October 5, 2020

Seema Verma Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically at www.regulations.gov

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

Dear Administrator Verma,

The Association for Clinical Oncology (ASCO) appreciates the opportunity to respond to CMS’ Request for Information (RFI) on electronic prescribing of controlled substances (EPCS). ASCO is a national organization representing nearly 45,000 physicians and other professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

Electronic Prescribing of Controlled Substances

Since Part D was signed into law in 2003, electronic prescribing (e-prescribing) has been optional for physicians and pharmacies for prescriptions made for covered Part D drugs. However, Part D sponsors offering drug plans have been required to have capabilities to support electronic prescribing. Section 2003 of the SUPPORT Act requires physicians to electronically prescribe a Schedule II, III, IV, or V controlled substance under Medicare Part D in accordance with an electronic prescription drug program beginning January 1, 2021. CMS states that although they believe e-prescribing is more efficient, it does take additional time and resources to implement as practices must have the electronic capabilities in addition to following DEA guidance requiring two-factor authentication. Additionally, CMS recognizes the challenges COVID-19 has placed on some prescribers to be prepared by January 1, 2021.

CMS is proposing to require all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022. CMS is requiring the NCPDP SCRIPT
standard as it is required in Medicare Part D; CMS believes that prescribers should use the same standard for e-prescribing controlled substances. To help inform CMS’s implementation of section 2003, the agency recently issued a Request for Information soliciting stakeholder feedback on whether CMS should include exceptions to the electronic prescribing of controlled substances (EPCS) requirement and under what circumstances and whether CMS should impose penalties for noncompliance with the EPCS mandate. CMS will use this public feedback to draft separate rules to further implement this SUPPORT Act provision. Additionally, in the proposed rule, Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule [CMS-1734-P] and Other Changes to Part B Payment Policies, CMS proposed delaying the e-prescribing of controlled substances requirement until January 1, 2022, allowing CMS sufficient time to address stakeholders’ comments. CMS believes that delaying implementation until 2022 affords providers time to prepare while still stressing the importance of expediting implementation.

ASCO supports delaying the requirement e-prescribing of controlled substances until January 1, 2022 allowing CMS sufficient time to address ASCO’s and other stakeholders’ comments. ¹

ASCO supports safe and unburdened access to opioids for all cancer patients.

ASCO supports e-prescribing of controlled substances for prescribers as it can improve workflow efficiencies, aid in the deterrence and detection of prescription fraud and irregularities, allow for timely and accurate data collection and may result in reduced provider burden. ASCO also recognizes the benefits e-prescribing provides Medicare beneficiaries, including reduced logistical burden and timely access to prescriptions. However, ASCO urges the Agency to consider the unique situation of patients with cancer who require controlled substances as an important component of their care. ASCO urged delay of the EPCS requirements in its response to the Medicare Physician Fee Schedule Proposed Rule, and we also urge the Agency to consider the following:

- **Patient access to appropriate pain medication is critical and CMS should not impose any restrictions, penalties, or limitations that may interfere with patient access.** ASCO supports waivers for practices with in-office dispensing, avoiding redundancies in e-prescribing that may prove inefficient for patients. Additionally, CMS should recognize that instances may occur when the beneficiary prefers a traditional prescription. For cancer patients who may benefit from receiving prescriptions from their physicians, the likelihood of adherence and quality improvement increases. This process should not be interrupted. CMS should be assured that reporting associated with prescribing of controlled substances can still occur in these instances. ASCO encourages CMS to finalize the waiver for practices with pharmacies, affording prescribing flexibilities to practices with in-office dispensing.

- **Costs associated with updating systems may also be prohibitive for some small practices that may not have electronic health records. Penalties should not be imposed while providers are working to implement technology that would allow them to comply.** As physicians have needed to increasingly rely on telehealth to provide care during the COVID-19 pandemic, prescribers who might not have optimized electronic health record (EHR) technology prior to the public health emergency may now have different electronic capabilities, and CMS should

analyze, discuss, and share available e-prescribing data from the COVID-19 pandemic. However, many providers are still in the process of EHR implementation and upgrades and need time to complete this transition. These practices will not be able to comply if the implementation date is January 2021, and interoperability of e-prescribing systems may continue to be a problem. While CMS works to resolve these issues, providers should not be penalized. Additionally, for those practices that have upgraded, there may still be limitations related to cost as some technology providers charge extra fees, and this could be costly—especially for small providers.

E-prescribing of controlled substances provides several benefits that will lead to improved quality of care. We thank CMS for the opportunity to provide comments on this Request for Information. If you have any questions or need additional information, please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org).

Sincerely,

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology