Supporting Statement A
Medicare Part D Electronic Prescribing Tools (42 CFR 423.128(d)(4)-(5) and 423.160(b)(1))
(CMS-10755, OMB 0938-1396)

Background

The Centers for Medicare & Medicaid Services (CMS) is seeking a Revision type of OMB approval for this ongoing collection of data required by section 1860D-4(e) of the Social Security Act (the Act) and codified at 42 CFR § 423.160(b)(1) to support secure electronic prior authorization (ePA) transactions though use of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard. CMS has removed one-time costs associated with ePA implementation and is adding ongoing annual costs for maintaining a rewards and incentives program for beneficiary RTBTs. We are also revising the burden for ePA transactions to reflect an increased number of Part D contracts.

The NCPDP SCRIPT standard is utilized to electronically transmit prescriptions for Part D drugs for Part D eligible individuals, as required at 42 CFR § 423.160(b)(1). This standard also includes a series of transactions which enable ePA to take place when the electronically prescribed drug requires PA. The ePA transactions within the NCPDP SCRIPT standard enable the secure exchange of information relevant to ePA between the prescriber's electronic health record (EHR) and the insurer, specifically providing standardized information fields that are relevant for medication use, mandatory questions, transaction messaging, and standardized ePA data elements exchanging the PA questions and answers between prescribers and payers.

The ePA transactions within the NCPDP SCRIPT standard require that elements of the Part D sponsors PA criteria conform to a specific format which can be readily adapted by programmers, as opposed to a free-form manual PA process which requires no particular format. Conforming manual PA criteria elements to the format required for electronic PA transactions represents an additional, one-time burden for some Part D sponsors, depending on the internal programming infrastructure and logic that Part D sponsors already have in place with respect to their current PA processes. Part D sponsors will incur ongoing costs for every ePA transaction, although these costs are offset by overall savings to Part D sponsors since the ePA process is more efficient than the manual PA process.

Beneficiary real-time benefit tools (RTBTs) enable patients to directly access drug coverage information from their plan in order to be able to make informed choices and collaborate with their prescriber regarding their prescription drugs. As codified at 42 CFR 423.128(d)(4), Part D sponsors must make available to enrollees—via beneficiary-specific portal or computer application—the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information:

- Cost-sharing amounts;
- Formulary medication alternatives for a given condition; and
- Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

As codified at 42 CFR 423.128(d)(5). Part D sponsors are permitted to offer rewards and incentives to enrollees who utilize the RTBT.

Legislative Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. It amended Title XVIII of the Social Security Act (the Act) by redesignating Part D as Part E and inserting a new Part D to establish a voluntary prescription drug benefit program. As part of that program, section 1860D–4(e) of the Act, as added by the MMA, required the adoption of Part D e-prescribing standards for electronic prescriptions and prescription-related transactions between Part D plan sponsors, providers, and pharmacies. The Secretary's selection of standards is informed by the National Committee on Vital and Health Statistics (NCVHS), an advisory committee that gives advice to the Secretary in accordance with the Federal Advisory Committee Act, including regarding implementation of the administrative simplification provisions of HIPAA. Under section 1860D-4(e)(4)(B) of the Act, NCVHS develops recommendations for Part D e-prescribing standards, in consultation with specified groups of organizations and entities. These recommendations are then taken into consideration when developing, adopting, recognizing, or modifying Part D e-prescribing standards. The statute further requires that the selection of standards be designed, to the extent practicable, so as not to impose an undue administrative burden on prescribers or dispensers, but to be compatible with standards established under Part C of title XI of the Act (the HIPAA standards), comport with general health information technology standards, and permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the Library of Medicine.

The standards adopted by CMS for purposes of the Part D e-prescribing program are in § 423.160. Part D plan sponsors are required to support the Part D e-prescribing program transaction standards, and providers and pharmacies that conduct electronic transactions for which a program standard has been adopted must do so using the adopted standard. (For additional information about the MMA program authority, see the February 4, 2005 (70 FR 6256) proposed rule.)

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115-271), hereinafter referred to as the "SUPPORT Act," was enacted on October 24, 2018. Section 6062 of the SUPPORT Act amended section 1860D-4(e)(2) of the Act to require the adoption of transaction standards for the Part D e-prescribing program to ensure secure ePA transactions between prescribers and Part D plan sponsors no later than January 1, 2021. The NCPDP SCRIPT standard includes multiple prior authorization transactions which each support a particular step in the overall ePA process. Such transactions include an ePA request transaction (for prescribers seeking an ePA from a Part D plan sponsor for a Part D-covered drug for a Part D-eligible individual, as well as an ePA response transaction for the Part D plan sponsor's response to the prescriber. A facsimile, a proprietary payer portal that does not meet standards specified by the Secretary or an electronic form are not treated as electronic transmissions for the purposes of ePA requests. The ePA standards adopted under this authority are to be adopted in consultation with the NCPDP or other standards development organizations the Secretary finds appropriate, as well as other stakeholders.

Finally, the SUPPORT Act also authorized the adoption of ePA transaction standards for Part D-covered drugs prescribed to Part D-eligible individuals "notwithstanding" any other provision of law.

Section 1860D-12(b)(3)(D) of the Act authorizes additional contract terms not inconsistent with the Part D statute. Under this authority, CMS codified the requirement that Part D sponsors offer a beneficiary RTBT so that formulary and benefit information could be provided to enrollees in a manner similar to what is provided to prescribers via prescriber RTBTs.

Final Regulation

This information collection request was initially associated with our December 31, 2020 final (85 FR 86824, CMS–4189–F), which revised § 423.160(b)(8) by requiring that Part D sponsors support version 2017071 of the NCPDP SCRIPT standard for use in ePA transactions with prescribers regarding Part D covered drugs to Part D eligible individuals. The June 17, 2024 final rule (89 FR 51238, CMS 4205-F2) updated the version of the NCPDP SCRIPT standard required for electronic prescribing, including ePA, and included technical reorganization to list the required version of the NCPDP SCRIPT standard and ePA transactions at § 423.160(b)(1). The June 17, 2024 final rule did not otherwise change burden or requirements associated with ePA.

The information collection for beneficiary RTBTs was established in the January 19, 2021 final rule (86 FR 5864, CMS-4190-F2).

A. **Justification**

1. Need and Legal Basis

The legal basis for the requirement that Sponsors support the NCPDP SCRIPT standard for use in ePA comes from the MMA provision mandating that Sponsors comply with the named e-prescribing standards. The naming of the specific ePA standard is required by the SUPPORT Act. The NCPDP SCRIPT standard is the only available pharmacy prescribing standard appropriate for ePA for prescription drugs that are covered under a pharmacy (e.g., Part D) benefit.

The legal basis for beneficiary RTBT is section 1860D-12(b)(3)(D) of the Act which authorizes additional contract terms not inconsistent with the Part D statute. CMS codified the beneficiary RTBT requirement as an additional mechanism through which Part D sponsors must provide specific information about prescription drug coverage to enrollees. This patient-specific and real-time information about their plan's formulary and benefits (i.e., cost sharing) can empower patients to work with their prescribers to select medications that are clinically appropriate and more affordable or without formulary restrictions.

2. Information Users

If the requirements of the ePA standard are to be finalized, the prior authorization information would flow from the prescriber's EHR to the point of prescribing using plan-supported EHRs.

This information would be used to help grant prior authorization for specific medications in a more secure and efficient manner than manual prior authorization (e.g., fax or phone call).

3. Use of Information Technology

CMS requires that the NCPDP SCRIPT standard is used to conduct ePA, but does not require prescribers to conduct ePA. Prescriber adoption of ePA is dependent on electronic health record (EHR) functionality or use of a separate ePA portal. The CMS requirement facilitates the use of information technology by requiring that Part D sponsors support the NCPDP SCRIPT standard for the electronic transmission of prior authorization transactions so that as ePA is adopted, prescriber and payer systems are compatible.

Beneficiaries can access the RTBT online or by phone from the plan's call center. Although a goal of requiring a beneficiary RTBT is to ensure beneficiaries can readily access their formulary and benefit information, we retained a requirement for Part D sponsors to provide the same information by phone for beneficiaries who are less comfortable with computer or mobile access to their plan information.

4. Duplication of Efforts

NCPDP SCRIPT is the industry standard for transmitting ePA between prescribers and payers/processors for drugs covered under the pharmacy benefit; therefore, there is no duplication as a result of our requirement to use the NCPDP SCRIPT standard for Part D ePA. The NCPDP Telecommunication standard named at 45 CFR § 162.1302(b)(2)(i) for authorization of retail pharmacy drugs is for claims adjudication between pharmacies and payers/processors and lacks the functionality to support complex ePA elements (e.g., clinical criteria, diagnoses) that prescribers are expected to submit with requests for prescription drug prior authorization. The X12 278 standard for ePA currently named at 45 CFR § 162.1302(b)(2)(ii) is for dental, professional and institutional prior authorizations and is not appropriate for prior authorization for drugs covered under the pharmacy benefit.

The beneficiary RTBT is the only tool to provide beneficiaries with drug-specific formulary alternatives for enrollees and beneficiary-specific prior authorization information. Although this information may be available to prescribers using the prescriber RTBT, the information is more impactful when enrollees can view it themselves. In addition, prescribers are not required to have a prescriber RTBT, so allowing beneficiaries to access this information, would increase the proliferation of this helpful data.

5. Small Businesses

Small businesses are not significantly affected by this collection. Our requirements for the beneficiary RTBT are designed to mirror those of the prescriber RTBT so that it would only require plans to provide data that they already have access to. The NCPDP SCRIPT standard is the industry standard for electronic prescribing of drug covered under the pharmacy benefit, therefore using this standard for ePA in addition to other electronic prescribing transactions minimizes burden associated with implementing ePA. Use of the industry standard also facilitates

compatibility between payer and provider systems. There is no ability to further minimize the burden to small businesses.

6. Less Frequent Collection

The information provided by the NCPDP SCRIPT standard for ePA and the beneficiary RTBT are required to be in real-time on a continuous, ad hoc basis. Information that is provided less frequently would be irrelevant, since drug prices change so frequently and beneficiaries often need access to information regarding their prescription drug coverage rapidly.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

Although organizations would be required to transmit information for the transaction and RTBT in real-time, this would be done regularly, since it would be a requirement for both proposals. This would not be necessitated by a special set of circumstances.

8. Federal Register/Outside Consultation

Federal Register

The 60-day Federal Register Notice (90 FR 22492) published in the Federal Register on 05/28/2025.
No comments were received during the 60-day comment period.

The 30-day Federal Register Notice (90 FR 38981) published in the Federal Register on 8/13/2025.

Outside Consultation

CMS periodically meets with industry stakeholders to discuss e-prescribing requirements. CMS does this through attendance at quarterly workgroups, annual conferences, and conversations with industry leaders. CMS participates in weekly NCPDP task group meetings during which we are able to hear real-world feedback from from various members of the pharmacy industry (e.g., payers, processors, electronic health record vendors, pharmacies) with respect to electronic prescribing tools.

9. Payments/Gifts to Respondents

Not applicable. Although there are no payments or gifts provided as part of completing ePA using the NCPDP SCRIPT standard, we believe there will be cost savings to plans and prescribers due to reduced administrative burden compared with manual prior authorization. Part D sponsors are permitted to offer their enrollees rewards and incentives for using the beneficiary RTBT, but we do not consider enrollees to be respondents for the purposes of this information collection since there is no requirements that beneficiaries utilize the RTBT.

10. Confidentiality

Although CMS is not involved in the transmission of this information, CMS trusts that the protected health information (PHI) transmitted through ePA and beneficiary RTBTs will be transmitted securely consistent with industry standards for encryption and in a Health Insurance Portability and Accountability Act (HIPAA)-compliant manner.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Collection of Information Requirements and Annual Burden Estimates

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialists, All Other	13-1199	44.41	44.41	88.81

As indicated, we are adjusting 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. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Associated with ePA (§ 423.160(b)(1))

Based on our informal conversations with the industry, we believe that the ongoing cost that plans will incur to process ePA transactions range from $1.20 to $2.85 per transaction, which varies based on vendor and volume. Across the pharmacy industry in general, approximately half of all prior authorizations are completed electronically while half continue to be completed manually through phone or fax.[1] CMS does not collect data on the number of prescription drug prior authorization requests that prescribers submit to plans. We previously estimated that 560,430 ePAs are performed every year across 772 contracts, for an average of 724 ePAs per contract, per year. There are 968 Part D contracts as of March 2025. Therefore assuming the same number of ePAs occurring per contract we revise the estimate to 700,832 ePAs annually (724 ePAs * 968 contracts). Each authorization requires two individual transactions, one for receiving and one for responding. Using $2.03 as the average cost per transaction ([$1.20 + $2.85]/2) we estimate $4.06 per authorization ($2.03/transaction × 2 transactions/authorization). In aggregate we project an ongoing transaction (both receiving and responding) cost of $2,845,378annually ($4.06/ authorization * 700,832) for all plans.

Burden Associated with Beneficiary RTBTs (§ 423.128(d)(4)-(5))

One-time costs associated with establishing beneficiary RTBTs, developing the rewards and incentives policy, and updating RTBT systems to collect usage data for rewards and incentives were described in the January 19, 2021 final rule CMS-4190-F2 (86 FR 5864 starting at 86 FR 6064). As these one-time costs are no longer applicable, they are not included in this renewal. We are including the ongoing annual costs associated with maintaining rewards and incentives programs associated with beneficiary RTBTs. We estimated that 10 percent of Part D sponsor parent organizations would create a rewards and incentives program for use of the beneficiary RTBT. For 2025, there are 329 parent organizations associated with plans offering Part D. Therefore, we expect 33 (329 * 0.10) parent organizations to maintain rewards and incentives programs. We estimate that 2 business operations specialists will each take 15 hours every month to maintain the program for a total annual burden of 360 hours per parent organization (15 hr/month * 12 months * 2 workers) and a total of 11,880 hr for 33 parent organizations (360 hr * 33 parent organizations). The total estimated annual cost is therefore $1,055,063 (11,880 hr * $88.81/hr).

The total annual costs are summarized in Table 1.

1 https://insights.covermymeds.com/medication-access-report/2020/electronic-prior-authorization

Table 1: Burden Summary for Electronic Prescribing Tools

Subject	Response Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
ePA Transactions (§ 423.160(b)(1))	RK*	968	n/a	724	700,832	n/a	2,845,378 **
Rewards and Incentives for Beneficiary RTBTs (§ 423.128(d)(4)-(5)	RK*	33	360	1	33	11,880	1,055,063
Total	**RK***	**1001**	**Varies**	**Varies**	**700,865**	**11,880**	**3,900,441**

*Recordkeeping
**Non-labor cost

Information Collection Instruments and Instruction/Guidance Documents

The regulation does not require the use of any specific instrument or instruction/guidance documents. CMS provided guidance to implement ePA in the December 31, 2020 final rule CMS-4189-F (85 FR 86824) and beneficiary RTBT in the January 19, 2021 final rule CMS-4190-F2 (86 FR 5864).

13. Capital Costs

There are no capital or start-up costs associated with this information collection. All costs have been accounted for in section 12. Sponsors have been required to have electronic standards in place since 2005 and most Sponsors already conduct ePA transactions.

14. Cost to Federal Government

The to the Federal government associated with this information collection is the labor associated with renewal of the information collection. This information collection is updated every 3 years and requires approximately 40 hours to update the supporting statement, complete the associated forms for posting in the Federal Register, and respond to public comments received. We use the 2025 Office of Personnel Management General Schedule (GS) locality pay adjusted for

Washington-Baltimore-Arlington, DC-MD-VA-WV-PA https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/ and assume fringe benefits at 100 percent of hourly wage.

Occupation Title	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Health Insurance Specialist, GS-13/Step 1	57.78	57.78	115.56

The total cost to the Federal government for a Health Insurance Specialist to complete this information collection is estimated at $4,622 (40 hrs * $115.56/hr) every 3 years.

15. Changes to Collection of Information Requirements, Burden, and Instruments

In this renewal, we are removing one-time costs associated with ePA implementation and adding ongoing annual costs for maintaining a rewards and incentives program for beneficiary RTBTs. We are also revising the burden for ePA transactions to reflect an increased number of Part D contracts.

Removed Burden

Subject	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
ePA Implementation (§ 423.160(b)(1))	-15	Varies	-33,000

Revised Burden

Subject	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
ePA Transactions (§ 423.160(b)(1))	+140,402	n/a	+570,032

Added Burden

Subject	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
Rewards and Incentives for Beneficiary RTBTs (§ 423.128(d)(4)-(5)	+33	+11,880	+1,055,063

Net Changes

Subject	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
Approved collection	560,445	Varies	2,308,346
Revised collection	700,865	11,880	3,900,441
Net Changes	**+140,420**	**+11,880**	**+1,592,095**

16. Publication/Tabulation Dates

There are no plans to publish the information.

17. Expiration Date

There are no standardized forms associated with this collection on which to display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods, surveys, or questionnaires.