

Introduction to the CMS EPCS Program

Presentation Transcript

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Kimberly Go:

Slide 1: Good afternoon everyone. Welcome to the CMSEPCS program webinar. We are excited to provide you with what we hope will be an informative and timely presentation today. Before we get started let's go over a few housekeeping items concerning the webinar. First, please submit questions pertinent to the webinar topic via the Q&A panel. We will monitor the questions received throughout the webinar and we'll answer questions at the end of the webinar as time permits. Additional questions will be addressed in the Q&A document to be published at a later date. As a reminder we do not use the raise hand feature in the chat tool during webinars. After this event submit any additional questions through the CMS EPCS program service center. Remember to include the webinar name, slide number, and speaker name when contacting the service center. For questions unrelated to the webinar topic we recommend first searching the CMSEPCS program website. If you do not find an answer please submit your question via the CMS EPCS program service center. We will respond to questions as soon as possible.

Slide 2: Welcome to the introduction to the CMSEPCS program webinar. We are excited to provide you with what we hope to be a timely presentation today.

Slide 3: First a disclaimer basically saying 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 this presentation, however, the ultimate responsibility for correctly prescribing for controlled substances lies with the provider of services.

Slide 4: My name is Kimberly Go and I am the Section 2003 SUPPORT Act program lead in the division of Program and Measurement Support Quality Measurement and Value-Based Incentives Groups Center For Clinical Standards and Quality of CMS.

Slide 5: The purpose of this presentation is to promote national awareness of the Medicare and Medicaid Services Electronic Prescribing for Controlled Substances or EPCS program.

Slide 6: Today we want to provide an overview of the CMS EPCS program. First, we will provide background information on electronic prescribing for controlled substances and the CMSEPCS program. Next, we will summarize the CMSEPCS program rules that apply to the 2023 measurement year. Finally, we will provide places where you can go to find more information such as the CMS EPCS program website and the CMS EPCS Program Service Center.

Slide 7: In this section we will provide background information on electronic prescribing for controlled substances and the CMSEPCS program.

Slide 8: 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 about the prescribing of a Schedule II, III, IV and V controlled substances under Medicare Part D prescription drug plans 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 contained in 42 CFR as referenced on the slide. The CMSEPCS 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 rule. Please be advised that the CMSEPCS program is separate from any other state or federal program requirements.

Slide 9: CMSEPCS program rules apply to controlled substances under Medicare Part D. The drug enforcement agency, or DEA, defines a controlled substance as a drug or other substance or immediate precursor included in schedule I, II, III, IV, or V of Part B of 21 USC §802(32)(A), as referenced on the slide. These are drugs whose use and distribution 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 the slide. Schedule I 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 I drugs include heroin and LSD. The remaining schedule II, III, IV, and V drugs 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 schedules III through V drugs include acetaminophen with codeine and diazepam.

Slide 10: This timeline shows the CMS EPCS program regulatory milestones. The first occurred in 2020, when CMS published a Request for Information, or RFI, for electronic prescribing uncontrolled substances under Medicare Part D. The RFI sought input around implementation of section 2003 of the SUPPORT Act, such as how to assess compliance of EPCS requirements, how to enforce compliance, and how prescribers should be able to seek waivers from EPCS requirements. As noted earlier, the CMS EPCS program rules have been addressed in the annual Physician Fee Schedule final rules. The 2021 final rule established the requirement that prescribers use the NCPDP SCRIPT standard version 2017071 for EPCS transmissions. The 2022 final rule mandated electronic prescribing of at least 70 percent of controlled substances schedule II through V that are Part D drugs each measurement year after exceptions are applied, and extended the date of compliance actions to no earlier than January 1st 2023. It also finalized a policy that compliance actions for prescriptions for beneficiaries in a long-term care facility will begin January 1, 2025, and prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until that date, and it established exceptions. We will discuss these exceptions in more detail later in the presentation. The 2022 final rule also finalized a policy to limit 2023 compliance actions to a notification of non-compliance. The recently published 2023 final rule finalized that the small prescriber exception for the 2023 measurement year would be assessed using 2023 data. The 2023 final rule also finalized that the PECOS address would be used to determine whether the exception is applicable for prescribers, and in the absence of a PECOS address, the prescriber's address in the National Plan and Provider Enumeration System, or NPDES, data would be used. Regarding penalties, the 2023 final rule finalized extending this compliance action to the 2024 measurement year.

Slide 11: Prescribers using electronic prescriptions for controlled substances must use a software application that meets all DEA requirements. Please refer to the DEA website for more information on the DEA regulations for electronic prescribing for controlled substances. 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.

Slide 12: Electronic prescribing for controlled substances provides multiple advantages over the traditional processing of paper prescriptions. These advantages include but are not limited to improved medication adherence; improved workflow efficiencies; deterring and detecting prescription fraud and irregularities; enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions; more timely and accurate data by avoiding data entry errors and pharmacy calls to prescribers to clarify written instructions; reduced burden on prescribers who need to coordinate and manage paper prescriptions among

staff, patients, facilities, other care sites and pharmacies; and benefits for social distancing through a reduction in face-to-face contact.

Slide 13: Since there are many benefits to using EPCS you may be asking yourself “are prescribers using the technology?” and the answer is yes. EPCS utilization continues to rise year over year. The percentage of Medicare Part D, including Medicare Advantage controlled substance prescriptions filled electronically, increased from 38 percent in 2019 to 74 percent in 2021. Additionally, there were 24.4 million electronic prescriptions filled under Medicare Part D, including Medicare Advantage, for controlled substances in 2017, and this number rose to 90 million in 2021. The CMS EPCS Program will continue to promote electronic prescribing for controlled substances.

Slide 14: We are now going to discuss the CMSEPCS Program rules for the 2023 measurement year.

Slide 15: This slide displays a timeline of a CMS EPCS Program for the 2023 measurement year. You can see that the calendar year 2023 final rule was released just recently on November 18, 2022. The next events are the compliance start and end dates for 2023, which are January 1st 2023 and December 31st 2023. After the calendar year 2023 data submission deadline in mid-2024, CMS will perform a 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 for EPCS compliance via an online EPCS dashboard. 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 16: As finalized in the calendar year 2022 Physician Fee Schedule final rule, the first measurement year for compliance with requirements of the CMSEPCS Program starts January 1st 2023 and goes through December 31st 2023. The CMS EPCS Program will include all controlled substance prescriptions under Medicare Part D issued with a pharmacy “date of service” between these dates, after exceptions. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. All prescribers who issue controlled substance schedule II through V prescriptions under Medicare Part D will be included in the CMS EPCS program after exceptions. These exceptions will be covered in the upcoming slides.

Slide 17: For the compliance analysis, CMS will analyze Medicare Part D claims and use the prescriber's National Provider Identifier, or NPI, regardless of the prescriber's practice location. As the CMSEPCS Program's timeline showed, the compliance calculations will begin after the PDE submission deadline in June 2024. The program sets a minimum 70 percent threshold for prescribers to be considered compliant. In other words, a prescriber meets the threshold by issuing at least 70 percent of controlled substance prescriptions electronically

during the measurement year. CMS calculates this rate by dividing the prescriber's number of electronically prescribed controlled substances under part D claims, after exceptions, by the prescriber's overall number of Part D prescription claims that were controlled substances after exceptions. If the rate is 70 percent or higher, the prescriber is considered compliant with the CMS EPCS Program.

Slide 18: 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 the 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 finalizes the transaction. Afterwards, the pharmacy will submit the electronic claim to the part D plan. In the final step, the part D plan submits the data to CMS via a specific record format for processing.

Slide 19: We will now cover the prescriptions and prescribers who will be provided exceptions from the CMSEPCS Program compliance analysis. We will start with prescriptions that fall into one of the two following categories: first, prescriptions for controlled substances issued when the prescriber and dispensing pharmacy are the same entity will not be considered for purposes of determining CMSEPCS Program compliance; second, prescriptions for controlled substances issued when the prescriber is located in the geographic area of an emergency or disaster declared by a federal, state or local government entity as determined by the prescriber's address in the Provider Enrollment Chain and Ownership System or PECOS, or NPPES in the cases where PECOS addresses are not available. Prescribers or their authorized representative may want to verify their contact information within PECOS and NPPES and update as appropriate.

Slide 20: Additionally, while not a formal exception to the CMS EPCS Program, prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025.

Slide 21: In addition to prescription level exceptions, prescriber level exceptions are also a part of the CMS EPCS Program. Prescribers will be exempt from CMS EPCS program requirements if they issue 100 or fewer qualifying Part D controlled substance prescriptions in a calendar year. The 2023 final rule finalized what the small prescriber exception for the 2023 measurement year would be assessed using 2023 data.

Slide 22: As mentioned on the previous slide, when prescribers encounter circumstances beyond their control that prevented them from electronically

prescribing controlled substances, they may request a waiver for the measurement year. Such extraordinary circumstances may include: economic hardship that prevents acquisition of a system necessary to conduct EPCS, technological limitations not within control of the prescriber, and other circumstances outside the prescriber's control. Regarding waiver timing, waiver requests will be accepted for 60 days after the notifications of non-compliance are delivered. Waivers for the 2023 measurement year will be granted in late 2024 and will be issued for a period of up to the entire 2023 measurement year. Waiver requests shall include documentation showing the existence of a circumstance beyond prescriber control that prevented the prescriber from conducting EPCS. Prescribers will be able to access the waiver application from the EPCS dashboard in 2024 after the 2023 compliance analysis is complete. The link 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 23: 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 email when possible and by regular mail if email is not available. Second, prescribers or their authorized representative will be able to log into an EPCS dashboard via their Healthcare Quality Information Systems Access Roles and Profile accounts, also known as HARP, to review their annual EPCS compliance status. The EPCS dashboard will be available by the end of January 2024 but compliance information will not be available on the EPCS dashboard 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 PDE submission deadline of June 2024.

Slide 24: The calendar year 2022 Physician Fees Schedule final rule finalized compliance actions for not meeting the EPCS mandate during the 2023 measurement year. That compliance action will be a notification of non-compliance, which will be sent by email when possible and by regular mail if email is not available. As a reminder, prescribers or their authorized representative may want to verify their contact information within NPPES and PECOS and update as appropriate. These notifications will tell prescribers that they are violating the EPCS requirement and also include information about how to achieve compliance, the benefits of EPCS, solicit information as to why they are not conducting EPCS, and contain a link to the CMS EPCS website to request a waiver, as needed. CMS is evaluating compliance actions for future measurement years and those compliance actions will be identified in future rulemaking

Slide 25: We will now review the resources for prescribers to learn more about the CMSEPCS Program.

Slide 26: The CMS EPCS Program has developed a variety of resources for providers to learn more about the program. The CMSEPCS website has an overview of electronic prescribing for controlled substances, current rulemaking, and the 2023 measurement year EPCS Program. Additionally, it provides links to documents such as a summary of frequently asked questions, or FAQs, a Getting Started Quick Reference Guide, a Glossary, and the Regulatory Milestones. The website will be updated throughout the measurement year as needed. The next resource is the CMSEPCS program listserv. The listserv sends out timely EPCS Program announcements and program information. You can enroll in the listserv via the link provided on this slide. Another good resource is the CMS EPCS Program service center which can answer questions that were not addressed in other resources or in this webinar. You can contact the service center online via telephone or via email.

Slide 27: We would now like to take some time for questions. We will answer as many questions as time allows and publish the questions and answers on the EPCS web site with this recording.