issue to the service center. Phone support is available Monday through Friday from 8 AM to 8 PM Eastern Time. We also have an option for you to e-mail your questions or submit your questions using the online form. We

encourage you to utilize the service center if you have questions that aren't answered.

That concludes the overview of the available CMS EPCS Program resources.

Please note: *The Q&A section of the webinar will be posted separately on the CMS EPCS Program website.*

Links mentioned after the Q&A section of the webinar:

- Medicare Provider Enrollment, Chain, and Ownership System (PECOS): <https://pecos.cms.hhs.gov/pecos/login.do#headingLv1>
- National Plan & Provider Enumeration System (NPPES): <https://nppes.cms.hhs.gov>
- HCQIS Access Roles and Profile (HARP): <https://harp.cms.gov/login>