CMS EPCS | Electronic Prescribing for Controlled Substances

CMS EPCS Program Glossary

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C

CMS EPCS Program

The program, established and authorized by Section 2003 of the SUPPORT Act, which mobilized federal efforts to improve safety and quality of health care requires that Schedule II, III, IV, or V controlled substance prescriptions under Medicare Part D (or under a MA-PD plan) be electronically transmitted, subject to any exceptions the Department of Health and Human Services (HHS) may specify.

Compliance Analysis Period

The time period after the measurement year where data are analyzed to determine whether prescribers have met the compliance threshold for the CMS EPCS Program.

Compliance Threshold

To be considered compliant, prescribers must transmit at least 70 percent of controlled substance (Schedule II-V) prescriptions under Medicare Part D electronically each measurement year, after exceptions are applied.

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D

Disaster

An event that disrupts the normal functioning of a community. A disaster can be short- or long-term with unexpected timing and consequences that impact the prescriber's ability to electronically prescribe controlled substances.

Drug Enforcement Administration (DEA)

The governmental agency that enforces the controlled substances laws and regulations of the United States and brings to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and recommends and supports non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

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E

Electronic Health Record (EHR)

An Electronic Health Record (EHR) is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that persons care under a particular provider. Prescribers of controlled substances generally carry out electronic prescribing within the EHR.

Electronic Prescribing for Controlled Substances (EPCS)

Electronic prescribing for controlled substances (EPCS) refers to the prescriber's ability to electronically transmit an accurate, error-free, and understandable prescription for controlled substances directly to a pharmacy from the point-of-care.

EPCS Program Prescriber

A provider who prescribes controlled substances to beneficiaries under Medicare Part D prescription drug plans and Medicare Advantage prescription drug plans (MA-PD) in accordance with state and federal laws, such as physicians, nurse practitioners, physician assistants, and dentists.

Exceptions

Prescribers must electronically prescribe at least 70 percent of their Schedule II, III, IV, or V controlled substances for patients with Medicare Part D, after exceptions. Prescribers will be exempt from this requirement in the following situations:

- Prescribers who issue 100 or fewer qualifying Medicare Part D controlled substance prescriptions in the measurement year.
- Prescribers located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.
- Prescribers who receive a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances due to circumstances beyond the prescriber's control.

Prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in determining compliance until January 1, 2025.

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H

HCQIS Access, Roles and Profile (HARP) system

The Healthcare Quality Information System (HCQIS) Access, Roles and Profile (HARP) System is a secure identity management portal provided by the Centers for Medicare & Medicaid Services (CMS). Creating an account via HARP provides users with a user ID and password that can be used to sign into many CMS applications. It also provides a single location for users to modify their user profile, change their password, update their challenge question, and add/remove two-factor authentication devices. A HARP account is required to access the CMS EPCS Program Prescriber Portal that will provide access to prescriber-level compliance information and the waiver application.

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L

Low Volume Prescriber

Prescribers who issue 100 or fewer Medicare Part D Schedule II, III, IV, or V controlled substance prescriptions in the measurement year.

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Measurement Cycle

Generally, a period of 24 months, consisting of a measurement year, the compliance analysis period, and the notification period.

Measurement Year

The time period (beginning on January 1 and ending on December 31 of each calendar year) during which data are collected to calculate outcomes for the CMS EPCS Program. The CMS EPCS Program measurement period for the 2024 measurement year is January 1, 2024 through December 31, 2024.

Medicare Part D

The prescription drug benefit offered by Medicare that includes stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans. Medicare Part D claims will be the data source for EPCS compliance.

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N

National Council for Prescription Drug Programs (NCPDP) SCRIPT standard

A standard that facilitates the secure electronic transmission of prescription information between pharmacists, prescribers, and payers. The CMS EPCS Program will automatically align with Part D e-prescribing standards.

National Provider Identifier (NPI)

A unique 10-digit identification number issued to health care providers as defined in 45 CFR 160.103 by the CMS-administered National Plan and Provider Enumeration System (NPPES).

Non-compliance Action

A consequence for not meeting the CMS EPCS Program compliance threshold, as described at § 423.160(a)(5), after exceptions have been applied. For the first two measurement years, the penalty will be a notice of non-compliance from CMS. Section 2003 of the SUPPORT Act authorizes the Secretary of the Department of Health and Human Services, through rulemaking, to enforce and specify appropriate compliance actions for non-compliance with the CMS EPCS Program. Any future compliance actions will be proposed through rulemaking in the Physician Fee Schedule.

Notification Period

The time 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.

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S

Scheduled Controlled Substances (II, III, IV, V)

Medications that have the potential for physical and psychological dependence and are included in the EPCS Program. Schedule I controlled substances are not included in the CMS EPCS Program. Note: Controlled substances schedule standards are set by DEA, and are subject to change with regulations.

- **Schedule II** drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.
- **Schedule III** drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drug abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, and testosterone

- **Schedule IV** drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, and Tramadol.
- **Schedule V** drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, and Parepectolin.

Source: DEA

SUPPORT Act (The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act)

The SUPPORT Act became law in October 2018. Broadly, this law addresses the nation's opioid overdose epidemic and includes measures affecting law enforcement, public health, and federal programs, including Medicaid and Medicare. Section 2003 of the SUPPORT Act establishes an electronic prescription drug program to ensure that health care providers who prescribe controlled substances under Medicare Part D transmit these prescriptions electronically.

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W

Waiver

A valid CMS-granted exception from the CMS EPCS Program requirements. Prescribers will have the opportunity to request a CMS EPCS Program waiver based on circumstances beyond the prescriber's control, such as technological limitations or other circumstance outside of the prescriber's control. Waivers for the CMS EPCS Program will be issued for the entire measurement year.

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ACRONYM List

CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
EHR	Electronic Health Record
EPCS	Electronic Prescribing for Controlled Substances
HARP	Healthcare Quality Information System (HCQIS) Access, Roles and Profile
HCQIS	Health Care Quality Information Systems
HHS	Department of Health and Human Services
LTC	Long-Term Care
MA-PD	Medicare Advantage Prescription Drug Plan
NCPDP	National Council for Prescription Drug Programs
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
PDPs	Prescription Drug Plans
SUPPORT Act	The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act