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

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Comments Due: October 5, 2020

On August 4, 2020, the Centers for Medicare & Medicaid Services (CMS) released a Request for Information (RFI) titled "Electronic Prescribing of Controlled Substances," seeking input from stakeholders about the implementation of a provision of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act that generally requires Medicare Advantage and Part D-covered controlled substance prescriptions to be electronically prescribed. The SUPPORT Act gives HHS the authority to enforce and specify appropriate penalties for noncompliance with electronic prescribing requirements as well as to specify any circumstances under which it may waive electronic prescribing of controlled substances (EPCS).

Comments on the RFI must be submitted to CMS by October 5, 2020. You may provide feedback via email to Carrie Monks, Director of Regulatory Affairs at cmonks@amcp.org by September 25, 2020 on any provisions included in the RFI. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the proposed rule that may be of interest to AMCP members:

A. SUPPORT Act EPCS Requirements

a. Section 2003 of the SUPPORT Act mandates electronic prescribing of controlled substances in Medicare Part D, unless otherwise waived by rules promulgated by HHS.
   - Part D plans have been required to have the capabilities to support electronic prescribing since the beginning of the Part D program, but electronic prescribing of Part D drugs has been optional for prescribers until this point.

B. EPCS Compliance Assessments

a. CMS seeks comments on these specific questions regarding assessing compliance with EPCS requirements:
   - 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 EPCS?
   - 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 CMS consider adopting a percentage of providers threshold that a practice must meet to be considered compliant with EPCS requirements? Should CMS 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 CMS communicate information on performance to the prescriber to drive improvement?

C. EPCS Enforcement

a. The SUPPORT Act provides the authority to enforce and specify appropriate penalties for non-compliance with the EPCS requirements. Examples of penalties for non-compliance in states that have electronic prescribing requirements include an increasing scale of fines for subsequent violations.

b. The SUPPORT Act also includes language that allows plans to cover and pharmacists to dispense covered Part D drugs from otherwise valid written, oral, or fax prescriptions.

c. CMS seeks comments on these specific questions regarding enforcement:
- What penalties, if any, would be appropriate for non-compliance with the federal EPCS mandate?
- How may penalties affect EPCS adherence?
- What mechanism(s) should CMS used to enforce penalties among non-participating Medicare or Medicaid providers?
- Are there other mechanisms CMS can use to encourage non-participating Medicare or Medicaid prescribers to use EPCS?
- Are there any circumstances under which penalties should be automatically 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 information about violations 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?
- Should penalties be significant enough that a provider not eligible for a waiver or exemption would be either forced to comply with the EPCS requirements or stop providing pharmacologic care across all covered classes of controlled substances? What are the implications for patients in either scenario?

D. EPCS Waivers

a. The SUPPORT Act details the circumstances listed as under which CMS can waive EPCS requirements, including when a prescription issued:
- When the practitioner and the dispensing pharmacy are the same entity.
    - CMS seeks comment on whether this exception is necessary and how these claims may be identified.
- That cannot be transmitted electronically under the most recently implemented version of the NCPDP SCRIPT Standard.

- By a practitioner who received a waiver of from the requirements due to demonstrated economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance.
    - CMS seeks comment on the types of economic hardship and technological limitations that would apply and what other exceptional circumstances would qualify.
- When it is determined that it would be impractical for the patient to obtain substances prescribed electronically in a timely manner and such delay would adversely impact the patient's medical condition.
    - CMS seeks comment on the types of circumstances that would qualify; whether this must be conveyed specifically to CMS to ensure compliance; or if CMS should infer that certain circumstances would qualify for an exception.
- By a practitioner prescribing under a research protocol.
    - CMS seeks comment on the circumstances in which this exception is necessary and how CMS would identify these prescriptions.
- For a drug for which the FDA requires the prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with REMS strategies.
    - CMS seeks comment on whether there are any drugs currently under REMS for which prescriptions are not conveyed electronically or cannot be modified for electronic transmittal.
- For a patient in hospice care, a resident of a nursing home, or dually eligible for Medicaid.
    - For patients in hospice care, CMS seeks comment on circumstances in which this exception is necessary and how this information would be conveyed to CMS.
    - For patients in nursing facilities, CMS seeks comment on the persistence of challenges for EPCS in nursing facilities, such as the need for three-way communications involving the prescriber, the pharmacy, and the facility.
    - For dually eligible beneficiaries, CMS seeks comment on whether there are additional issues, gaps, situations, or barriers the agency needs to consider in implementing EPCS requirements for these beneficiaries receiving home and community-based services or home health services.

b. CMS seeks input on additional circumstances under which it may be appropriate to provide waivers from the EPCS requirements.
    - Given the benefits of electronic prescribing both for providers and patients, CMS seeks to narrowly define any exceptions.