The Electronic Prescribing of Controlled Substances Coalition

SUBMITTED ELECTRONICALLY TO: WWW.REGULATIONS.GOV

September 6, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare Program: CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS–1770-P)

Dear Sir or Madam:

The Electronic Prescribing of Controlled Substances Coalition (the "Coalition") respectfully submits these comments in response to the CY 2023 Physician Fee Schedule Proposed Rule (the "Proposed Rule") issued by the Centers for Medicare & Medicaid Services ("CMS"). Our comments focus solely on CMS's proposal to modify its timeline for enforcing the requirement that Part D prescribers use an electronic prescribing module to prescribe controlled substances as required by Section 2003 of the SUPPORT for Patients and Communities Act of 2018 (the "SUPPORT Act").

The Coalition is composed of a broad group of health plans, pharmacy benefit managers, pharmacies, and vendors of health information technology solutions. The Coalition's mission is to advocate policies and practices that support the use of electronic prescribing for controlled substances to improve patient safety, reduce administrative burdens, and prevent the filling of fraudulent prescriptions.

We commend CMS for its continued commitment to implementing the mandate that Part D prescribers use an electronic prescribing module to prescribe controlled substances. Not only does the electronic prescribing of controlled substances (EPCS) represent progress in the movement toward the use of interoperable technology in our health care system, but it also supports the inclusion of a fully-verifiable and traceable history on the prescribing of controlled substances, thereby undercutting drug diversion and the theft of prescription pads.[1]

[1] *See* Centers for Medicare & Medicaid Services, Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 86 Fed. Reg. 39104, 39327-28 (July 23, 2021). CMS identified the following advantages of EPCS over paper prescriptions:

- EPCS reduces burden for patients, particularly during the COVID-19 Public Health Emergency, as patients with a paper prescription might need to make multiple trips to providers and pharmacies to receive and fill needed prescriptions – trips that could potentially put seniors at risk of exposure.
- EPCS reduces the burden of prescribers who would otherwise need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. EPCS

According to the Centers for Disease Control, more than 107,000 Americans died of drug overdoses in 2021, representing a 15% increase in drug overdose deaths across the United States as compared to the previous year.[2] With opioid abuse continuing to surge amidst the COVID-19 public health emergency, now more than ever we need targeted policies like EPCS that will help curb opportunities for and prevent drug abuse.

In addition, with seniors particularly vulnerable to more severe outcomes if infected by COVID-19, health care providers are increasingly using telemedicine to treat seniors and avoid unnecessary infection risks posed by in-office visits. Health care providers in practices that have not yet implemented EPCS are in many cases nevertheless forced to ask seniors to come into the office to pick up a prescription for a controlled substance. Seniors affected by this must then make two visits to their pharmacy to drop off and pick up the prescription or wait at the pharmacy as their prescriptions are filled, increasing potential points of exposure for seniors, providers, staff, pharmacists, and others to the virus. This paper-based workflow also creates unnecessary burdens for the prescribers, pharmacists, and the patients they serve.

For these reasons, we implore CMS to begin enforcement of the EPCS mandate prior to late CY 2024. CMS should adhere to its commitment in the CY 2022 Medicare Physician Fee Schedule Final Rule to commence compliance actions in CY 2023 by sending notices to non-exempted prescribers that have not used EPCS for at least 70% of their prescriptions for controlled substances.

EPCS is not new. Already, 77.2% of prescribers nationwide are EPCS-enabled and fully 96.6% of pharmacies nationwide are EPCS-enabled.[3] Based on our research, at least 30 states have passed legislation mandating that prescribers use EPCS when prescribing controlled substances.[4]

State experience demonstrates the importance of enforcement mechanisms. For

---

also reduces prescriber burden by creating a single electronic workflow for prescribing both controlled and non-controlled drugs.

- EPCS can deter and help detect prescription fraud and irregularities as a result of the extra layer of identity proofing required to send an electronic prescription for a controlled substance.
- EPCS minimizes the likelihood that a prescription can be tampered with, as electronic prescriptions are securely transmitted directly to pharmacies.
- EPCS is more timely and accurate than paper prescriptions, avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions.
- EPCS (dispensed medication) data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history and aid in clinical decision making.

[2] Centers for Disease Control and Prevention, National Center for Health Statistics, "U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020 – But Are Still Up 15%" **********.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm (May 11, 2022).

[3] Surescripts, "Electronic Prescribing for Controlled Substances: Integrating EPCS within existing technology offers new dimensions of safety and security for controlled substance prescriptions" ********surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-for-controlled-substances/. Note that Surescripts interactive map also provides state prescriber and pharmacy EPCS adoption data.

[4] Imprivata, "EPCS Ready: Federal and State Regulations" **********.imprivata.com/federal-and-state-regulations.

example, states such as New York that have implemented enforcement mechanisms have seen adoption of EPCS from the effective date of the enforced mandate at a faster rate than states without an enforcement mechanism. This means that sending non-compliance letters in CY 2023 will improve EPCS adherence. The exceptions that CMS established for prescribers that prescribe 100 or fewer controlled substance prescriptions for Part D drugs per calendar year and prescribers that face extraordinary circumstances, such as an influx of patients due to a pandemic, will sufficiently protect those prescribers that do not have the resources to implement EPCS. CMS's additional exception, allowing prescribers to use paper for up to 30% of their prescriptions for controlled substances without being subject to enforcement, provided further leeway for prescribers to comfortably transition to EPCS beginning on January 1, 2021.

State and federal requirements for EPCS help trigger adoption without creating significant cost or time expenses for health care providers. In fact, EPCS adoption leads to improved workflows and *decreased* costs. In a 2018 survey of EPCS vendors conducted by HealthTechZone, several vendors indicated that EPCS costs are included within the cost of an EHR system and therefore would not impose additional implementation costs on prescribers. Other EPCS vendors indicated that they charge an annual per-provider fee to implement EPCS. The annual fees quoted by the survey ranged from $90 per provider per year to $500 per provider per year.[5] Given the wide-ranging benefits of EPCS adoption, including the added convenience and administrative savings gained by prescribers, such fees do not appear to present a material barrier to adoption by health care providers.

We believe that delaying the commencement of enforcement actions, as proposed in the CY 2023 Physician Fee Schedule Proposed Rule, sends the wrong message to prescribers about the need to comply. CMS should continue to move forward with sending enforcement notices in CY 2023.

Implementation of EPCS will help improve workflows and reduce costs. A 2018 study of Geisinger's implementation of EPCS indicated that the health system was saving more than $800,000 dollars per month as a result of prescribing controlled substances electronically as opposed to through a paper-based process. Additionally, according to a 2018 study from PCMA,[6] if the use of EPCS with access to comprehensive medication history were required for Medicare Part D prescriptions and its use by prescribers rose to optimal levels, the federal government would realize savings of more than $2 billion annually, based on estimated annual savings related directly to Medicare beneficiaries of:

- $2 to $4 billion saved due to decreased health care costs, decreased treatment

[5] HealthTechZone, "Three Factors Contributing to Lagging Provider Adoption of EPCS" **********.healthtechzone.com/topics/healthcare/articles/2018/04/03/437665-three-factors-contributing-lagging-provider-adoption-epcs.htm.

[6] PCMA, "Mandatory Electronic Prescribing of Controlled Substances (EPCS) Can Help Combat the Opioid Crisis and Save the United States up to $53 Billion Annually" **********pcmanet.org/wp-content/uploads/2018/04/Savings-from-Mandatory-Use-of-EPCS-FINAL-1.pdf.

costs, workplace productivity gains, and reduced criminal justice costs; and

- $0.5 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers.

We further note that when the Congressional Budget Office scored the EPCS mandate included in the SUPPORT Act, it indicated that the mandate would save the federal government $250 million over the next 10 years, a figure we believe is a conservative estimate given the data cited above.

In short, EPCS works – it will save lives and money. A majority of states mandated adoption in 2021– and there is no reason why there should be further delay in enforcing the federal EPCS mandate from the SUPPORT Act. We urge CMS to commence compliance actions in CY 2023.

Response to Request for Information Relating to Future EPCS Penalties

The Coalition appreciates the opportunity to provide feedback to CMS on potential proposals for additional penalties for non-compliance with the EPCS prescribing requirements that CMS intends to implement in 2025. CMS's suggestions for additional enforcement mechanisms in the Proposed Rule would each seem appropriate and effective in increasing prescriber compliance without being overly burdensome. The Coalition is particularly supportive of CMS's proposal to require non-compliant prescribers to agree to binding corrective action plans that require compliance within two years, although the Coalition believes that CMS could require prescribers to comply with the regulation within one year of entering into a corrective action plan barring extenuating circumstances.

The Coalition would like to offer an additional enforcement approach for CMS's consideration. Currently under the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), MIPS Eligible Clinicians are required to send at least one prescription electronically using their certified EHR technology to receive any credit for the Promoting Interoperability performance category. Failure to e-prescribe using certified EHR technology would therefore result in a loss of 25 points from the MIPS Eligible Clinician's MIPS performance score (unless the clinician could claim a Promoting Interoperability exclusion).

CMS could modify the e-prescribing measure within the Promoting Interoperability performance category to include a requirement to use EPCS for controlled substances. For example, CMS could require the MIPS Eligible Clinician to attest that the clinician used an EPCS module to electronically prescribe at least one controlled substance during the performance period. The clinician could claim an exclusion if the clinician did not prescribe controlled substances during the performance period. Failure to attest "yes" or claim an exclusion would result in a loss of the 25 points available to the MIPS Eligible Clinician under the Promoting Interoperability performance category. The Coalition believes that including an EPCS requirement within the Promoting Interoperability performance category would further influence prescribers to adopt

EPCS without creating additional reporting burdens.

Conclusion

The Coalition appreciates this opportunity to provide comments on the CMS Proposed Rule. Please contact me at schapman@thornrun.com or 202.510.1996 or Emily Katz at emily.katz@bcw-global.com with questions about this EPCS Coalition comment letter.

Sincerely,

Stuart Chapman