



Physicians Caring for Texans

September 25, 2020

Demetrios Kouzoukas, Principal Deputy Administrator for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3394- NC
PO Box 8013
Baltimore, MD 21244-8010

Re: Medicare Program: Electronic Prescribing of Controlled Substances

Comments submitted electronically via Federal Register

Dear Deputy Administrator Kouzoukas:

On behalf of our more than 53,000 Texas physicians and medical student members, the Texas Medical Association writes in response to the request for information titled “Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI),” as published in the Aug. 4, 2020, edition of the *Federal Register*.

TMA appreciates that the Centers for Medicare & Medicaid Services (CMS), within the proposed 2021 Medicare Physician Fee Schedule, proposes to postpone the electronic prescribing for controlled substances (EPCS) requirement by one year to Jan. 1, 2022. The agency acknowledged the need to create a system to prevent fraud or abuse with controlled substance prescribing. CMS also recognizes that significant resources are required to comply with this mandate.

While physicians may have reserved funds to upgrade their systems to meet the mandate, the COVID-19 public health emergency has financially devastated physician practices and health systems. A [TMA Practice Viability Survey](#) conducted in May 2020 asked physicians how the pandemic has affected their practice revenue. Sixty-three percent of the respondents reported their revenue had decreased by 51% to 100%. Any reserves physicians had have been exhausted to keep their practices open.

TMA encourages CMS to finalize its proposed rule to postpone EPCS requirement by one year to Jan. 1, 2022.

TMA offers CMS the following responses to its questions posed in the RFI.

A. EPCS Compliance Assessments

1. 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?

Workflow and technical challenges are the two primary challenges cited by Texas physicians that discourage them from electronically prescribing controlled substances.

Regarding workflow challenges:

- Not all EPCS systems integrate with state prescription drug monitoring programs (PDMPs). This creates an inefficient and awkward workflow where physicians must leave their electronic health record (EHR) system, log into their state's PDMP system, then go back into their EHR and manually enter information they checked in the PDMP. **To address this, TMA encourages CMS to require EHR ambulatory and hospital-based certified EHR vendors and all stand-alone EPCS systems to integrate with all state PDMP systems.**
- Certain stand-alone EPCS systems do not integrate with a practice's EHR system. Similar to EPCS challenges with PDMPs, the lack of integration creates a workflow burden by forcing physicians to log into multiple systems and manually move patient data between them. **TMA encourages CMS to require all certified ambulatory and hospital-based EHRs to integrate with stand-alone EPCS systems.**

Regarding technical challenges with EPCS:

- Some EPCS systems and pharmacies cannot cancel prescriptions electronically or have other technical deficiencies. **TMA urges CMS and other appropriate entities to align pharmacy system requirements with these physician requirements.**
 - Some pharmacies do not have adequate technology to support efficient EPCS processing. **TMA encourages CMS to provide EPCS exceptions when a patient's desired pharmacy does not have adequate technology.**
 - Additional technical challenges include internet downtimes and EHR planned and unplanned downtimes. **TMA requests that CMS offer exceptions for these instances.**
2. What level of compliance with EPCS would be appropriate to require before levying any penalties on a noncompliant 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?

TMA considers these questions flawed and based on an unhealthy premise about physician compliance with EPCS use. The implied premise in these questions is that poor compliance with EPCS use results from unreasonable physician resistance and that the remedy is to identify and punish these physicians. Physicians will adopt a new tool and workflow like EPCS if it improves quality of care and provides desirable value to their practice. Noncompliance is a problem with the

tools, value equation, or processes, and the remedy is to help identify those impediments and remove them. Most delayed adopters will transition to EPCS once the value exists and it is the more attractive and efficient alternative to the manual workflow of writing paper prescriptions. To this end:

- **TMA strongly urges CMS to focus on getting EPCS tools integrated with the technology tools physicians already use successfully rather than punishing physicians for their behavior, especially when that behavior is driven by burdens caused by the lack of integration between these tools.**
 - TMA urges CMS to consider how it handles EPCS vendor noncompliance, which can lead to the inability of physicians to prescribe as required by law.
 - **TMA suggests that CMS should support a free EPCS system within each state's PDMP to increase the value for physicians and to encourage adoption, because for low-volume prescribers, the value may never exist.**
3. 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?
- **TMA suggests annually evaluating for compliance.**
 - Instead of penalizing physicians, CMS could annually evaluate EPCS use and, if needed, meet with practices to understand the reasons for not adopting or fully using EPCS. Some of the reasons may very well be related to patient preference and have nothing to do with the physician's desire to use EPCS.
 - Regarding communications to the prescriber, TMA suggests incorporating the EPCS evaluation into the Merit-Based Incentive Payment System report.

B. EPCS Enforcement

We offer CMS feedback on the following questions with respect to enforcement.

1. What penalties, if any, would be appropriate for non-compliance with a Federal EPCS mandate?

With regard to penalties, carrots generally work better than sticks. TMA believes penalizing physicians is inappropriate since they and health systems have spent a significant amount of human resources and dollars implementing these EHR and EPCS technologies. They are also navigating differences between state and federal law while trying to remain compliant.

Instead of penalties, TMA suggests a couple of approaches for CMS' consideration:

- One approach is to offer some compensation for implementation of these systems, as this would more likely result in wider adoption and help offset the cost of adoption. As

suggested above, supporting a free, integrated system that works with state PDMPs would be a positive offering to encourage compliance.

- CMS could implement a continuing medical education program about EPCS.

2. How may federal penalties affect EPCS adherence?

While it may appear that penalties should encourage compliance, TMA is concerned that if penalties are instituted, they may unintentionally deter physicians from prescribing necessary medications, which may result in serious patient harm.

3. What mechanism(s) should CMS use to enforce penalties among nonparticipating Medicare or Medicaid prescribers?

Again, TMA urges CMS to not impose penalties. If CMS does institute any penalties, TMA cautions that those penalties should not be so onerous that they may unintentionally deter nonparticipating Medicare or Medicaid physicians from prescribing necessary medications, which may result in patient harm.

4. Are there other mechanisms CMS can use to encourage non-participating Medicare or Medicaid prescribers to use EPCS?

Again, we suggest CMS support a free EPCS system within a state's PDMP to encourage adoption by all physicians.

5. Are there any circumstances under which penalties should automatically be waived?

While TMA does not believe CMS should impose any penalties, if it does, penalties should of course be waived for any prescriber who qualifies for a waiver, which should be granted:

- During planned and unplanned EPCS/EHR downtimes,
- Because of unforeseen circumstances (e.g., wildfires, floods, hurricanes, and power outages),
- Upon patient request,
- For physicians who prescribe fewer than 100 controlled substances a year,
- When the practitioner and the pharmacy are in the same location,
- For non-patient specific prescriptions, or
- For compound medications.

Details on the above-listed waivers are included in section C of this document. We also ask that CMS build discretion into the rules to allow it to grant a waiver for any other appropriate reason so there is flexibility to capture a situation that may not be realized at this time.

6. How should CMS approach the design and use of an appeals process for enforcement?

Rather than subjecting physicians to onerous audits, CMS should seek to help physicians who choose to not use EPCS and seek ways to encourage adoption. CMS could consider providing free EPCS software to low-volume prescribers. CMS benefits from the use of EPCS and should

encourage and assist rather than penalize. If CMS does finalize penalties and institutes an appeals process, the agency could consider the following steps:

- Level 1: CMS reconsideration of the finding
- Level 2: Review of the issue by independent review entity. TMA recommends physicians be included as part of the independent review panel.
- Level 3: Review by appropriate administrative body, such as an administrative law judge
- Level 4: Federal district court

7. If CMS were to impose civil money penalties, what penalty structure (including amounts) should be adopted?

We urge CMS to not impose penalties. If CMS finalizes a penalty structure, TMA recommends the assessment be very low so as to not burden physician practices and further degrade the practice's viability, especially practices in small and rural practice settings.

8. 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?

TMA strongly urges CMS to not penalize physicians who do not use EPCS. Physicians who violate section 2003 of the SUPPORT Act should not be publicly shamed by CMS or any other agency. TMA respectfully requests that CMS seek alternative ways, such as education, to encourage EPCS adoption.

9. Should CMS assess penalties after some interval following implementation of this requirement? If yes, what interval(s)?

TMA strongly urges CMS to not impose penalties. Penalties may have unintended consequences such as limiting access to care or not prescribing needed medications to patients. If CMS finalizes the regulation with a penalty, TMA recommends a minimum seven-year interval between implementation of final regulations and assessing a penalty, giving physicians time to adapt to the requirements.

10. 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.

TMA strongly urges CMS to not assess penalties. Penalties may have unintended consequences, such as possibly deterring physicians from prescribing, which can limit access to care. CMS needs to understand why a small minority of controlled-substance prescribers do not use EPCS. It likely will be linked to volume. Those who regularly prescribe controlled substances likely have already adopted this upgraded version of e-prescribing.

If CMS insists on moving forward with penalties against the concerns voiced by TMA, the structure may be based upon percentage of eligible prescriptions sent using EPCS with an upward trajectory (e.g., 20% of eligible prescriptions are sent electronically in year one), allowing physicians time to adjust to the new requirement. It should NOT be an all-or-nothing approach.

TMA notes that physicians are already burdened with numerous public- and private-payer programs requiring constant monitoring for compliance. Adding yet another is burdensome.

11. 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?

There should be no penalties for noncompliance, and waivers should be permitted for low-volume prescribers. There could be significant implications to patients if their physicians are not able to provide such pharmacologic care across all covered classes of controlled substances, particularly for the lower-class drugs (Schedules IV and V).

C. EPCS Waivers

CMS specifically asked for input on any other possible exceptions that should apply to the EPCS requirement. The statute provides circumstances under which the U.S. Department of Health and Human Services (HHS) may waive the EPCS requirement, as well as flexibility to develop others that do not conflict with the statute. TMA strongly urges HHS to consider additional exceptions, specifically:

- During planned and unplanned EPCS/EHR downtimes – Unplanned downtimes might include unforeseen circumstances (e.g., wildfires, floods, hurricanes, and power outages), internal technical complications, or external internet infrastructure problems. EHR systems commonly require downtimes for upgrades or technical patches for glitches. Even when those planned downtimes are done at night or over the weekend, some physicians, such as emergency department physicians, must manually write prescriptions. This is important and distinct from a waiver for technological limitations that are not reasonably in control of the practitioner. As just one example for this needed distinction, it is not clear whether the current hardship/technological limitations waiver will apply retroactively to a technological hiccup or if the waiver must be obtained in advance. Adding an exception specifically for a temporary hardship or a technological or electronic failure expressly captures short-term circumstances that do not allow the practitioner to apply for a waiver in advance but nonetheless prevent him or her from using the electronic prescribing platform.
- Because of unforeseen circumstances – CMS could issue waivers as needed during times of disaster that impact specific geographic regions (e.g., wildfires, floods, hurricanes, and power outages).
- Upon patient request – Patients request written prescriptions for a variety of reasons, for example, when they do not know which pharmacy they want to use, or the patient wants to research and have the prescription filled at the lowest-cost pharmacy. A patient may be traveling and want a paper prescription to take to a pharmacy he or she finds on the way. Additionally, at night, patients may not know which pharmacy is open.
- For physicians who prescribe fewer than 100 controlled substances a year – The cost of EPCS systems may be unreasonable for physicians writing few prescriptions. When running the costs versus number of prescriptions, a physician who writes such few prescriptions a year may be deterred from continuing to prescribe controlled substances to patients. In rural

areas where access to care is limited, this could place a significant burden on the patient. Also, patients who receive a prescription for a controlled substance to treat chronic pain may have a hard time finding a new physician to take over that care as regulations on chronic pain treatment have tightened further. Additionally, these low-volume prescribers benefit only minimally, if at all, from the advantages of e-prescribing (such as decreased administrative burdens regarding data entry, or coordinating paper prescriptions with staff, the pharmacy, facilities, and the patient) compared with the costs of maintaining an e-prescribing platform. Indeed, the costs associated with the technology may disproportionately impact small or rural practices. A threshold waiver would relieve this burden.

- When the practitioner and pharmacy are in the same location – The SUPPORT Act provides a waiver for a prescription issued when the physician and dispensing pharmacy are the same entity or operating under the same license. This should be extended to when the practitioner and dispensing pharmacy are in the same location. The operational mechanics are essentially the same, and like practitioners and pharmacies operating under the same license, practitioners and dispensing pharmacies operating in the same location do not experience many of the burdens e-prescribing intends to relieve (administrative burdens, fraud, burden on patients). Thus, it makes sense to extend the waiver to these circumstances as well.
- For non-patient-specific prescriptions – It is important to also incorporate a waiver for non-specific prescriptions, such as pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, or in response to a public health emergency or other circumstances where the physician may issue a non-patient-specific prescription.
- For compound medications – Physicians who write compound medications do not have a way to e-prescribe those medications as they are not included in the e-prescribing software’s medication picklist. It may be that CMS already intends this as one of the waivers, and if so, that should be clarified in the regulations.

On behalf of its more than 53,000 members, TMA appreciates the opportunity to comment on this request for information. Any questions should be directed to Shannon Vogel, director, Health Information Technology and Special Projects, at Shannon.Vogel@texmed.org.

Sincerely,



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President
Texas Medical Association