

Supporting Statement – Part A
Requirement for Electronic Prescribing for Controlled Substances (EPCS)
for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan
CMS-10834, OMB Control Number 0938-1455

A Background

This is a revision package. Section 2003 of the SUPPORT for Patients and Communities Act of 2018 requires that prescribing of a Schedule II, III, IV, and V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the calendar year (CY) 2021 and 2022 Physician Fee Schedule (PFS) final rules (85 FR 84803) and, (86 FR 65361), CMS finalized the electronic prescribing for controlled substances (EPCS) requirements and exceptions at 42 CFR 423.160(a)(5). Prescribers need to electronically prescribe at least 70 percent of the applicable prescriptions to be compliant with the requirements. Certain prescribers and prescriptions are exempted from this requirement, such as, prescribers who do not prescribe many Medicare Part D controlled substances, prescribers who are in an area with an emergency, and prescribers who apply for a waiver for circumstances beyond their control. Compliance for prescribers not in long-term care facilities begins in CY 2023. Compliance for prescribers in long-term care settings begins in CY 2028.

EPCS requirements do not require prescribers or pharmacies to submit additional data to CMS. However, CMS did finalize one exception that requires data collection. The EPCS exception, at § 423.160(a)(5)(iv), requires a prescriber to apply for a waiver if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. This information collection request is being revised based on OMB recommendation OMB previously recommended CMS to monitor the number and types of waiver applications, then based on the volume and merits of the waiver application, revise the instruction, criteria for application, and/or information collect in the waiver application, which CMS revised all of these documents.

B Justification

1. Need and Legal Basis

Authority for collection of this information is from section 1860D-4(7) of the Social Security Act (the Act)), as added by section 2003 of the SUPPORT for Patients and Communities Act of 2018, requires prescribing Schedule II, III, IV, and V controlled substances under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January a, 2021, subject to any exceptions, which HHS may specify.

This collection is required because some prescribers need to apply for a waiver to qualify for the exception if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. The waiver is needed starting with the 2023 EPCS compliance period.

2. Information Users

Information users include CMS and EPCS prescribers/authorized staff.

EPCS prescribers and their authorized staff fill out the waiver applications for circumstance beyond control that prevented the prescribers from meeting the EPCS compliance requirement. Prior to submitting waiver, the EPCS Portal that hosts the waiver application gives instruction for prescribers and their authorized staff for checking prescriber compliance status. The instructions also shows that only those who are not yet compliant can apply for the waiver for circumstance beyond control. The EPCS prescribers and their authorized staff can check their waiver approval/denial status in the EPCS Portal and supply additional information if asked.

CMS uses the waiver Portal to receive waiver applications, then CMS review these applications to approve, ask further information, or deny the waiver for circumstance beyond control. CMS also uses the waiver information to understand prescriber compliance pain points and improve education, outreach, and operations as appropriate. Should a waiver request be denied, a prescriber's final non-compliance may be subjected to CMS processes for investigating fraud, waste, and abuse.

3. Use of Information Technology

Prescribers who are requesting a waiver would apply through an online portal. Prescribers also have the option of contacting the support desk if they do not have access to the portal.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

We expect that many prescribers that submit an application for the EPCS waiver will qualify for small business status under the Small Business Administration (SBA) standards. To Minimize burden to small practices, the EPCS requirements has a separate automatic exclusion for prescribers that have 100 or fewer Medicare Part D prescriptions for controlled substances. These prescribers would not need to apply for a waiver.

6. Less Frequent Collection

If the waiver for EPCS is collected on a less than annual basis, then CMS would not be able to identify prescribers who are exempt from EPCS requirements due to circumstances beyond the prescriber's control for a calendar year. This may lead to CMS incorrectly identifying a prescriber as non-compliant.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on XXXXXXXXXX.
The 30-day Federal Register notice published on XXXXXXXXXXXX.

9. Payments/Gifts to Respondents

Respondents will not receive a payment or gift.

10. Confidentiality

The following is the privacy statement provided to respondents.

The Centers for Medicare & Medicaid Services (CMS) collects information from Medicare prescribers to approve hardship waivers from participation in electronic prescribing for controlled substances (EPCS) due to circumstances beyond the prescriber's control. Authority for collection of this information is from section 1860D-4(7) of the Social Security Act (the Act), as added by Section 2003 of the SUPPORT for Patients and Communities Act of 2018, which requires prescribers to electronically prescribe Schedule II, III, IV, and V controlled substances under Medicare Part D in accordance with an electronic prescription drug program. CMS may use and disclose prescriber's responses as specified in the System of Records Notice (SORN)

"Quality Payment Program (QPP)", System No. 09-70-0539, 83 Federal Register 6587, February 14, 2018 and as permitted by the Privacy Act of 1974. Your response is voluntary. However, failure to respond may affect CMS' efforts to review your hardship waiver and limit your requirements under the EPCS requirements.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. The adjusted hourly wage is used to calculate the labor costs associated with our final requirements. As indicated, we continue to adjust our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 1: National Occupational Employment and Wage Estimates for Physicians

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Anesthesiologists	29-1211	163.21	163.21	326.42
Family Medicine Physicians	29-1215	115.77	115.77	231.54
General Internal Medicine Physicians	29-1216	118.01	118.01	236.02
Obstetricians and Gynecologists	29-1218	133.97	133.97	267.94
Pediatricians, General	29-1221	98.97	98.97	197.94
Physicians, All Other	29-1229	119.54	119.54	239.08
Psychiatrists	29-1223	123.53	123.53	247.06
Orthopedic Surgeons, Except Pediatric	29-1242	181.85	181.85	363.70
Pediatric Surgeons	29-1243	216.02	216.02	432.04
Surgeons, All Other	29-1249	165.38	165.38	330.76
Surgeons	29-1240	167.74	167.74	335.48
Total	2,960.92			
Average Wage (2,960.92/11)	269.17			

Burden for Electronic Prescribing for Controlled Substances Requirement—Waiver Application

Prescribers may apply for a waiver from the EPCS requirement, should they be facing circumstances beyond their control that prevent them from electronically prescribing, and these circumstances are not the result of a natural disaster or emergency. From data from the previous year, we received a total of 278 waiver applications, and we will use the assumption of a 10% increase per year for a total of 306 waivers for this calculation.

As shown in Table 2, we assume the staff involved in the waiver application are prescribers for which we use the average physician wage rate. We have seen from the data that each waiver application will take 10 minutes and 15 seconds (0.170 hr) for a prescriber at \$269.17/hr to complete.

In aggregate, we estimate an annual burden for filling out applications of 52 hours (306 applications × 0.170 hr) at a cost of \$13,996.84 (52 hours × \$269.17).

Table 2: Burden for Electronic Prescribing of Controlled Substances Requirement—

Waiver Application

Burden Data Description Burden	Burden Estimate
# of Respondents Applying for a Waiver (a)	306
Total Annual Hours for Waiver Application (b)	0.170
Total Annual Hours for Waiver Application (c) = (a)*(b)	52 hours
Labor rate to Apply for a Waiver @ prescriber's labor rate of \$269.17/hr. (d)	\$269.17/hr
Total Annual Cost for Waiver Application (e) = (c)*(d)	13,996.84

Information Collection Instruments/Instructions

Appendix 1: EPCS Waiver Application

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The total annual cost to the Federal government for waiver application is estimated to be 8,886.00.

This cost is based on the management analyst at an hourly wage of \$111.08 for a full 40-hour work week to operationalize this aspect of it ($\$111.08/\text{hr} \times 40 \text{ hr} = 4443.20$).

As with the wage rates above, we calculate the cost of overhead, including fringe benefits, at 100% of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly between employers, and because methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Table 3: National Occupational Employment and Wage Estimates

Occupation Code	Occupation Title	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)	Hours	\$Total
13-1111	Management Analysis	\$55.54	\$55.54	\$111.08	40	\$4,443.20

We also estimate it would be about 40 hours of a contractor time within an existing contract which would equate to \$4,443. To derive contractor costs, we used wage data from the Bureau of Labor Statistics Occupational Employment and Wages most recently available published tables May, 2023. The total cost to the Federal Government would be \$8,886.00(\$4,443+\$4,443).

15. Program or Burden Changes

The number of respondents increased from 100 to 306. The annual burden hours increased from 17 to 52.

16. Publication and Tabulation Dates

There are no publication dates.

17. Expiration Date

The expiration date will be displayed on the waiver application.

18. Certification Statement

There are no exceptions to the certification statement.