October 1, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-3394-NC Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)

Submitted electronically via http://www.regulations.gov

Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the Electronic Prescribing of Controlled Substances (EPCS) RFI. Trinity Health is committed to the use of Electronic Prescribing for both non-controlled and controlled medications. This is evidenced in that, as of today, Trinity has successfully deployed Electronic Prescribing for non-Controlled medications in all our Health Ministries within our hospitals and physician office practices. In addition, Trinity utilizes EPCS in most of our Health Ministries and was on track to successfully deploy to the remaining sites by July 2021. This would have been accomplished through our system wide Electronic Health Record standardization work as we are moving all our sites to EPIC. However, the COVID 19 pandemic required us to reprioritize our work and resources – both human and financial - to properly support both our colleagues caring for and the patients and families impacted by this unfortunate event. Today, we are once again moving forward with our deployment of the EPIC Electronic Health Record across Trinity with a newly released timeline for implementation. Unfortunately, with the challenge of the COVID 19 pandemic, that timeline is further delayed even with our best intentions. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 106 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.2 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 123,000 colleagues,

including more than 6,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models.

Trinity Health participates in 11 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes five markets partnering as an MSSP Track 3 ACO. We also have three markets partnering as a Next Generation ACO and 2 participating in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

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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?

   The need for a second factor authentication system which is a DEA mandate. All of the Trinity Health sites that are doing EPCS today have been able to make this work, but we suspect other providers may view this requirement as a barrier. In addition, the actual system used to do EPCS – the electronic record management system –may have “clunky” workflows, making it less efficient.

2. 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 a prescriber's 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?

   Consideration for a 90% of a provider's controlled substance prescriptions being done through EPCS as a threshold is reasonable, as long as CMS excludes the following types of patients/ prescriptions:
   - hospice,
   - nursing home/ long term care facilities,
   - dual eligibles receiving care in the home through home and community-based services, and

- prescribers not enrolled in Medicare or Medicaid

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?

   Recommended evaluation time periods depend on CMS' goal and how data is obtained. If CMS is going to collect and publish the data to drive change, a quarterly evaluation timeframe is reasonable. However, if CMS requires providers to supply the EPCS rates, Trinity Health recommends a semi-annual or annual timeframe to reduce provider burden.

EPCS Enforcement

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

   Federal penalties will have a positive impact on adherence of these requirements. A number of states have already implemented similar EPCS mandates, including NY, PA, and IA. Trinity Health strongly recommends CMS review penalties put in place in these states and learn about unintended consequences of state polices and issues that have been appealed prior to finalizing guidance. In addition, CMS can gain insight on what mechanisms could and should be used to enforce penalties among non-participating prescribers and other ways CMS can use to encourage participation.

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

   CMS should waive penalties for providers who put forth a good faith effort to comply with the EPCS requirements. In addition, CMS should build into the penalty process a method by which a provider can appeal the penalty as, even with all of the feedback received through this RFI, CMS may not come up with all the potential valid situations for non-compliance. Again, Trinity Health recommends CMS look at NY, PA, and IA, who have already mandated similar requirements to identify best practices.

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

   Trinity Health strongly supports an appeals process for EPCS enforcement. We urge CMS to review processes implemented in the states that have already implemented similar requirements to identify best practices.

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

   The example in the Federal Register from PA outlines the following: $100 per violation for the first through the tenth and $250 per violation for the eleventh and subsequent violations up to $5,000 per year per provider. This structure seems reasonable and we recommend CMS review other states who have implemented a similar requirement to identify other penalty structures for comparison.

5. 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?

   Trinity Health does not see a benefit in making these penalties publicly available.

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

   Trinity Health recommends CMS allow an implementation period of 6 – 12 months with reporting measurements following the implementation of the requirement without penalties. After such time, fines should be imposed if this pattern of noncompliance continues.

7. 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.

   It is reasonable to incrementally increase the penalty based on lack of compliance over time. The example from the Federal Register from PA we highlight above of: $100 per violation for the first through the tenth, $250 per violation for the eleventh and subsequent violations up to $ 5,000 per year per provider seems reasonable. And a review of other states who have already mandated this requirement may provide other examples. If a prescriber would reach the maximum penalty of $ 5,000 (or whatever is determined to be the penalty) and continue to remain noncompliant, the maximum penalty for each subsequent year of non-compliance should double (i.e.: year 2 = $10,000, year 3 = $20,000, year 4 = $40,000, etc.). This incremental increase in the penalty would continue to motive behavioral change.

8. 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?

   Under these circumstances, Trinity Health recommends CMS complete a review of the waiver conditions to determine whether and expansion of the defined eligibility conditions for the waiver are necessary (providing the prescriber has been making a good faith effort toward compliance). The unintended consequence of having a negative impact to the patient as an outcome of penalties associated with implementing EPCS needs to be carefully evaluated and accounted for in the creation of waiver conditions.

9. 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.

   If this is meant to describe physician dispensing, then this exception reasonable. However, if this is intended to describe a health system that may own and operate retail pharmacies and employ providers, it is unclear to Trinity Health why this should be excepted and a condition for a waiver. If it's the latter, CMS should clarify why the waiver if necessary.

EPCS Waivers

1. 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.

   Health systems and providers had planned to implement EPCS in their system/offices and were actively working toward this goal until the COVID pandemic hit. Since then, these providers have needed to re-prioritize resources – both financial and human – to better care for patients impacted by COVID. In addition, the financial impact that COVID has had on providers have required the EPCS implementation plans to be revised and pushed out (by 1-3 years in some cases). Therefore, Trinity Health recommends CMS develop a waiver when providers can demonstrate their plan of implementation and to be in compliance within 1-2 years of the Jan 1, 2022 date proposed in the CY21 Medicare Physician Fee Schedule rule.

2. 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
   - If CMS should infer that certain circumstances would qualify for an exception
   - Whether this must be explicitly conveyed to CMS to ensure compliance

   Per the RFI, 97% of retail pharmacies are capable of receiving EPCS today. Trinity Health is unclear on what circumstances would cause a timing issue that would result in a delay of care for the patient. We defer to others to elaborate on situations such as these and, if an issue that would lead to a delay is identified, we would support a waiver. Trinity Health also reiterates EPCS should not adversely affect patient care, even as an unintentional outcome.

3. 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.

   Trinity Health supports this exception given the controls around research and how closely managed these drugs are.

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

   And

   A prescription issued by a practitioner for an individual who is –

- A resident of a nursing facility; and
- Dually eligible for Medicare and Medicaid

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

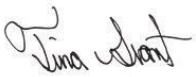
Trinity Health recommends CMS look at NY, PA, and IA, who have already mandated similar requirements to identify how these issues were addressed. Programs that cover these populations have requirements in place that may obviate the need for EPCS. Individuals who are dually eligible for Medicare and Medicaid 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.

Patients that are dual eligible may have other systems/rules/ regulations in place that may obviate the need for EPCS. However, referring to the states who have already implemented EPCS for how and if they address this will be the best way to understand if and how this should be addressed.

Conclusion

We appreciate CMS's ongoing efforts to improve payment systems across the delivery system. If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



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