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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the Secure Electronic Prior Authorization for Medicare Part D Prescription Drug Program (Part D) proposed rule. **In general, the AMA supports the proposed adoption of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 for use in electronic prior authorization (ePA) transactions for Part D-covered drugs prescribed to Part D beneficiaries by January 1, 2021.**

However, overall volume of required prior authorizations (PAs) should be reduced in Part D to protect patient safety and support medication adherence. The AMA is concerned that CMS will allow Part D plans to use ePA to facilitate an overall increase in PA practices generally with the rationale that because PA automation relieves certain aspects of practice burden, it should be used more frequently to control costs and utilization rates. Nevertheless, when PA is required, physicians should be allowed to use standard electronic transactions. **We believe that NCPDP SCRIPT version 2017071 offers the best opportunity to potentially reduce the time it takes for a patient to receive medically necessary medications, ease physician administrative burden, and automate the prior authorization process.** With limited use of PA, the AMA supports such PA being electronic and incorporated into the clinical workflow, including integration into the electronic health record (EHR) and electronic prescribing (eRx) systems.

Clarifying Application to Prescribers

The AMA seeks clarification from CMS regarding the application of the NCPDP SCRIPT standard version 2017071 to prescribers. Specifically, we request that CMS affirmatively state that prescribers are only required to use the standard when performing ePA transactions for Part D-covered drugs they wish to prescribe to Part D beneficiaries. **Thus, like eRx, no requirement exists that a prescriber must implement ePA.**

The AMA understands that 42 C.F.R. 423.160(a)(2) requires prescribers to transmit prescriptions and prescription-related information using electronic media to use certain standards when e-prescribing for covered Part D drugs. Moreover, we appreciate preamble language in the proposed rule stating that the CMS proposal is only required for ePA transactions. This statement recognizes the enormous differential

in available resources between health plans, which are large companies capable of meeting requirements to implement standard electronic transactions to improve the efficiency of their business processes, and physician practices, which are often very small businesses that have neither the available capital nor expertise to adopt new technologies to comply with regulatory mandates. However, the proposed regulatory language is not clear because the proposed rule also states that "prescribers must comply with the NCPDP standard." Furthermore, the preamble also states that CMS believes that section 6062 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act explicitly authorizes CMS "to require the use of a PA standard in the Part D context. . . ."[1]

Accordingly, to avoid ambiguity and any confusion, the AMA requests CMS affirmatively state that prescribers are not required to implement ePA and are only required to use the standard when performing an ePA transaction for a Part D-covered drug they wish to prescribe to Part D beneficiaries.

ePA Transaction Standards Outside of the Part D Context

The AMA is concerned about potentially opening the door to prescribers having to use different standards for different plans and with EHRs' ability to accommodate multiple standards. If the NCPDP SCRIPT version 2017071 proposal is finalized, physicians will not want non-Part D plans to use a different version of SCRIPT ePA or the X12 278 for ePA. For example, in practice, SCRIPT eRx is the de facto e-prescribing standard regardless of the drug plan or the eligibility of a patient. While the AMA understands that the proposed rule is limited to Part D plans, we urge CMS to work with the industry to embrace NCPDP SCRIPT version 2017071 as the de facto standard for ePA all drugs covered under a prescription drug benefit across all payers.

CMS states, based on conversations with the health care industry, that most EHRs are capable of processing transactions using more than one standard for a given transaction. From the physician perspective, the AMA disagrees with this assessment. Instead, the AMA is aware of the *lack* of EHR support for the ePA transactions, which has created a major barrier to physician use of the transactions—only 21 percent of physicians in our 2018 PA survey reported that their EHR supports prescription ePA.[2] Thus, we urge CMS to have additional conversations with the health care professional community to delineate what an EHR is potentially "capable" of doing compared to what is implemented in practice. CMS should work with its sister agencies to ensure that EHRs facilitate ePA for providers who wish to use it and that such processes do not impose additional burden in real-world settings.

Strategies to Mitigate Burden

CMS also sought comments on strategies to mitigate burden to support successful adoption of ePA. The AMA believes that CMS should implement the following strategies to mitigate burden:

1. Require that ePA requests and responses be integrated into a health care professional's EHR or eRx system;

[1] 84 Fed. Reg. 28450, 28453 (June 19, 2019).
[2] AMA, *Industry Checkup: Measuring Progress in Improving Prior Authorization*, (Mar. 2019), https://www.ama-assn.org/system/files/2019-03/prior-auth-survey.pdf.

2. Work with ONC to require certification of EHRs to the ePA transactions included in SCRIPT version 2017071;
3. Support physician adoption of ePA by urging EHR and eRx vendors to offer ePA technology at no cost and encouraging education about ePA; and
4. Reduce the overall volume of prior authorizations requirements to ensure timely access to medically necessary care for patients and reduce practice administrative burden.

First, to qualify as an electronic transmittal, the AMA strongly believes that the prior authorization request and response must be integrated into a health care professional's EHR or eRx system. "Integrated" means that the process is seamless to the health care provider, can be conducted completely within the EHR or eRx system, does not require the health care provider to log into separate payer portal(s), and does not require the health care provider to reenter or transfer data that is already in the EHR or practice management system. Thus, the AMA appreciates CMS' acknowledgement that an ePA transactions standard would allow a prescriber using an eRx system or an EHR with eRx capability to perform PA functions electronically. Accordingly, the AMA urges CMS to maintain this requirement of the use of an eRx system or an EHR by explicitly stating that portals do not constitute compliance with the final rule.

Second, in the Office of the National Coordinator for Health Information Technology (ONC) proposed rule on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, the AMA supported aligning the EHR certification criteria to the SCRIPT version 2017071, as CMS has retired SCRIPT version 10.6 and adopted version 2017071, effective January 2020 for Part D. We recognize there may be challenges and expenses for practices to upgrade with their EHR vendor, but given the fact that the new version of SCRIPT will be required under Medicare Part D, it would seem helpful to align the EHR certification criteria with the same version of SCRIPT. It is our understanding that SCRIPT version 2017071 is not backwards-compatible with SCRIPT 10.6, which is why—unlike with previous eRx standard updates—there is no transition period. We agree that permitting continued certification to SCRIPT version 10.6 if the eRx criteria are finalized prior to January 2020 makes sense in this regard.

Moreover, in addition to having EHR certification criteria align with same version of SCRIPT, the AMA asks that CMS work with ONC to require certification to the SCRIPT electronic prior authorization (ePA) transactions included in the 2017071 standard. The lack of availability of the transactions in EHRs is one of the big barriers to physician adoption. As previously stated, only 21 percent of physicians in our PA survey reported that their EHR supports prescription ePA.

Third, CMS should support physician adoption of ePA by urging EHR and eRx vendors to offer ePA technology at no cost to physician practices. The AMA is aware of EHR vendors charging for the implementation and development of ePA even though ePA product vendors offer their ePA tools at no cost to EHRs. Costs can be a major barrier to adoption. Moreover, CMS should encourage education about ePA for physicians to support adoption of this technology. Specifically, CMS should work with EHR and eRx vendors to offer education on their particular ePA implementation. The AMA is happy to work with both public and private stakeholders in providing physician education.

Fourth, CMS needs to reduce the overall volume of PAs, improve care continuity, and increase transparency. According to a recent AMA survey of 1,000 practicing physicians, 65 percent of surveyed physicians reported waiting at least one business day for PA decisions from health plans, while 26 percent

reported waiting at least three business days.[3] Not surprisingly, 91 percent of physicians said that PAs can delay a patient's access to necessary care. These delays may have serious implications for patients and their health, as 75 percent of physicians reported that PAs can lead to treatment abandonment, and 91 percent indicated that PAs can have a negative impact on patient clinical outcomes. Most alarmingly, over one-quarter (28%) of physicians reported that PAs have led to a serious adverse event (e.g., hospitalization, disability, death) for a patient in their care. These physician burdens and patient care barriers are routinely experienced by Medicare Advantage (MA) beneficiaries. According to a U.S. Department of Health and Human Services (HHS) Office of Inspector General review of MA service denials in 2014-2016, more than 116,800 PA requests were denied and eventually overturned on appeal for drugs/services to which the patient was entitled, a total that is particularly concerning because beneficiaries and providers appealed only one percent of denials.[4]

In 2017, the AMA, working with organizations representing physicians, hospitals, patients, and other health care stakeholders, released reform principles identifying problems with and recommending improvements to PA, step therapy, and other utilization management (UM) programs.[5] Additionally, the AMA partnered with groups including the American Hospital Association, American's Health Insurance Plans, the American Pharmacists Association, the Blue Cross Blue Shield Association, and the Medical Group Management Association on a consensus statement for reducing PA burdens.[6] Notably, the consensus statement includes several recommendations on reducing the overall volume of PAs, including the selective application of PA requirements to only outlier physicians and regular review and adjustment of drugs that require PA to eliminate low-value PAs. It is critical to note that only one out of the five reform areas identified in the Consensus Statement addressed process automation. While the AMA and our partners in this agreement support adoption of standardized ePA technology, we strongly believe that other key reforms, such as overall PA volume reduction, improved transparency, and continuity of care protections, are needed to meaningfully improve the PA process.

We have serious concerns about CMS' final rule that MA plans will no longer be prohibited from utilizing step therapy protocols for physician administered drugs covered under Medicare Part B this year. We find the growing trend towards the use of restrictive and burdensome utilization management tactics by payers concerning, and urge CMS to reconsider its stance on this critical patient care issue. To that end, we appreciate Secretary Azar's recent comments before the AMA's National Advocacy Conference stating that it is "disturbing" that patients switching from one insurance plan to the next can be required to start over for a step therapy or fail-first regimen, and that such a policy is "not just injurious to [the patient's] health, it is also penny wise and pound foolish." Furthermore, CMS should implement the following recommendations to improve the PA process.

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[3] Survey summary available at https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf..

[4] HHS OIG, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials*, (Sept. 2018), *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp.

[5] AMA, Prior Authorization and Utilization Management Reform Principles (2017), *available at* https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf.

[6] AMA, Consensus Statement on Improving the Prior Authorization Process (2018), *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

Recommendations:

- CMS should not follow the recommendations in the May 2018 Government Accountability Office on PA efforts,[7] but rather carefully consider the care delays associated with PA and the resulting impact on beneficiaries and their health and well-being when evaluating any additional PA requirements for the Medicare program;
- CMS should ensure that all utilization management (UM) requirements are based on accurate and up-to-date, publicly available clinical criteria and never cost alone;
- CMS should require all MA and Part D plans to publicly disclose to both patients and physicians in a searchable electronic format all drugs and medical services that are subject to coverage restrictions (PA, step therapy, formulary restrictions, quantity limits) including the criteria to satisfy these restrictions and provide this information to vendors to be displayed in EHRs;
- CMS should require a 60-day grace period for UM requirements when a patient changes MA and Part D plans, align PA approvals with the duration of the prescribed/ordered treatment, and prohibit plans from requiring patients to retry therapies failed under previous plans;
- MA and Part D plans should abide by PA decisions and pay for any services approved in a PA request by performing eligibility and all other medical policy coverage determinations as part of the PA process and not revoking or restricting coverage for authorized care provided within 45 business days from the date the authorization was received;
- Except where there is evidence of widespread misuse, PA should not be required for drugs that are standard treatment for the patient's condition and/or have been previously approved for treatment of an ongoing/chronic condition;
- CMS should ensure that any "peer-to-peer" reviews utilize physicians from the same specialty/subspecialty as the ordering or prescribing physician; and
- CMS should restrict PA requirements to "outlier" providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix.

Technical Amendment

In the proposed regulatory language, Part D Sponsors and prescribers must comply with SCRIPT version 201701 "to provide for the communication of a prescription or related prescription-related information."[8] The AMA requests that CMS either (a) change "communication" to "transmission" to match the statutory language in § 6062 of SUPPORT and the other regulatory provisions in 42 C.F.R. § 423.160 or (b) explain why the ePA NCPDP SCRIPT version 2017071 is different from the NCPDP SCRIPT version 2017071 mandated for other eRx transactions and how a communication is different than a transmission.

Agencies should not introduce unnecessary ambiguity into regulations. The AMA's preference is for CMS to change the proposed regulatory language, so that it reads "to provide for the transmission ~~communication~~ of a prescription or prescription-related information." First, the authorizing statutory language does not use the term communication.[9] Instead, the statute calls upon a program to provide for the secure electronic transmission of a prior authorization request.[10] Moreover, the statute specifies that

[7] GAO, *Medicare: CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending, (May 2018*), *available at* https://www.gao.gov/products/GAO-18-341.
[8] 84 Fed. Reg. 28450, 28458 (June 19, 2019) (emphasis added).
[9] *See* 42 U.S.C. § 1395w–104(e)(2)(E).
[10] *Id.* at (e)(2)(E)(i).

such transmission shall comply with technical standards adopted by the Secretary—the subject of this proposed rule.[11] Furthermore, throughout 42 C.F.R. § 423.160, the term transmission is used instead of any other term such as communication.[12]

We thank you for the opportunity to provide input on the Secure Electronic Prior Authorization for Medicare Part D proposed rule. The AMA supports the CMS proposed adoption of the NCPDP SCRIPT standard version 2017071 for use in ePA transactions for Part D-covered drugs prescribed to Part D eligible individuals by January 1, 2021. We look forward to continuing to work with CMS in implementing the ePA program in Medicare Part D. If you have any questions regarding this letter, please contact Laura Hoffman, Assistant Director of Federal Affairs, at laura.hoffman@ama-assn.org or 202-789-7414.

Sincerely,

James L. Madara, MD

[11] *Id.* at (e)(2)(E)(ii)(II).
[12] *E.g.*, 42 C.F.R. § 423.160(a)(1)("when transmitting"), (a)(2)("that transmit") & (a)(3)("entities transmitting prescriptions").