



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-3394-NC]

RIN 0938-AU25

Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires generally that prescriptions for controlled substances covered under a Medicare Part D prescription drug plan or Medicare Advantage Prescription Drug Plan (MA/PD) be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program, beginning January 1, 2021. Further, section 2003 of the SUPPORT Act provides CMS with the authority to, through rulemaking, enforce and specify appropriate penalties for noncompliance with the requirement for electronic prescribing of controlled substances (EPCS). The SUPPORT Act requires CMS to specify, through rulemaking, circumstances and processes by which it may waive the EPCS requirement. This Request for Information (RFI) seeks input from stakeholders about whether CMS should include exceptions to the EPCS and under what circumstances, and whether CMS should impose penalties for noncompliance with this mandate in its rulemaking, and what those penalties should be.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the “ADDRESSES” section, no later than 5 p.m. on **[Insert date 60 days after date of publication in the Federal Register]**.

ADDRESSES: In commenting, refer to file code CMS-3394-NC.

Comments, including mass comment submissions, must be submitted in **one** of the following three ways (please choose only **one** of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the ““Submit a comment”” instructions.
2. By regular mail. You may mail written comments to the following address **ONLY**:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3394-NC,
P.O. Box 8013,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3394-NC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Ashley Hain, (410) 786-7603, for general inquiries related to the RFI. Joella Roland, (410) 786-7638, for Part D electronic-prescribing issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

I. Background

In 2018, President Trump signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or the SUPPORT for Patients and Communities Act, into law, which mobilized Federal efforts to address the nation's ongoing opioid crisis. Section 2003 of the SUPPORT Act mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D should be done electronically in accordance with an electronic prescription drug program, beginning 2021, subject to any exceptions, which the Department of Health and Human Services (HHS) may specify. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are at section 1860D-4(e)(7) of the Act, as added by section 2003 of the SUPPORT Act, and include--

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;

- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

- A prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

- A prescription issued by a practitioner prescribing a drug under a research protocol;

- A prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

- A prescription issued by a practitioner—

- ++ For an individual who receives hospice care under title XVIII; and

- ++ That is not covered under the hospice benefit under title XVIII; and

- A prescription issued by a practitioner for an individual who is—

- ++ A resident of a nursing facility (as defined in section 1919(a) of the Act); and

++ Dually eligible for benefits under titles and XVIII and XIX.

Since Part D was signed into law in 2003, electronic prescribing (e-prescribing or e-Rx) has been optional for physicians with respect to prescriptions made for covered Part D drugs. However, Part D sponsors offering drug plans have been required to have the electronic capabilities to support electronic prescribing. CMS adopted the first set of standards for e-prescribing for Part D in 2005.¹ Those standards included the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 5, Release 0. Since then, CMS has continued to adopt updated e-prescribing standards² with the most recent standard described in a final rule published April 16, 2018, where CMS finalized its update of its Part D standards to NCPDP SCRIPT standard version 2017071 for e-Rx and medication history, effective January 1, 2020 (83 FR 16440).

We maintain a prescription drug events (PDEs) system to capture Part D prescriptions processed (see OMB Control Number 0938-0982). The PDE format includes a field in which the plan must indicate whether the prescription was written via paper, electronic or telephonic means. CMS has collected data on controlled substances and non-controlled substances since the Drug Enforcement Agency (DEA) permitted the electronic prescribing of controlled substances in 2010.³

However, as HHS and other Federal departments and agencies work to implement various provisions of the SUPPORT Act, including the electronic prescribing requirements for controlled substances under Part D, the health care system faces new challenges. The United States is currently responding to an outbreak of respiratory disease caused by a novel (new)

¹ See 70 FR 67568.

² CMS regulations adopting updated versions of the NCPDP SCRIPT standard: 73 FR 18918 (NCPDP SCRIPT version 8.1) and 77 FR 688892 (NCPDP SCRIPT version 10.6).

³ See 75 FR 16284, including revisions adopted to 21 CFR 1304.04.

coronavirus now detected in 50 States and the District of Columbia. This virus has been named “severe acute respiratory syndrome coronavirus 2” (“SARS-CoV-2”), and the disease it causes has been named “coronavirus disease 2019” (“COVID-19”). In January 2020, HHS Secretary Alex M. Azar II determined that a Public Health Emergency (PHE) exists for the United States to aid the nation’s health care community in responding to COVID-19 (hereafter referred to as the PHE for the COVID-19 pandemic), and on April 21, 2020, Secretary Azar renewed, effective April 26, 2020, the determination that a PHE exists. In March 2020, President Trump declared the COVID-19 pandemic a national emergency. Certain individuals, including older adults and persons with chronic conditions, who comprise a predominance of the Medicare beneficiary population, are at elevated risk of more severe illness and potential death from COVID-19. The Centers for Disease Control’s guidance on the COVID-19 pandemic notes that “people in their 50s are at higher risk for severe illness than people in their 40s. Similarly, people in their 60s or 70s are, in general, at higher risk for severe illness than people in their 50s. The greatest risk for severe illness from COVID-19 is among those aged 85 or older.”⁴ As a result of the PHE, and as the nation reopens, some individuals, such as those who are at high risk, may continue to practice self-isolation and social distancing.⁵

We have taken many regulatory and policy actions to swiftly aid the nation’s health care system to address effectively the COVID-19 pandemic. These actions include new flexibilities for telehealth and other electronic technologies⁶ to ease the burden on providers and help assure appropriate and safe care in a range of settings for beneficiaries. Also, DEA has adopted certain new temporary flexibilities to allow DEA-registered practitioners to prescribe controlled substances without having to interact in person with some patients, effective for the duration of

⁴ See <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>.

⁵ See <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html>.

⁶ See <https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf>.

the PHE.⁷ DEA's COVID-19 information page may be found at:

<https://www.deadiversion.usdoj.gov/coronavirus.html>. DEA has acknowledged the prevalence of paper prescribing of controlled substances and attempted to address some of the hardships it poses for prescribers and patients during the PHE. We believe that social distancing is, in part, responsible for the increase in EPCS during this PHE. In 2020, electronic prescribing increased to 50 percent of all PDEs being prescribed as compared to 38 percent in 2019.⁸ With the use of electronic prescribing, a patient and provider can conduct a visit via telehealth and then have the prescription electronically transmitted to the pharmacy without having to see each other in-person and risk transmitting COVID-19. Some insurers, including Part D plans, may be permitting medication refills, including for controlled substances, earlier than usual or for a more extended period of time than was previously allowed. Pharmacies that were not previously doing so may deliver medications, or deliver at no charge, and communities and individuals have worked together to design ways for vulnerable persons to continue to receive access to prescribed medications in tandem with these new government and private sector flexibilities.

DEA has the primary responsibility for establishing requirements for prescribing and dispensing of controlled substances. In 2010, DEA issued an Interim Final Rule with Request for Comment, "Electronic Prescriptions for Controlled Substances," that provided practitioners with the option of writing prescriptions for controlled substances electronically (75 FR 16236). The rule also permitted pharmacies to receive, dispense, and archive these electronic prescriptions. Any electronic controlled substance prescription issued by a practitioner must meet the

⁷ See [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-023\)\(DEA075\)Decision_Tree_\(Final\)_33120_2007.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf).

⁸ Based on Prescription Drug Event data processed through April 30, 2020.

requirements in DEA's EPCS interim final rule. On April 21, 2020, DEA reopened the 2010 interim final rule to solicit comments from the public on specific EPCS-related issues.⁹

Since the issuance of DEA's EPCS interim final rule in 2010, CMS has seen a steady increase in the volume of controlled substance prescriptions submitted electronically. For example, in 2018, 26.57 percent of controlled substance prescription drug events (PDEs) were transmitted electronically. In 2019, e-prescribing for controlled substances PDEs increased to 37.31 percent. However, in our 2020 data, 51.15 percent of those PDEs have been transmitted electronically. States have instituted electronic prescribing requirements; some include penalties for not using e-prescribing for controlled substances. As of 2020, all states in the U.S. and the District of Columbia allow electronic prescribing of controlled substances for schedules II through V.¹⁰

EPCS provides multiple advantages over the traditional processing of prescriptions.¹¹ In addition to improving workflow efficiencies, electronic prescribing of controlled substances can

⁹ See <https://www.federalregister.gov/documents/2020/04/21/2020-07085/electronic-prescriptions-for-controlled-substances>.

¹⁰ Schedule I drugs are not included in EPCS discussions because they have no currently accepted medical use. See <https://www.deadiversion.usdoj.gov/schedules/#define> for additional detail on definitions of controlled substances.

¹¹ Phillips et. al. "Market Guide for Identity Proofing and Corroboration." April 24, 2018. Gartner, Inc. Retrieved from <https://www.fedscoop.com/gartner-guide-identity-proofing-corroboration-2018/> on April 30, 2020. Ryan, D. "FinCEN: Know Your Customer Requirements." February 7, 2016. Harvard Law School Forum on Corporate Governance. Retrieved from <https://corpgov.law.harvard.edu/2016/02/07/fincen-know-your-customer-requirements/#2b> on April 30, 2020. Nix, M. "Five Questions: Ken Whittemore Talks Past, Present & Future of E-Prescribing Controlled Substances." March 31, 2020. SureScripts. Retrieved from [https://surescripts.com/news-center/intelligence-in-action/opioids/five-questions-ken-whittemore-talks-past-present-future-of-e-prescribing-controlled-substances?utm_campaign=IIA percent2FBlog percent20Subscription&utm_source=hs_email&utm_medium=email&utm_content=85955401&_hsenc=p2ANqtz-8xs36u7xTFZ-ieOxJk3309SApbE7to_fnk1SZvz2jqwz0pA3k7TtW9byiOq2zBlheLInMOeajCMCKeQUTzcEDP79HEaeXI52QiadhAYAWU3Px2eZc&_hsmi=85955401](https://surescripts.com/news-center/intelligence-in-action/opioids/five-questions-ken-whittemore-talks-past-present-future-of-e-prescribing-controlled-substances?utm_campaign=IIA%20Blog%20Subscription&utm_source=hs_email&utm_medium=email&utm_content=85955401&_hsenc=p2ANqtz-8xs36u7xTFZ-ieOxJk3309SApbE7to_fnk1SZvz2jqwz0pA3k7TtW9byiOq2zBlheLInMOeajCMCKeQUTzcEDP79HEaeXI52QiadhAYAWU3Px2eZc&_hsmi=85955401) on April 30, 2020. Zhang et. al. "T2FA: Transparent Two-Factor Authentication." June 15, 2018. IEEE Access. Retrieved from <https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=8386653> on April 30, 2020. Konoth R.K., van der Veen V., Bos H. (2017) How Anywhere Computing Just Killed Your Phone-Based Two-Factor Authentication. In: Grossklags J., Preneel B. (eds) Financial Cryptography and Data Security. FC 2016. Lecture Notes in Computer Science, vol 9603. Springer, Berlin, Heidelberg. Retrieved from [https://link.springer.com/chapter/10.1007 percent2F978-3-662-54970-4_24](https://link.springer.com/chapter/10.1007%2F978-3-662-54970-4_24) on April 30, 2020. Cal and Zhu. "Fraud detections for online businesses: a perspective from blockchain technology." *Financial Innovation* (2016) 2:20. Retrieved from <https://link.springer.com/content/pdf/10.1186/s40854-016-0039-4.pdf> on April 30, 2020.

deter and help detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. It can also provide more timely and accurate data than paper prescriptions. By allowing for the direct transmission of electronic prescriptions for controlled substances between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. In addition, EPCS data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history at the time of prescribing. It is also important to continue the assurance of privacy and security in the prescribing process, such as by controlling prescriber access through improved identity controls and authentication protocols. EPCS can assure prescribers' identity more easily and may permit a single workflow for prescribing both controlled and non-controlled drugs, improving the overall prescribing process.¹²

From the patient standpoint, EPCS may reduce the logistical burden on patients who may otherwise be required to make multiple trips between providers and pharmacies to transport paper prescriptions when filling time-sensitive prescriptions while in pain or otherwise in need of treatment with controlled substances, as Schedule II, III, IV, or V drugs that may be used to treat a number of conditions. EPCS can lessen the time needed to obtain prescriptions by minimizing trips to the physician to pick up paper prescriptions for refills, minimize transportation costs to and from the provider's office, and even help lessen stigma, well-known to be associated with chronic pain when opioid therapy is used as a treatment modality.¹³ EPCS' security advantages

¹² HHS Office of the National Coordinator, The ONC Doctors' Perspective: Electronic Prescribing of Controlled Substances (EPCS) Is on the Rise, and We Must Work Together to Address Barriers to Use: <https://www.healthit.gov/buzz-blog/health-it/the-onc-doctors-perspective-electronic-prescribing-of-controlled-substances-epcs-is-on-the-rise-and-we-must-work-together-to-address-barriers-to-use>.

¹³ Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force Report, May 2019: <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

also assure prescribers, patients, and pharmacies that prescriptions are processed as intended. In addition to helping with the reduction in fraud previously described, EPCS minimizes the likelihood that prescriptions have been tampered with, since electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, which minimizes the likelihood of exposure to patients or other third parties with potentially malicious intent.

II. Solicitation of Public Comments

We are issuing this RFI and requesting comment from stakeholders regarding how the SUPPORT Act's EPCS requirements can be implemented with minimal burden to those prescribers participating in the Part D program during and after the PHE. We are committed to helping health care providers streamline operations, and want to strongly encourage prescriber EPCS adoption across the health care continuum as another mechanism to further ease burden, ensure prescribing safety, and improve beneficiary health and satisfaction.

We seek responses to this RFI from beneficiary and advocacy groups; beneficiaries and caregivers; primary care and specialty providers; health plans and supplemental insurers; state, local, and territorial governments; research and policy experts; industry and professional associations; long-term care facilities, hospice providers, pharmacists, and pharmacy associations; and other interested members of the public.

In the following sections of this RFI, we discuss compliance assessments, enforcement (including penalties), and waivers. We seek comments in response to questions related to each of these topics in each subsection.

Commenters are requested to provide responses to the following questions that are most relevant to their interest and experience. A response to every question is not required.

Additionally, commenters may identify and comment on other issues that they believe are significant for CMS to consider in implementing the SUPPORT Act's EPCS requirements.

Respondents are requested to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses whenever possible.

A EPCS Compliance Assessments

Based on a published report of 2019 data reflecting the majority of prescribing activities across the country,¹⁴ 97 percent of U.S. pharmacies were capable of processing electronic prescriptions for controlled substances, yet only 49 percent of prescribers were capable of electronically prescribing controlled substances. The same report showed that 38 percent of controlled substance prescriptions were electronically prescribed, while 85 percent of non-controlled substances were electronically prescribed. Pain management specialists appear to be using electronic prescribing for controlled substances more often than other prescribers, and family practitioners are using electronic prescribing less often. Electronic prescribing also varies across practice size and ownership and among physicians who practice in groups owned by a health plan, health maintenance organizations, hospital, or other healthcare entity. Use of the technology does not vary significantly between rural and urban areas, but it does vary between states, likely associated with differences in regulations, penalties, waivers, populations, and culture.¹⁵

The reasons for this disparity between capability and practice are likely to be multifaceted. For instance, we hypothesize that there may be challenges associated with some prescribers' ability to electronically prescribe controlled substances within their normal workflow, and reluctance to alter workflow habits use new technology, although the recent

¹⁴ Surescripts. "National Progress Report 2019." March 2020. Retrieved from https://surescripts.com/docs/default-source/national-progress-reports/7398_ab-v2_2019-npr-brochure.pdf on April 20, 2020.

¹⁵ HHS Office of the National Coordinator, *The ONC Doctors' Perspective: Electronic Prescribing of Controlled Substances (EPCS) Is on the Rise, and We Must Work Together to Address Barriers to Use*: <https://www.healthit.gov/buzz-blog/health-it/the-onc-doctors-perspective-electronic-prescribing-of-controlled-substances-epcs-is-on-the-rise-and-we-must-work-together-to-address-barriers-to-use>.

COVID-19-related need to shift to remote forms of patient care may have already rapidly and substantially altered many such preferences. Other prescribers may be dependent on health care groups, clinics, or hospital systems to implement the necessary technology. There are also costs associated with the adoption of technology, which may disproportionately impact small or rural practices or pharmacies. Though EPCS uptake continues to grow,¹⁶ based on pre-COVID-19 data, there is clearly more opportunity for greater adoption of electronic prescribing of controlled substances.

Substantial adoption of EPCS has occurred in the thirteen states that require it.¹⁷ Some states have chosen to use penalties to increase prescribers' compliance with EPCS requirements. For example, New York mandated EPCS with a penalty for non-compliance and subsequently experienced an EPCS adoption rate for controlled substances of nearly 99 percent for pharmacies and 82 percent for prescribers in 2019.¹⁸ CMS does not currently impose penalties for providers prescribing controlled substances under the Part D program who do not use e-prescribing. Rather, Part D plans may reject improper transactions or transactions that do not adhere to the CMS transaction standards.

Given that the SUPPORT Act generally mandates electronic prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D, we seek comment on the following specific questions with respect to assessing compliance with EPCS requirements:

¹⁶ Burger, M. "Accelerating ePrescribing for Controlled Substances." HIT Perspectives: Controlled Substances, February 2014. Retrieved from <https://www.pocp.com/hitperspectives-controlled-substances/> on April 30, 2020. Imambaccus N, Glace S, Heath R. Increasing the uptake of electronic prescribing in primary care. *BMJ Quality Improvement Reports* 2017;6:u212185. w4870. doi:10.1136/bmjquality.u212185.w4870. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5457970/pdf/bmjqir.u212185.w4870.pdf> on April 30, 2020. Monegain, B. "E-prescribing takes off like a rocket." *Healthcare IT News*, June 18, 2015. Retrieved from <https://www.healthcareitnews.com/news/e-prescribing-takes-rocket> on April 30, 2020.

¹⁷ Arizona, Connecticut, Florida, Indiana, Iowa, Maine, Minnesota, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, and Virginia have adopted mandates that will be in effect in 2020. DrFirst. Mandates Driving EPCS and PDMP Utilization. Accessed April 29, 2020. <https://drfirst.com/resources/regulatory-mandates/>

¹⁸ Surescripts, 2019 National Progress Report. Accessed April 29, 2020. https://naspa.us/wp-content/uploads/2020/04/7398_2019-NPR-Brochure-Web-Final.pdf.

- What types of challenges might discourage prescribers from incorporating electronic prescribing into their normal workflows? How could CMS structure its EPCS policy to remove roadblocks to effective adoption of electronic prescribing for controlled substances?

- What level of compliance with EPCS would be appropriate to require before levying any penalties on a non-compliant prescriber, and why? For example, should we consider adopting a percentage of prescribers threshold that a practice must meet to be considered compliant with EPCS requirements? Should we instead consider specifying a number or percentage of a practice's patients?

- What time period (or periods) should CMS use to evaluate compliance (for example, quarterly, semi-annually, annually) and how should we communicate information on performance to the prescriber to drive improvement?

B. EPCS Enforcement

Section 2003 of the SUPPORT Act provides authority to the Secretary to enforce and specify appropriate penalties for non-compliance with the EPCS requirements. To ensure compliance with EPCS mandates, some States have imposed penalties for prescribers who fail to use EPCS. For example, Pennsylvania enforces prescriber penalties of \$100 per violation for the first through tenth violations and \$250 per violation for the eleventh and subsequent violations, up to \$5,000 per year.¹⁹ Based on stakeholder experience with the States and their varying penalties, we seek comment on what, if any, penalties stakeholders believe would be appropriate for non-compliance with a Federal EPCS mandate.

We note that the SUPPORT Act places limits on the Secretary's authority to require Part D plans, MA organizations offering MA-PD plans, or pharmacists to verify that a practitioner

¹⁹ Pennsylvania Department of Health Q&A on Act 96 of 2018 and applicable Federal requirements, revised 10/31/2019. Retrieved from https://www.health.pa.gov/topics/Documents/Programs/PA_EPCS_FAQ.pdf on May 1, 2020.

has a waiver or is otherwise exempt from EPCS requirements,²⁰ in addition to language in section 1860D-4(e)(7)(C)(ii) of the Act, which ensures that plans may cover and pharmacists may dispense covered Part D drugs from otherwise valid written, oral, or fax prescriptions, and in section 1860D-4(e)(7)(C)(iii) of the Act, which ensures that Medicare beneficiaries can designate a particular pharmacy to dispense their covered Part D drugs. We view those limitations as important protections for Medicare beneficiaries that will ensure continued access to needed medications. We are interested in feedback from the public about the most appropriate ways to encourage EPCS compliance in the face of practical limits on real-time compliance enforcement options.

Additionally, we seek feedback on how we should implement the EPCS requirement for prescribers of Part D drugs who are not enrolled in Medicare or Medicaid. We request feedback on what policies would be most appropriate within the SUPPORT Act's statutory limits to encourage EPCS adoption among prescribers of Part D drugs who are not enrolled in Medicare or Medicaid.

We seek comment on the following specific questions with respect to enforcement:

- What penalties, if any, would be appropriate for non-compliance with a Federal EPCS mandate?
- How may Federal penalties affect EPCS adherence?
- What mechanism(s) should CMS use to enforce penalties among non-participating Medicare or Medicaid prescribers?
- Are there other mechanisms CMS can use to encourage non-participating Medicare or Medicaid prescribers to use EPCS?

²⁰ See section 1860D-4(e)(7)(C)(i) of the Social Security Act, as added by section 2003 of the SUPPORT Act..

- Are there any circumstances under which penalties should automatically be waived?
 - How should CMS approach design and use of an appeals process for enforcement?
 - If CMS were to impose civil money penalties, what penalty structure (including amounts) should be adopted?
- Should any details about penalties for violations of section 2003 of the Support Act be posted publicly? What types of details should be included in information available to the public?
 - Should CMS assess penalties after some interval following implementation of this requirement? If yes, what interval(s)?
 - Should CMS assess penalties' severity incrementally based on repeat analyses demonstrating lack of improved compliance? If yes, please describe what type of analyses would be most effective.
 - Should penalties be significant enough that a prescriber not eligible for a waiver or exemption would be either forced to comply with the electronic prescribing requirement for controlled substances, or stop providing such pharmacologic care across all covered classes of controlled substances? What are the implications for patients in either scenario?

C. EPCS Waivers

Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the EPCS requirement.

We are interested in receiving input on circumstances for which the Secretary should waive the EPCS requirement, including those circumstances specified by section 2003 of the SUPPORT Act. For instance, an ONC Data Brief published in September 2019²¹ indicated that

²¹ Parasrampur *et. al.* "Electronic Prescribing of Controlled Substances among Office-Based Physicians, 2017." Office of the National Coordinator for Health Information Technology Data Brief. Retrieved from <https://www.healthit.gov/sites/default/files/page/2019-09/officebasedphysicianelectronicprescribingofcontrolledsubstance2017.pdf> on May 20, 2020.

larger physician practices and practices owned by hospitals had the highest rates of physician EPCS, suggesting that smaller practices may struggle to adopt the technology and practice. As we discuss in the following paragraph, we are interested in stakeholder input on any waivers and accompanying limits to the waivers that would be appropriate, the specific reasons that such waivers and limits may be necessary, and any operational or policy considerations that we should take into account when considering the need for and adopting waivers in connection with the EPCS requirement.

The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and also permits HHS to develop other appropriate exceptions. Given the numerous benefits of electronic prescribing for prescribers and patients, and in accordance with section 2003 of the SUPPORT Act, CMS seeks to define any exceptions narrowly. We also want to clarify that all prescribers may prescribe electronically (provided it is done in accordance with DEA regulations with respect to controlled substances), even if a waiver may apply, and we continue to encourage clinicians who prescribe to use electronic prescribing. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are as follows:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity. We seek comments on whether this exception is necessary, and how these claims may be identified.

- A prescription issued that cannot be transmitted electronically under the most recently adopted version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard. We believe that the current adopted standard NCPDP SCRIPT version 2017071 allows for most electronic prescribing transmissions. We seek comment on this assumption and on any

specific circumstances in which a prescription for a controlled substance could not be transmitted electronically under this standard.

- A prescription issued by a practitioner who received a waiver for a period of time (not to exceed 1 year) from the SUPPORT Act's section 2003 requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner. We seek comment on the types of economic hardships and technological limitations that would be demonstrated to CMS, and what other types of exceptional circumstances would qualify.

- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically, the practitioner reasonably determines it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and the delay would adversely impact the individual's medical condition. We seek comment on the following:

- ++ The types of circumstances that would qualify.

- ++ Whether this must be explicitly conveyed to CMS to ensure compliance.

- ++ If CMS should infer that certain circumstances would qualify for an exception.

- A prescription issued by a practitioner prescribing a drug under a research protocol.

We seek comment on the circumstances in which this exception is necessary and how CMS would identify these prescriptions.

- A prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use. We seek comment on whether there are any drugs currently under

risk evaluation and mitigation strategies for which prescriptions are not conveyed electronically or cannot be modified for electronic transmittal.

- A prescription issued by a practitioner –
 - ++ For an individual who receives Medicare hospice care; and
 - ++ That is not covered under the Medicare hospice benefit.

We seek comment on the circumstances in which this exception is necessary, and how this information would be conveyed to CMS.

- A prescription issued by a practitioner for an individual who is –
 - ++ A resident of a nursing facility; and
 - ++ Dually eligible for Medicare and Medicaid.

We recognize that electronic prescribing for residents in nursing facilities can be challenging due to necessary three-way communication involving the prescriber, the facility and the pharmacy. Waiting for the prescriber to transmit controlled substance prescriptions electronically for new admissions could create delays in initiating urgent medication therapy because a prescriber could be required to log in to the electronic health record or other health IT system to enter a complete and compliant prescription and may not have immediate access to the system if not on site at the nursing facility. We also recognize that early versions of the NCPDP SCRIPT standard, such as NCPDP SCRIPT standard version 5.0 and 8.1, did not support the workflows in the long-term care setting that require prescribers to issue a prescription for a patient to a non-prescriber (such as a nursing facility) that in turn forwards the prescription to a dispenser (LTC pharmacy). Nonetheless, many key Part D initiatives such as electronic prior authorization are anchored within the NCPDP SCRIPT standard version 2017071. CMS recognizes and is encouraged by the NCPDP's efforts to ensure that e-prescribing standards accommodate the unique needs of nursing facility residents. As these efforts progress, we

believe that electronic prescribing will become more widely adopted in these settings. Additionally, as nursing residents are at high risk for infection, serious illness, and death from COVID-19, we are especially interested in how to assure streamlined and timely prescribing. We seek comments on our understanding of the persistence of such challenges for EPCS in the nursing facility setting and on any other specific circumstances which would support this exception.

Individuals who are dually eligible for Medicare and Medicaid often receive care in the home, through home and community-based services (HCBS) or home health services, instead of in a facility like a nursing facility. We seek comment on whether there are any additional issues, gaps, situations or barriers CMS needs to consider in implementing section 2003 for dually-eligible beneficiaries receiving HCBS or home health services.

We are also interested in receiving input on any other possible exceptions, such as in cases where a practitioner reasonably determines it would be impractical for the individual involved to obtain controlled substances prescribed using EPCS in a timely manner and the delay would adversely impact the individual's medical condition, or where EPCS would present an economic hardship. If commenters believe such exceptions should apply, please provide details on the circumstances that would require the exception, and the reasoning on whether the exception should be for a certain timeframe or indefinitely, and to whom the exception should apply.

III. Collection of Information Requirements

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the

Federal Register or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about potential policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement

would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received or a summary of those public comments.

Dated: July 20, 2020.

Demetrios Kouzoukas,

Principal Deputy Administrator for Medicare,

Centers for Medicare & Medicaid Services.

Dated: July 29, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.