Supporting Statement A
CMS Medicare Part D E-Prescribing Tools in 42 CFR 423.160(b)(7)
CMS-10755 (OMB 0938-1396)

Background

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 request and response transactions between prescribers and Part D plan sponsors no later than January 1, 2021. Such transactions are to 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.

Final Regulation

This information collection request is associated with our December 31, 2020 (85 FR 86824) rule (CMS–4189–F, RIN 0938–AT94), which revises § 423.160(b)(7) by requiring that Part D plan Sponsors (Sponsors) support version 2017071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for use in electronic Prior Authorization (ePA) transactions with prescribers regarding Part D covered drugs to Part D eligible individuals. Requiring that plans support this standard will increase use of ePA in Part D by facilitating use of a more appropriate Part D e-prescribing standard than the currently-named standard.

A. **Justification**

1. Need and Legal Basis

The legal basis for the requirement that Sponsors support NCPDP SCRIPT 2017071 standard for use in electronic Prior Authorization (ePA) in our December 2020 final rule 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. Naming the NCPDP SCRIPT 2017071 standard is simply naming the most appropriate standard within the parameters for the SUPPORT Act.

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.

3. Use of Information Technology

Both the electronic transaction standard and beneficiary RTBT are done almost completely electronically. The one exception to this is for beneficiaries who use the plan's call center to get the beneficiary RTBT information. We considered exempting plans from this requirement or requiring that plans provide the information in multiple electronic mediums, rather than require that plans provide this information via their call center. However, we decided to retain the requirement that plans use the call center, since so many beneficiaries do not feel comfortable using computers or smart phones. Based on current beneficiary RTBT usage, we estimate that 70% of the RTBTs are used electronically.

4. Duplication of Efforts

Although ePA information could currently be sent using the currently named X12 standard, keeping that standard would not comport with the SUPPORT Act mandate to provide for a new standard. In addition, the X12 standard has become outdated for sending ePA information for medications. In fact, CMS has eliminated potential duplication by requiring use of the NCPDP SCRIPT 2017071 standard for Part D ePA by January 1, 2022

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. Where small businesses may participate in these programs, they are required to share this data with their enrollees. Our requirements 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. For use of the ePA standard, the requirement is already the requirement used by most plans, which is to use the NCPDP SCRIPT 2017071 standard. There is no ability to further minimize the burden to small businesses.

6. Less Frequent Collection

The information provided by the NCPDP SCRIPT 2017071 standard and the beneficiary RTBT are required to be in real-time and beneficiaries would be required to have continuous access to it. Information that is provided less frequently would be irrelevant, since drug prices change so frequently and beneficiaries often need access to their medications 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 proposed rule (CMS–4189–P, RIN 0938–AT94) published in the Federal Register on June 19, 2019 (84 FR 28450).

Although the proposed rule indicated that the changes would be submitted under control number 0938-0763 (CMS-R-262), after further internal review we have since determined that the changes should be set out under a new collection of information request. The 0938-0763 information collection is our Part D plan benefit package and formulary information. However, these Part D e-prescribing tools have changed in function where they are more similar to each other, than to the Part D plan benefit package and formulary information. The change was discussed on page 86832 of our December 31, 2020, final rule.

We received 4 PRA related comments, which we addressed on page 86833 of the final rule and in the attached document. That is comments associated with the collection of information, the reporting of information, the disclosure of information, and/or recordkeeping.

The final rule (CMS–4189–F, RIN 0938–AT94) published in the Federal Register on December 31, 2020 (85 FR 86824).

Outside Consultation

CMS periodically meets with industry stakeholders to discuss what e-prescribing requirements would enhance agency interoperability. CMS does this through attendance at workgroups, conferences, and conversations with industry leaders. In these proposed rules, CMS requested comment on our proposals. We will take all comments into consideration when developing the final rule requirements.

Both of these information collections were developed, due to industry feedback. The industry informed us that both of these tools were already widely used within the industry. As a result, we tailored our requirements to what was already being done.

9. Payments/Gifts to Respondents

Although there are no monetary payments or gifts to respondents, Sponsors are permitted to offer rewards and incentives for use of the beneficiary RTBT by their enrollees.

10. Confidentiality

Although CMS is not involved in the transmission of this information, CMS trusts that this information will be transmitted securely. The NCPDP SCRIPT 2017071 standard uses XML syntax for transmission, which is a newer syntax than the syntax used in the previously-approved X12 standard, and helps ensure security of transactions through the encryption of personal health information and through use of XML transaction processing. As part of our requirements for the beneficiary RTBT, we required that plans use a portal or app. Both of these tools require that beneficiaries login for access.

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

Labor Estimates

After consulting with industry stakeholders, we have concluded that implementing or building the type of logic which will allow systems engineers to produce the interactive logic which the SCRIPT standard requires can vary based on how the PA criteria are currently documented, but $100,000 is the approximate average cost. The cost varies based on the size and expertise of the plan. This figure includes only the plan's internal costs including labor, initial development and programming, and systems support to transform each of its CMS-approved PA criteria from a free flowing document suitable for implementation by a clinical professional into a step-by-step document that can be adapted for use by programmers.

Information Collection Requirements and Burden Estimates

Section 6062 of the SUPPORT for Patients and Communities Act, requires the adoption of technical standards for the Part D e-prescribing program to help ensure secure ePA requests and response transactions. In response, § 423.160(b)(7) requires that Sponsors have the technical capability to support the NCPDP SCRIPT standard version 2017071 when performing electronic ePA for Part D-covered drugs prescribed to Part D-eligible individuals.

While the regulation does not impact the PA criteria which Sponsors have in place, the electronic process will make the PA process less burdensome for plans and prescribers. Prescribers who are currently using an electronic prescribing software already have access to the ePA transactions and may generally access the transactions without cost, since the eRx software includes all transactions within the NCPDP SCRIPT standard. As ePA is implemented the current system of manual processing (fax and phone calls) has been eliminated, since plans are able to use this more appropriate standard.

We estimate a one-time cost for plans to implement the necessary changes to support the ePA transactions within NCPDP SCRIPT standard version 2017071.

Based on our internal data, we estimate that there are 990 plans.

We estimate that only 20 percent (or 198) of the plans (990 plans × 0.20) do not have the internal ePA process that would be required to build the logic into the NCPDP SCRIPT standard's ePA transactions. In that regard we estimate a one-time implementation cost of $19,800,000 (198 plans × $100,000/plan) or $6,600,000 annually when factoring in OMB's 3-year approval period ($19.8 million/3 years). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

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. Based on internal CMS data, for the 774 plans we estimate that 560,430 PAs are performed every year and that 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 $2,275,346 annually ($4.06/ authorization × 560,430 authorizations) for all plans.

With regard to current practice, 98 percent (or 15) of the plans (774 plans × 0.02) already have the capacity to process automated PAs. However, when they perform these processes manually, they spend an average of $10.00/fax PA for 549,221.4 authorizations (560,430 authorizations × 0.98) at a cost of $5,492,214 (549,221 PAs × $10.00/PA). The remaining 15 plans that rely on phone or fax and manual review spend an average of $25.00/manual PA for 11,209 authorizations (560,430 authorizations × 0.02) at a cost of $280,225, (11,209 PAs × $25.00/PA). In this regard the transaction cost for the current practice is approximately $5,729,439 ($5,492,214 + $280,225).

In addition, we believe that there will be added savings due to fewer appeals being processed. We estimate that 900 appeals are processed annually due to mistakes emanating from the use of manual PA, including missing PA information and the PAs not being received by the correct party. We believe that these appeals would be eliminated, since ePA requires input of all necessary information for the transactions to be processed and provides a secure means of delivery to the recipients. We estimate that it costs $101.63 to process each of these appeals based on the 1.25 hours at $69.72/hr that it takes a quality officer at each organization to process the appeal and the cost of sending the appropriate notices, which would lead to a savings to plans of $91,467 (900 appeals × $101.63). When we add this savings to the $3,454,093 already saved, we project a total annual savings of $3,545,560 ($3,454,093 + $91,467). This figure differs slightly from the estimate that was set out in our June 19, 2019 proposed rule. That rule had inadvertently excluded the savings emanating from the revised number of appeals. In addition, the rule had overestimated the amount of plans that would need to make changes to implement the standard and the burden to implement it. We are correcting that oversight in this final rule.

Since this final rule only requires plans, and not prescribers, to implement the standard, we are not

estimating costs that assume prescribers will transition to this standard. As a result, we did not include the aforementioned transaction costs and appeals savings in our tabulation of the final costs of implementing this rule. Therefore, we believe that the final cost of this rule will be the $100,000 for plans to implement this standard.

The total annual cost is:

$6,600,000 one-time implementation cost (factored over a 3-year period)
$2,275,346 ongoing transaction cost (both receiving and responding)
$5,729,439 ongoing transaction cost (current practice)
($3,545,560) savings (fewer appeals)
$100,000 ongoing standard implementation
$11,159,225 TOTAL

Information Collection Instruments and Instruction/Guidance Documents

The regulation does not require the use of any specific instrument or instruction/guidance documents. The only information that CMS provides to implement these provisions is in the December 31, 2020, final rule and § 423.160(b)(7).

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

There is no cost to the Federal government for this effort, since this effort is being done entirely by Sponsors.

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

Not applicable. This is a new collection of information request.

16. Publication/Tabulation Dates

There are no plans to publish the information.

17. Expiration Date

CMS has no objections to displaying 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.