

#	Question	Response	Category
1	What are repercussions to the provider and hospital to providers falling below the performance of 70%?	Compliance is assessed at the individual prescriber-level using the prescriber's National Provider Number (NPI). Starting in the 2023 measurement year, the non- compliance action will be a notice of non-compliance. The notice will include information to prescribers that they are violating the CMS EPCS Program requirement, information about how they can come into a compliance, benefits of EPCS, and a link to the CMS EPCS Prescriber Portal where they can check compliance information and may request a waiver. Notices will be sent via email when possible, to available email 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 email address accurate and up to date in both systems. A prescriber's non-compliance under the CMS EPCS program may be considered in CMS processes for assessing potential fraud, waste, and abuse.	Compliance
2	Are residents held to the same standards?	CMS will use the prescriber NPI on Medicare Part D claims to identify how many qualifying prescriptions were attributed to the NPI, regardless of practice type.	Compliance
3	Do the same compliance regulations and exceptions apply to US territories?	All prescribers who issue controlled substance prescriptions under Medicare Part D are included in the CMS EPCS Program, after exceptions.	Compliance
4	It is common for pharmacies to dispense partial fills for controlled substances. Is partial fill also treated the same as refills? The partial fills will have the same Rx number.	CMS will use only one instance of the prescription number for the compliance calculation. Therefore, refills or partial fills will not count as an additional prescription in the compliance threshold calculation unless the refill or partial fill is the first occurrence of the unique prescription in the measurement year.	Compliance
5	What happens if you as a physician prescribe by EPCS a control substance to himself. How is that processed if he is on Medicare?	This scenario would follow the CMS EPCS Program rules; the prescription would be attributed to the prescriber NPI as found on the Medicare Part D claim. Please note prescribers must follow all applicable State, Federal, and local laws that may prohibit prescribing of controlled substance prescriptions for personal use of the prescriber, friends, or family members. Further guidance can be found at https://deadiversion.usdoj.gov/faq/prescriptions-faq.html.	Compliance



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6	Is there any way, through CMS, to monitor compliance throughout the year or does that have to come from the EMR?	Currently, there is not a mechanism through CMS to monitor the prescriber compliance throughout the year. CMS analyzes claims data after it's adjudicated, which takes over six months. It is recommended to utilize your EHR to look at controlled substance prescribing reports, if possible. You also may be able to utilize your state PDMP to track your controlled substance prescribing throughout the year. A prescriber's compliance information for the 2023 EPCS measurement year will be available in the EPCS Prescriber Portal in Fall of 2024.	Compliance
7	What about locum providers that come to organization infrequently but still write 100 prescriptions?	Per Section 2003 of the SUPPORT Act, all prescribers must meet the CMS EPCS Program requirement for prescriptions under Medicare Part D or Medicare Advantage prescription drug plans. CMS will use the prescriber NPI on Medicare Part D claims to identify how many qualifying prescriptions were attributed to the NPI, regardless of practice type or location.	Compliance
8	What do you recommend for setup for locum providers?	Per Section 2003 of the SUPPORT Act, all prescribers must meet the CMS EPCS Program requirement for prescriptions under Medicare Part D or Medicare Advantage prescription drug plans. CMS will use the prescriber NPI on Medicare Part D claims to identify how many qualifying prescriptions were attributed to the NPI, regardless of practice type or location. If the locum cannot use EPCS due to circumstances beyond their control, they may apply for a waiver.	Compliance
9	Does this apply only to physicians who write prescriptions for Medicare patients, or does it apply to all prescriptions for patients with other insurance payers?	The CMS EPCS program only looks at Medicare Part D controlled substance prescription claims. Please note the CMS EPCS Program is specific to Medicare Part D, however, many states have their own EPCS requirements separate from the federal program and may include all patients regardless of insurance coverage.	Compliance



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10	There is conflicting information on the CMS website. One reference is for physicians who prescribe 100 prescriptions or less, and another reference is for physicians that prescribe 150 prescriptions or less. The actual reference states "Prescribers issuing 150 prescriptions or less annually are exempt from the mandate until Jan. 1, 2029. After that, anyone annually issuing 50 prescriptions or less is exempt." Which is correct please?	For the CMS EPCS Program, the Small Prescriber Exception is for prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year. The CMS EPCS Program is separate from state e-prescribing for controlled substance requirements, which may have different standards for Small Prescriber Exceptions. The example referenced in the questions appears to be a state- specific rule under Illinois statute.	Compliance
11	Why are you using NPI# instead of DEA#?	CMS has elected to utilize the prescriber's NPI number, rather than a DEA number or another number, for the purposes of the CMS EPCS Program. CMS is looking for information directly provided by the pharmacy to the health plan and the health plan to CMS. The prescriber NPI, which is your national provider ID, is the most reliable information that is coming to CMS through that data source. The prescriber NPI number is required for all Medicare Part D claims.	Compliance
12	Is the 100 prescriptions (all medications including refills) or patients?	Prescribers who issued 100 or fewer qualifying Part D controlled substance prescriptions in the measurement year will be granted an exception for the CMS EPCS Program. CMS will use only one instance of the prescription number for the compliance calculation. Therefore, refills or partial fills will not count as an additional prescription in the compliance threshold calculation unless the refill or partial fill is the first occurrence of the unique prescription in the measurement year.	Compliance
13	What data will be available when HARP opens up at the end of the year? i.e. will 2023 compliance be available along with the first part of 2024?	Compliance data will be available in the portal for the 2023 measurement year in Fall 2024. At that time, using your HARP account, you'll be able to go into the portal and look up your prescriber NPI, and see the number of controlled substance prescriptions issued under Medicare Part D plans that were filled during the measurement year; the number electronically submitted or transmitted to the pharmacy; and the compliance rate. Through the portal, you also will have information available regarding whether you received an exception (e.g. the small prescriber exception, the declared disaster exception). And finally, if you apply for a waiver, the waiver information will be made available in the portal.	Compliance



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14	Do I need to register for the program or report any data to CMS for the CMS EPCS Program?	No. Prescribers do not have to register or report data to CMS for the CMS EPCS Program. Medicare Part D claims data will be analyzed to determine compliance for the program. A HARP account will be needed to access the CMS EPCS Prescriber Portal to review compliance status and submit an EPCS waiver, if needed.	Eligibility
15	Are prescribers who do not participate in Medicare included in the CMS EPCS Program?	Under Section 2003 of the SUPPORT Act, all prescribers, regardless of their Medicare participation status or specialty taxonomy, must meet the CMS EPCS Program requirement for prescriptions under Medicare Part D or Medicare Advantage prescription drug plans, after exceptions.	Eligibility
16	I work in a teaching hospital and have residents that range in their level of training depending on what year they are in the program - do these standards apply to all residents? Some residents do not have their DEA license yet - how will this affect them/our hospitals compliance?	CMS will use the prescriber NPI on Medicare Part D claims to identify how many qualifying prescriptions were attributed to the NPI, regardless of practice type or level of training. The CMS EPCS Program does not utilize the DEA number in its compliance analysis.	Eligibility
17	I am having trouble logging in to electronically prescribe controlled substances. What should I do?	Technical issues related to logging in to your e-prescribing system, multi-factor authentication errors, or prescription transmission errors would be handled through your electronic prescribing system, EHR vendor, or available IT support.	eRx Vendor
18	How do we know which programs are the best to use? We are not on an EMR so we just need to be able to set up on a computer to send scripts.	While CMS cannot specifically recommend EPCS systems or vendors, we do encourage you to search for the system that best fits the needs of your practice. The cost for standalone EPCS systems has come down in recent years. Checking with colleagues, specialty associations, and your state PDMP resources are good places to start. Regardless of which eRX system you select, it must meet DEA certification requirements. https://www.deadiversion.usdoj.gov/ecomm/ecomm.html	eRx Vendor
19	What about controlled prescriptions for hospice patients? These medications are usually paid for by the hospice company.	The CY 2022 Medicare Physician Fee Schedule (PFS) final rule states that "we are not creating an exemption for prescribers issuing prescriptions for individuals enrolled in hospice." Please note that the program does not utilize hospice claims (generally Medicare Part A) for analysis, but if a hospice patient has a controlled substance prescription covered under Part D rather than the hospice benefit claim, the prescription will be counted.	Exceptions



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20	Are Medicare Part D prescriptions the only medications that need to be prescribed electronically?	The CMS EPCS Program only looks at Medicare Part D prescription claims for Schedule II-V controlled substances. Please note the CMS EPCS Program is specific to Medicare Part D, however, many states have their own EPCS requirements separate from the federal program and may include patients outside of those covered under Medicare Part D.	LTC
21	Are controlled substances dispensed to ALFs excluded like Nursing Facilities? (The DEA sometimes consider ALFs the same a Nursing Facilities.)	When calculating prescriber compliance, we will exclude LTC facility prescriptions for measurement year 2023 and 2024, as Patient Residence Code values of 03 (Nursing facility/long-term care facility) and 09 (intermediate care facility) from the prescription drug event (PDE) records for Part D claims data. If the controlled substance claim has those values, it will be excluded as LTC facility prescriptions for measurement year 2023 and 2024.	LTC
22	Does the LTC beneficiary clause apply for patients returning after an inpatient discharge stay?	When calculating prescriber compliance, we will exclude LTC facility prescriptions for measurement year 2023 and 2024, as Patient Residence Code values of 03 (Nursing facility/long-term care facility) and 09 (intermediate care facility) from the prescription drug event (PDE) records for Part D claims data. If the controlled substance claim has those values, it will be excluded as LTC facility prescriptions for measurement year 2023 and 2024. Please note that the program does not utilize inpatient claims (generally Medicare Part A) for analysis.	LTC
23, 24, 25	 What are the penalties going to be and how will it be monitored and applied? What are the ramifications for a provider who receives a non-compliance notice? What is the penalty for not meeting the 70% threshold? 	Compliance is assessed at the individual prescriber-level. Starting the 2023 measurement year, the non-compliance action will be a notice of non-compliance, sent in the fall of the following year (Fall of 2024, in the case of the 2023 measurement year). The notice will include information to prescribers that they are violating the CMS EPCS Program requirement, information about how they can come into a compliance, benefits of EPCS, and a link to the CMS EPCS Prescriber Portal where they can check compliance information and may request a waiver. Notices will be sent by email when possible, to available email 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 email address accurate and up to date in both systems. A prescriber's non-compliance under the CMS EPCS program may be considered in CMS processes for assessing potential fraud, waste, and abuse	Penalties



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26	Will there be monetary penalties for the 2024 measurement year for providers who do not utilize EPCS?	The action for non-compliance for the 2024 measurement year is a notice of non- compliance. At this time, there is not a monetary penalty for the CMS EPCS Program. A prescriber's non-compliance under the CMS EPCS program may be considered in CMS processes for assessing potential fraud, waste, and abuse. Any changes to CMS actions for non-compliance with the program will be proposed through future rulemaking.	Penalties
27	If the requirement is only for Medicare Part D patients, why are major pharmacy chains denying all paper scripts unless they are submitted electronically?	Under the CMS EPCS Program: There are no compliance requirements for pharmacists or pharmacies in the CMS EPCS Program, as the compliance requirement are limited to prescribers of controlled substances under Medicare Part D. A pharmacist is not required to verify that a prescriber has a waiver from the CMS EPCS Program prior to dispensing a controlled substance under Medicare Part D. A pharmacist is not required to verify that a prescriber or prescription qualifies for an exception from the CMS EPCS Program requirement prior to dispensing a controlled substance under Medicare Part D. The CMS EPCS Program does not limit pharmacists or pharmacies from dispensing covered Part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with current laws and regulations, including but not limited to state EPCS mandates or Drug Enforcement Administration (DEA) requirements. Please note the CMS EPCS Program is specific to Medicare Part D, however, many states have their own EPCS requirements separate from the federal program and may include patients outside of those covered under Medicare Part D. CMS has posted a guidance document regarding the role of the pharmacy/pharmacist on the CMS EPCS Program website to assist prescribers with this issue. (https://www.cms.gov/files/document/cms-epcs-program-guidance-regarding-role- pharmacy/pharmacist.pdf)	Pharmacy



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28	Can you clarify - will all prescribers be able to see their compliance results in the CMS EPCS Prescriber Portal? Or will it only be for non-compliant prescribers?	In the Fall after the measurement year, EPCS compliance results will be available for all prescribers, compliant and non-compliant, via the CMS EPCS Prescriber Portal. EPCS compliance information and waiver application will be available via the CMS EPCS Prescriber Portal in Fall 2024 for the 2023 measurement year. CMS anticipates releasing more information on the CMS EPCS Prescriber Portal in April of this year (2024) via the CMS EPCS listserv, <u>click here to subscribe</u> .	Prescriber Portal
29	Do all prescribers have to have a HARP account?	Prescribers or their representatives will use their HARP credentials (username and password) to log into the CMS EPCS Prescriber Portal later this year (2024) to view their compliance status for the 2023 measurement year and apply for a waiver if needed. However, they do not need a HARP account to prescribe controlled substances for patients covered by Medicare Part D.	Prescriber Portal
30	Is the EPCS portal open now to create an account?	The CMS EPCS Prescriber Portal will not have compliance data until Fall 2024. A HARP account, which can be created at any time, will be needed to access the portal. If you do not have a HARP account, we would suggest registering for one at https://harp.cms.gov/register beginning in April 2024.	Prescriber Portal
31	Can I as an office manager create an EPCS login under my HARP to monitor for my providers?	Clinicians, or their authorized representative, can create a HARP account to access the CMS EPCS Prescriber Portal.	Prescriber Portal
32	You mentioned that the CMS EPCS Program will use the same version of standards as Part D. Where can I find the e-prescribing standards for Part D?	The CMS EPCS Program will automatically adopt the electronic prescribing standards in Title 42 Code of Federal Regulations (CFR) 423.160(b) (https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart- D/section-423.160). Currently NCPDP SCRIPT standard version 2017071 is the e- prescribing standard for transmitting prescriptions and prescription-related information. A proposed rule released in November 2023 (88 FR 78488), is proposing to require use of NCPDP SCRIPT standard version 2023011, after a transition period, for communication of a prescription or prescription-related information supported by Part D sponsors. The transition period would end on January 1, 2027. If finalized as proposed, starting January 1, 2027, NCPDP SCRIPT standard version 2023011 would be the only version of the NCPDP SCRIPT standard available for the CMS EPCS Program.	Standards



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33	Are controlled substances dispensed in Nursing Facilities still excluded until 2025 when a new standard is scheduled?	The current policy is that Per current rulemaking, prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in determining compliance until January 1, 2025; however, we noted in the 2024 PFS rule (88 FR 79287), that if the updated NCPDP SCRIPT standard is finalized for a date after January	Standards
	If the new standard is delayed, will exclusion continue until the new NCPDP standard is effective?	1, 2025, we may explore whether a waiver is appropriate for prescribers who are not compliant solely as a result of prescriptions they have written for beneficiaries in LTC facilities or we may revisit the compliance start date, if needed, through future rulemaking.	
34	How long does a waiver last? And does the waiver status need to be captured in the prescriber's eRx system?	Waivers for the CMS EPCS Program will be issued for the entire measurement year. There is no requirement to capture EPCS waiver status in a prescriber's eRX system. EPCS compliance information and waiver application will be available via the CMS EPCS Prescriber Portal in Fall 2024 for the 2023 measurement year. The CMS EPCS Program waiver is specific to the federal program only. Please check to see if your state has separate requirements for EPCS, including waiver requirements.	Waiver



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35	With the National Opioid shortage, it is a hardship on Providers to continue resending narcotic prescriptions to different pharmacies as they are being told that these pharmacies don't have particular narcotics in stock (Norco/Percocet). The pharmacies are telling us they can't transfer the RX and therefore, we need to send RX to another pharmacy. Our staff continues to call around to different pharmacies (attempting to help) but it takes a lot of time and is a hardship on the staff. It seems to be easier to print these particular narcotic RX's and then the patient can determine which pharmacy to fill RX. Would a hardship be considered with the National Opioid shortage if our Providers don't meet the 70% requirement? We are an Oncology practice.	CMS understands there will be circumstances beyond the prescriber's control that prevent them from meeting the 70% requirement. Prescribers will have the opportunity to apply for the Extraordinary Circumstances waiver. CMS will consider all circumstances, including the National Opioid Shortage, when reviewing the waiver applications. Prescribers will be required to document the circumstances beyond the prescriber's control with their waiver application. Prior to the waiver application, prescriber's compliance status for the measurement year will be available in the Fall of the following year in the CMS EPCS Prescriber Portal: the information includes e-prescribing percentage and exceptions (CMS auto- calculated) met, and the opportunity to apply for the waiver if non-compliant at that time. Non-compliance notices will be sent to non-compliant prescribers at that time, and the notice will include the link to the portal, where the prescriber may apply for the waiver application is approved.	Waiver
36	Is there a list of approved waiver application reasons?	There is not an approved list of waiver application reasons. CMS will consider all circumstances when reviewing waiver applications. Prescribers will be required to documenting the circumstances beyond the prescriber's control with their waiver applications.	Waiver