

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-TBD

A Background

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 excepted from this requirement, such as instances where the prescriber and the pharmacy are the same entity, 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 2025.

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 is a new information collection request to obtain approval to collect the waiver information.

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 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.

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

The data collected will be used by CMS to determine whether or not a prescriber is exempt from

the EPCS requirements. The information will only be available to the prescriber and CMS. CMS staff may also use this information to understand trends in waivers in the program.

3. Use of Information Technology

Prescribers who are requesting a waiver would submit an application 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 apply for the EPCS waiver will qualify for small business status under the Small Business Administration (SBA) standards.

To minimize the 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 CY 2022 PFS proposed rule (86 FR 39104, CMS-1751-P, RIN 0938-AU42) was published in the Federal Register on July 23, 2021. Although the proposed rule indicated that the changes would be submitted under control number 0938-1396 (CMS-10755), after further internal review we have since determined that the changes should be set out under a new Information Collection Request. We are soliciting feedback from the public on the waiver application form.

The 60-day Federal Register notice published on March 10, 2023 (88 FR 15037). There were no public comments received.

The 30-day Federal Register notice published on May 30, 2023 (88 FR 34502).

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 2021 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	159.22	159.22	318.44
Family Medicine Physicians	29-1215	113.43	113.43	226.86
General Internal Medicine Physicians	29-1216	116.44	116.44	232.88
Obstetricians and Gynecologists	29-1218	142.41	142.41	284.82
Pediatricians, General	29-1221	95.40	95.40	190.80
Physicians, All Other	29-1229	111.30	111.30	222.60
Psychiatrists	29-1223	120.08	120.08	240.16
Orthopedic Surgeons, Except Pediatric	29-1242	147.22	147.22	294.44
Pediatric Surgeons	29-1243	139.57	139.57	279.14
Surgeons, All Other	29-1249	143.17	143.17	286.34
Surgeons	29-1240	141.60	141.60	283.20
Total	2,859.68			
Average Wage (2,859.68/11)	259.97			

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. Due to the high prevalence of EPCS, the miniscule compliance actions for noncompliance, and the number of prescribers that we expect to exempt from the mandate, we only expect to receive about 100 waiver applications per year.

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 expect that each waiver application will take 10 minutes (0.1667 hr) for a prescriber at \$259.98/hr to complete.

In aggregate, we estimate an annual burden for filling out applications of 17 hours (100 applications × 0.1667 hr) at a cost of \$4,419 (17 hours × \$259.97).

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

Burden Data Description	Burden Estimate
# of Respondents Applying for a Waiver (a)	100
Total Annual Hours for Waiver Application (b)	0.1667
Total Annual Hours for Waiver Application (c) = (a)*(b)	17 hours
Labor rate to Apply for a Waiver @ prescriber’s labor rate of \$259.97/hr. (d)	\$259.97/hr
Total Annual Cost for Waiver Application (e) = (c)*(d)	\$4,419

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 \$7,349.

This cost is based on an operations manager and compliance officer working together at a combined hourly wage of \$183.72/hr (\$110.82./hr + \$72.90/hr) a full 40-hour work week to operationalize this aspect of it (\$183.72/hr x 40 hr= \$7,349). 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 title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Operations Manager	11-1021	55.41	55.41	110.82
Compliance Officer	13-1041	36.45	36.45	72.90

We also estimate it would be about 40 hours of a contractor time within an existing contract.

15. Program or Burden Changes

This is a new information collection.

16. Publication and Tabulation Dates

CMS is planning to generate an experience report after the compliance calculations are finalized

which may include information about the number of waivers applications received.

17. Expiration Date

The expiration date will be displayed on the waiver application.

18. Certification Statement

There are no exceptions to the certification statement.