CMS EPCS Program Update and CY2024 PFS Proposed Rule

Presentation Transcript

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Mei Zhang: Slide 6: My name is Mei, and I am the EPCS Program Lead in the Division of Program and Measurement Support, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality at CMS. I would like to welcome you to the program webinar. We are excited to provide you with what we hope will be an informative and timely presentation. Although we will not be taking questions during this call, we will provide you with instructions to assist you in providing public comment on the calendar year 2024 Physician Fee Schedule Proposed Rule regarding the electronic prescribing for controlled substances program, or EPCS Program. We will also assist you in obtaining informational support for your questions on the CMS EPCS Program.

Pre-registered attendees should have received a copy of this presentation via email. You may also download a copy of the slides directly from this webinar platform.

Slide 7: First, please note that 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 services. Our support contractor, Health Services Advisory Group will now walk us through today's webinar objectives and presentation.

Allison Peel: Slide 8: Thank you, Mei. The purpose of this presentation is to provide you with information on the background of the program, the current year program requirements, to provide an overview of newly proposed changes to program requirements which was published in the 2024 Physician Fee Schedule Notice of Proposed Rulemaking, released on July 13, 2023. We will then review currently available educational resources and describe how prescribers can provide feedback on these resources. CMS is currently seeking public comment on the proposed program changes.

Slide 9: Let's begin our discussion today with reviewing the CMS EPCS Program background.

Slide 10: In October 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT Act, was enacted into law to address the opioid crisis. Section 2003 of the SUPPORT Act mandates that the prescribing of a Schedule II, III, IV, and V controlled substances under Medicare Part D and Medicare Advantage prescription drug plans be done electronically in accordance with an electronic prescription drug program. Federal regulatory authority governing the CMS EPCS Program is referenced on this slide. The CMS EPCS Program rules, which

operationalize Section 2003 of the SUPPORT Act, have been addressed in the Calendar Year 2021, 2022 and 2023 Physician Fee Schedule Final Rules. Please be advised that the CMS EPCS Program is separate from any other state or federal program electronic prescribing requirements.

Slide 11: Before we start our program overview, we would like to define some terms to provide consistency and clarity moving forward:

First, the official name of our program is the CMS EPCS Program and is sometimes referred to as the EPCS Program

We refer to the consequences for not meeting the EPCS Program requirements as non-compliance action or action for non-compliance

The measurement year means the time period, beginning on January 1 and ending on December 31 of each calendar year

The requirement that at least 70 percent of a prescriber's non-excepted controlled substance prescriptions under Medicare Part D must be transmitted electronically each measurement year is referred to as the compliance threshold

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

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

Overall, we refer to each iteration of compliance measurement as the measurement cycle. This is generally a period of 24 months, consisting of a measurement year, the compliance analysis period, and the notification period

Slide 12: Slide 12 is the display of previous EPCS Program regulatory milestones.

In response to passage of Section 2003 of the SUPPORT Act, CMS published a Request for Information, or RFI, for electronic prescribing of controlled substances under Medicare Part D. The RFI, released in 2020, sought input around implementation of this new program including how to assess EPCS compliance, how to enforce compliance, and how program waivers should be handled.

As noted earlier, the CMS EPCS Program rules have been addressed in the annual Physician Fee Schedule Final Rules. These final rules addressed the initial requirements for the program, including mandating the use of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 for EPCS transmissions, assigning an electronic prescribing threshold of 70%, establishing initial program exceptions, establishing actions for non-compliance, and determining the data sources for prescriber demographic information. Additionally, the rules set the first compliance measurement year to begin on January 1st of 2023 for all Schedule II-V controlled substance prescriptions that are Part D drugs except those for patients in long-term care facilities. Long term care facilities prescriptions will be included in the compliance analysis beginning with measurement year 2025.

Slide 13: CMS EPCS Program rules apply to Schedule II-V controlled substances that are Medicare Part D drugs. Prescribers issuing electronic prescriptions for controlled substances must use a software application that meets all Drug Enforcement Administration, or DEA, requirements. Additionally, please remember to check your local state laws, because you may need additional registration for controlled substance prescriptions or have state-specific EPCS requirements.

The DEA defines a controlled substance as a drug or other substance, or immediate precursor, included in schedule I through V at 21 U.S.C. §812 as referenced on this slide. Use and distribution of these drugs is tightly controlled because of abuse potential or risk. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States and based on their risk of abuse or harm.

Examples of the drugs in each schedule are listed on this slide. Schedule 1 drugs have no currently accepted medical use, and a high potential for abuse. These drugs are not included in the CMS EPCS Program. Examples of Schedule 1 drugs include heroin and LSD. The remaining Schedule II through Vdrugs are included in the EPCS Program. Schedule II drugs have a high abuse risk, with use potentially leading to severe psychological or physical dependence. Examples of Schedule II drugs include morphine and oxycodone. Schedule III,IV and V drugs have less potential for abuse than Schedule II drugs. Examples of Schedule III through V drugs include acetaminophen with codeine and diazepam.

Slide 14: You may be asking yourself “are prescribers using EPCS technology?” Yes, EPCS utilization continues to rise year over year. The percentage of filled Medicare Part D (including Medicare Advantage) Schedule II-V controlled substance prescriptions transmitted electronically to the pharmacy increased from 38% in 2019 to nearly 81% in 2022.

Additionally, there were 24.4 million electronic prescriptions filled under Medicare Part D (including Medicare Advantage) for Schedule II-V controlled substances in 2017, and this number rose to 97.5 million in 2022. The CMS EPCS Program will continue to promote electronic prescribing for controlled substances.

Slide 15: Now that we have discussed the need for the program, let's spend a few minutes reviewing the CMS EPCS Program Rules for the current 2023 Measurement Year.

Slide 16: This slide displays a timeline of the first measurement year, 2023, for compliance with requirements of the EPCS Program. The Calendar Year 2023 final rule was released on November 18, 2022. We are currently in the 2023 measurement year, which began on January 1st and continues through December 31st.

The health plans have until June 30th of the following year to submit Medicare Part D claims. The validation period for those claims is July 1st through July 31st. Claims data will be finalized on August 1, 2024, after which CMS will begin the compliance analysis for the 2023 Measurement Year.

After the compliance analysis is complete, notifications of non-compliance will be sent in mid to late 2024 to prescribers violating the EPCS mandate. Prescribers will also be able to check their compliance rate via an online EPCS Prescriber Portal.

As the last step for the measurement year, we have proposed in the CY2024 Physician Fee Schedule that waiver applications will be accepted for 60 days after the notifications of non-compliance are sent out, and prescribers will be notified of their waiver approval or denial for the 2023 Measurement Year in late 2024.

Slide 17: This slide presents which prescription claims will be included in the compliance threshold calculation. They are Medicare Part D prescription claims, including Medicare Advantage claims, for Schedule II through V controlled substances in the measurement year.

To gain a better understanding of the processing of Medicare Part D prescription claims, refer to the graphic on this slide. It starts when the prescriber issues a prescription for a Medicare beneficiary. The pharmacy will then contact the Part D plan for information regarding payment and will fill and finalize the transaction. Afterwards, the pharmacy will submit an electronic claim to the Part D Plan. In the final step, the Part D Plan submits the data to CMS.

Slide 18: For the 2023 compliance analysis, CMS will analyze Medicare Part D claims and use the prescriber's National Provider Identifier, or NPI, regardless of prescriber's practice location. As noted earlier, exceptions will be applied during the analysis and will not include long-term care prescriptions until the 2025 measurement year.

The program sets a minimum 70% threshold for prescribers to be considered compliant. In other words, a prescriber meets that threshold by issuing at least 70% of Schedule II-V controlled substance prescriptions electronically during the measurement year. CMS calculates this rate by dividing the prescriber's number of electronically prescribed Schedule II-V controlled substances under Part D claims, after exceptions, by the prescriber's overall number of Part D prescription claims for Schedule II-V controlled substances, after exceptions. The exceptions to the EPCS Program are discussed on the next slide. If the rate is 70% or higher, the prescriber is considered compliant with the CMS EPCS Program.

Slide 19: We will now cover the prescriptions and prescribers who will be provided exceptions from the 2023 measurement year compliance analysis.

First, prescriptions for Schedule II-V controlled substances issued when the prescriber is located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity will not be counted toward compliance. CMS will apply this exception by comparing the location of the declared emergency or disaster with the location information of the prescriber as found in the CMS Medicare Provider Enrollment, Chain, and Ownership System (PECOS) system. In the cases where PECOS addresses are not available, the National Plan and Provider Enumeration System (NPPES) system will be used. Prescribers or their authorized representative may want to verify their contact information within PECOS and NPPES is updated. Second, prescriptions for Schedule II-V controlled substances issued when the prescriber and dispensing pharmacy are the same entity will not be considered for purposes of determining CMS EPCS Program compliance.

In addition to prescription-level exceptions, prescriber-level exceptions are also a part of the CMS EPCS Program. Prescribers will be exempt from the EPCS Program requirements if they issue 100 or fewer qualifying Part D Schedule II-V controlled substance prescriptions in a calendar year. The 2023 final rule finalized that the small prescriber exception for the 2023 Measurement Year would be assessed using 2023 data.

Slide 20: As mentioned on the previous slide, when prescribers encounter circumstances beyond their control, that are not declared disasters, which prevent them from electronically prescribing Schedule II-V controlled

substances, they may request a waiver. Such reasons to apply for waiver may include technological limitations or other circumstances outside of the prescriber's control. Prescribers will be able to access the waiver application from the EPCS Prescriber Portal in the Fall of 2024, after the 2023 compliance analysis is complete. Prescribers must include supporting documentation with their waiver application.

The link to the waiver application will be shared on the CMS EPCS website and through listserv announcements. In extreme cases where internet is not available to the prescriber, waiver requests will be available via phone through the CMS EPCS Service Center. Prescribers will be notified of their waiver approval status for the 2023 Measurement Year in late 2024.

Slide 21: There are two ways CMS will communicate to prescribers that they are not compliant with the CMS EPCS program. First, non-compliance notifications for the 2023 Measurement Year will be sent in the fall of 2024 by e-mail available in NPPES or PECOS, when possible, and by other methods such as regular mail if e-mail is not available. The non-compliance notifications will direct prescribers to the EPCS Prescriber Portal for more information on their compliance status.

Prescribers or their authorized representatives will be able to log into the EPCS Prescriber Portal via their Health Care Quality Information Systems Access Roles and Profile account, also known as HARP. The EPCS Prescriber Portal will be available in Spring of 2024, but compliance information will not be available on the EPCS Prescriber Portal until late 2024. As described earlier in this presentation, the notifications come out in fall of 2024 since CMS compliance calculations will begin after the Part D claims validation. The compliance action for not meeting the EPCS mandate during the 2023 Measurement Year will be the notification of non-compliance.

Slide 22: We have reviewed the current year's EPCS requirements. Now let's take a look at proposed requirements changes that CMS has recently released for public review and comment.

Slide 23: The CMS EPCS Program section of the proposed rule has several sections. The first provides a summary of prior regulatory actions and the second introduces commonly used EPCS Program terminology that we discussed earlier. The proposed rule then addresses standards for the EPCS Program, including the NCPDP standards and the standards for the same legal entity. CMS then proposed a definition of a prescription as used in the compliance calculation. Next, a proposed update to EPCS Program exceptions for cases of recognized emergencies and extraordinary circumstances. Finally, CMS proposed updates to the

actions for non-compliance. Let's go into these proposals in more detail in the next slides.

Slide 24: Currently, the CMS EPCS program includes the requirement that Part D prescribers use applicable standards found in 42 CFR 423.160(b), including the NCPDP script version 2017071 for EPCS prescription transmissions. SCRIPT is a standard developed and maintained by the National Council for Prescription Drug Programs (NCPDP). The standard defines rules for electronic transmission of medical prescriptions in the United States. This version of the SCRIPT was adopted initially because prescribers were already required to use this standard when e-prescribing Part D drugs.

For the EPCS Program, our intent is for prescribers to use the same version of the NCPDP SCRIPT standard used in other Part D rules. The CMS EPCS Program will continue to automatically adopt the electronic prescribing standards in 42 CFR 423.160(b), including any changes to the applicable SCRIPT standard, as they are updated through other CMS rulemaking, based on our current regulations.

Slide 25: We previously finalized an exception for prescriptions issued where the prescriber and dispensing pharmacy are the same entity because we believed it promoted patient safety, workflow efficiency, and healthy IT performance. We did not want to burden entities that utilize an internal electronic system between their prescribers and pharmacies by mandating that they update these systems in order to comply with EPCS requirements.

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, we found that Medicare Part D electronic prescribing regulations permit the use of either Health Level Seven International (HL7) standard messages or the NCPDP SCRIPT standard when all parties are a part of the same legal entity. We also found that Medicare Part D claims indicate when prescribers are using an electronic system for prescribing. Therefore, we are proposing to remove this exception and cross reference the existing standard. We would identify electronic prescriptions using the Prescription Origin Code of 3 (meaning electronic) data element in the Part D claim, where a value of 3 indicates electronic transmission.

Slide 26: When a prescription is written, the number of refills is documented in 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 oral instructions. Previously, the program did not detail how a prescription refill found in the Part D claims data would be handled. In claims data, a prescription, including its refills, are given a unique prescription number by the pharmacy. If refills were included in the compliance calculation, small prescribers may no longer qualify for the small prescriber exception. Each measurement year, CMS proposes to use only one instance of the prescription number for the compliance calculation. Therefore, refills would not count as an additional prescription in the compliance threshold calculation unless that refill is the first occurrence of the unique prescription in the measurement year.

Slide 27: Next, we are going to discuss the established exception for recognized emergencies. Currently, this exception applies to prescribers practicing in the geographic location of a recognized emergency declared by a Federal, State, or local government entity when the dispensing date of the medication occurs during the declared disaster. Additionally, CMS uses the PECOS or NPPES address data to determine whether the exception is applicable, so it is important for prescribers to keep their information current in these systems.

We are proposing to identify which events trigger this exception by reviewing each emergency situation on a case-by-case basis but would generally look to events designated as a FEMA major disaster or a public health emergency declared by the Secretary. We also intend to align the determination of the emergency exception with the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program's automatic extreme and uncontrollable circumstances policy and expect alignment deviations to be rare. Prescribers would be informed of which emergencies qualify for the exception in the CMS EPCS Program through normal communication channels such as listserv announcements and the CMS EPCS Program websites.

Finally, in an effort to continue aligning the CMS EPCS Program with the Quality Payment Program, we propose that, prescribers impacted by the CMS EPCS Program recognized emergency exception would be excepted for the entire measurement year, and not just for the duration of the emergency. We believe this would protect prescribers who may not be able to monitor their compliance status over multiple periods of time.

Slide 28: Now let's discuss the currently established Duration and Timing of the Extraordinary Circumstances Waiver Exception. Currently, this exception may be granted in situations where the "prescriber has received a CMS approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber's control". To be eligible for the exception, prescribers must provide documentation of the extraordinary

circumstance. Prior rulemaking also established that waivers or a renewal thereof will be approved for a period of time, not to exceed one year, as determined by the Secretary.

To ensure a smooth transition to a process where CMS identifies the events that trigger the recognized emergency exception, we are proposing to remove the restriction "other than an emergency or disaster" from the definition of an "extraordinary circumstance" for the extraordinary circumstances waiver. This would allow prescribers to submit a waiver for emergencies outside of those identified for the EPCS program.

We are proposing that approved waivers for the CMS EPCS Program would apply to the entire applicable measurement year and would expire on December 31 of the applicable measurement year. Prescribers who receive a waiver and continue to experience exceptional circumstances beyond December 31 of a measurement year would be required to complete a new waiver application for the subsequent measurement year.

Additionally, we are proposing that waiver requests must be received by CMS within 60 days from the date of the notice of non-compliance.

Slide 29: The final proposal that we are going to discuss today relates to the actions for non-compliance. For the 2023 and 2024 CMS EPCS Measurement Years, CMS will send notices to non-compliant prescribers after the annual compliance analysis. These notices will consist of a notice to prescribers that they are violating the CMS EPCS Program requirements, provide information about how they can come into compliance, provide the benefits of EPCS, and seek prescriber feedback as to why they are not conducting EPCS. Finally, a link to the CMS EPCS Program Prescriber Portal will be made available so that if applicable a prescriber may request a waiver.

We are proposing to continue sending non-compliance notices to non-compliant prescribers for subsequent measurement years. We believe that continuing to send non-compliance notices would support increased EPCS adherence and encourage increased EPCS adoption rates. A prescriber's non-compliance information may 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, a prescriber's non-compliance is one risk to public safety and may be considered in our processes for assessing for potential fraud, waste, and abuse.

We welcome comments on the proposed rule and will accept and address them through the formal process only. On the next slide, we will talk about the formal process for public comments.

Slide 30: Please keep in mind that feedback during this presentation isn't considered as formal comment, and we welcome you to submit comments regarding our proposed changes to the EPCS Program by using the formal process. Be sure to submit your feedback by the September 11, 2023 deadline. You can officially submit your comments electronically through Regulations.gov, by regular mail, or by express or overnight mail. Instructions for submitting comments can be found on the first pages of the proposed rule.

As a reminder, this presentation is intended to be an overview, so please refer to the Calendar Year 2024 Medicare Physician Fee Schedule Notice of Proposed Rulemaking for complete information on proposed changes to the requirements for EPCS.

Slide 31: Next, let's look at where to find additional information about the current 2023 EPCS Program.

Slide 32: CMS encourages stakeholders to subscribe to our listserv so that you may receive updates about the program. The listserv will announce key program milestone dates, provide important guidance information, and let you know when the EPCS Prescriber Portal application is available. We have also provided information about the program and helpful downloadable documents on the CMS EPCS Program website. Consider the website your primary source for these materials.

Examples of the types of materials available on the website are listed on this slide and we have included a sample graphic of our Pharmacy/Pharmacist guidance document as well.

This pharmacy guidance document was created in response to feedback we received from prescribers and pharmacists regarding the role of pharmacies in the implementation of the program. The feedback we received enabled CMS to quickly develop guidance to assist both prescribers and pharmacies and to ensure Medicare beneficiaries continued and timely access to needed medications.

Slide 33: This slide shows the CMS EPCS Program website. The main page contains information about the EPCS Program as well as information of interest to the electronic prescribing community such as standards for transmission of prescriptions. If you want to find the EPCS Program downloadable resources discussed previously, scroll to the bottom of the page.

Slide 34: After scrolling to the bottom of the page, you will find the downloadable resources, some of which are shown here. Access these documents by clicking on the link. CMS continuously looks for ways to improve our educational documents. For some selected documents, you can click on the "Send CMS feedback about this document" link to provide suggestions for improvements to an existing document or to suggest additional materials that you would like us to consider for development. We look forward to hearing from you!

Slide 35: Another good resource is the CMS EPCS Program Service Center, which can answer questions that are not addressed in the other resources or in this webinar. You can contact the service center online, via telephone, or via email.

Slide 36: The EPCS Program is committed to including prescribers and prescriber staff members in the process of improving the program's educational products and user experience. We are now going to share exciting details about the new, voluntary EPCS Prescriber User Group that was created for you to share your feedback. The group will have a direct impact on the content, look and feel of the EPCS Program educational documents as well as the EPCS Prescriber Portal.

Slide 37: CMS is currently in the process of accepting applications for the user group. As shown on this slide, CMS believes that the user group will provide important feedback by sharing with us the needs of prescribers seeking access to information and who will be accessing the EPCS Prescriber Portal when it becomes available in 2024. This group will review and provide feedback on educational products under development and will also participate in usability testing of the EPCS Prescriber Portal during its development.

Slide 38: CMS is seeking prescribers or their staff representative for prescriber user group membership. Participation is voluntary and potential members should plan on volunteering approximately 10 hours of time over a 12-month period. We are looking for members who are willing to attend a small number of virtual meetings, review materials, and participate in testing out the EPCS Prescriber Portal. Meetings will be scheduled at a time that is convenient for members regardless of time zone.

Slide 39: The EPCS Prescriber User Group will be limited to nine members. We will review the applications submitted and invite members that will represent a diverse group of stakeholders. For example, we are seeking representation from prescribers practicing in urban settings as well as prescribers practicing in rural settings. We are also hoping to have a variety of specialties represented and will include both low-volume and high-volume prescribers in the group. If you are interested in applying for

the Prescriber User Group, please submit an application by August 30th. We hope to hold our kickoff meeting this September. You can access the application by clicking on the link provided on the slide or by requesting an application from the EPCS Service Center.

Slide 40: If you have questions or comments on the CMS EPCS Proposed Program Rules for the 2024 Measurement Year, we welcome you to submit comments regarding our proposed changes to the program by using the formal process. Be sure to submit your feedback by the September 11, 2023 deadline. Instructions for submitting comments can be found on the first pages of the proposed rule.

If you have general questions or comments on the EPCS Program, please contact the service center online, via telephone, or via email.

Slide 41: We want to thank everyone today for attending and look forward to hearing from you. Thank you.