August 15, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
202 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Re:CMS-4189-P, Medicare Program; Secure Electronic Prior Authorization for Medicare Part D

Dear Administrator Verma:

The Medical Group Management Association (MGMA) is pleased to submit the following response to the Centers for Medicare & Medicaid Services' (CMS') proposed rule establishing a standard for electronic prior authorization (ePA) transactions for Medicare Part D medications. Streamlining access to information will assist both clinicians and patients make informed healthcare decisions and decrease administrative costs for physician practices. While we strongly oppose requiring prior authorization before a clinician can deliver health services to Medicare beneficiaries, when prior authorization is imposed, we support any opportunity to facilitate automation of this highly burdensome process.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights, and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 45,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 practices of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

General Comments on Prior Authorization

Prior authorization continues to be one of the most onerous administrative processes faced by physician practices and we are very supportive of eliminating or streamlining this process. As health plan-driven cost-control process that requires providers to qualify for payment by obtaining approval before performing a service, prior authorization is overused, costly, inefficient, opaque, and, most importantly, often responsible for delays in the delivery of patient care.

Health plan utilization-management requirements that mandate and misuse clinician and staff time while interrupting or delaying appropriate care need to be dramatically reshaped to ensure they are clinically valid and implemented in a way that is transparent, timely, efficient, flexible and standardized. This message is the core of a comprehensive set of 21 prior authorization principles developed by MGMA and a coalition of 16 other organizations representing clinicians, medical groups, hospitals, pharmacists and patients and endorsed by more than 100 clinical organizations. We urge CMS to closely review these principles with the goal of incorporating as many as possible into revised federal policy.

While the 21 principles were primarily directed to health plans and utilization review entities, there are several that could be addressed by better use of EHRs and, as a result, have an impact on EHR and e-prescribing software vendors. For example, principle No. 9 outlines that utilization review entities

provide, and vendors display, accurate, patient- specific, and up-to-date formularies that include prior authorization and step therapy requirements in EHR systems for purposes that include e-prescribing.

It is widely believed that the formulary information available to prescribers in the EHR is incomplete, and coverage restrictions aren't always available or displayed. This principle seeks to address the issue from two perspectives. First, to ensure that the health plans include complete coverage restriction data in the formulary files provided to the EHRs. Second, to ensure that the EHR and e-prescribing software vendors have developed their products to accurately display the coverage restrictions.

Principle No. 12 proposes that a utilization review entity requiring healthcare providers to adhere to prior authorization protocols should accept and respond to prior authorization and step-therapy override requests exclusively through secure electronic transmissions using the standard electronic transactions for pharmacy and medical services benefits. The integration of ePA functionality in EHRs has been slow. EHR and e-prescribing vendors are moving conservatively to embrace ePA because of uncertainty of utilization by providers, despite the fact that there are state mandates requiring ePA. When all utilization management (UM) entities support ePA, provider demand will be sufficient to implore their software vendors to build ePA functionality.

Principle No. 18 encourages utilization review entities to standardize criteria across the industry to promote uniformity and reduce administrative burdens. This principle is of vital importance to EHR and e-prescribing software vendors because it will enable vendors to query stored clinical data and respond to UM questions, rather than necessitate practice staff complete and fax paper forms. Standardization of the query data means that questions are phrased the same way when asking for the same data (e.g. requiring patient's date of birth vs. patient's age).

Some of the other principles can be enhanced by a new standard that is being developed at the National Council for Prescription Drug Programs (NCPDP) and that companies are deploying that provides patient-specific, real-time formulary and benefit information at the point-of-care. As health plans are beginning to leverage this emerging technology, CMS should work with the industry to facilitate broad adoption.

Additional opportunities exist to streamline prior authorization by leveraging existing electronic transaction standards and mandating a new standard for clinical documentation transmission. The automation of prior authorization processes will be significantly increased by fully implementing the X12 278 electronic transaction and supporting operating rules, when available. According to the most recent CAQH Index, industry use of the 278 transaction is only at 12 percent – by far the lowest adoption rate of any of the HIPAA-mandated transactions. We urge that CMS, through more aggressive enforcement, ensure that X12 278 electronic transaction and any supporting operating rules are offered and supported by all health plans.

New standards needed

The current practice for medical groups is to fax, mail, or upload to proprietary websites the clinical data necessary to conduct administrative transactions. We have called on CMS to release the electronic attachments (X12 275) regulation to automate the collection and transmission of clinical data. Mandated by Congress in HIPAA (1996) and re-mandated in section 1104 of the Affordable Care Act in 2010, this transaction has the potential to significantly reduce administrative burden by supporting claim submissions; meeting clinical documentation requirements for prior authorization transactions; supporting referrals, transitions of care, and care coordination documentation requirements; and simplifying other clinical and administrative situations where patient data needs to be shared efficiently and securely.

The advent of new FHIR-based standards has the potential of reducing the burden of prior authorization and other administrative tasks. However, we urge CMS to ensure the following issues are considered as FHIR standards and administrative and clinical use cases are being developed:

- Seek clinician input in the standards development process: The HL7 Da Vinci project's current list of participants includes some of the nation's largest health plans, EHR developers, and other Health IT vendors. Clinicians and professional associations are not generally not part of the Da Vinci process. Without the involvement of these constituencies, the industry runs the risk of standards being developed that do not meet the needs of clinicians and do not receive clinician support.

- Integrate into the current standards environment: While these standards show great promise, there has been considerable investment made by practices in the current X12 electronic transactions. We urge that FHIR-based standards be offered as an additional option (for willing trading partners) to the X12 standards, but not yet as a replacement.

- Identify administrative use cases: We are pleased to see that the Da Vinci project and the Document Requirement Lookup Service initiative from CMS hold great promise for addressing critical administrative issues facing practices, not least of all the burdens associated with prior authorization. We urge that the developers of FHIR-based standards closely align their work with those engaged in alleviating clinician administrative burdens.

- Focus on template and rules transparency: Transparency of health plan clinical documentation requirement templates and plan coverage rules as use cases will result in a significant reduction in administrative burden.

- Avoid costly mandates on practices: Adopting the technology and workflow modifications necessary to support any new standard requires considerable investment by practices. With this in mind, new standards need to be fully tested and EHR and practice management system software vendors must incorporate them fully prior to any mandate on practices to use them. The cost for practices to implement any new standard must be considered prior to any mandate.

The government should support and expand on current effort to identify common data elements and standardized templates that can be implemented by health IT developers to facilitate additional automation around these processes. We also concur that CMS should explore opportunities to incentivize clinicians to adopt technology certified to conduct these transactions according to recognized standards.

Overall, documentation requirements for items and services associated with prior authorization and ordering for certain medical services are significant sources of administrative burden. We assert that CMS can play an important role in evaluating and addressing administrative processes and clinical workflow factors contributing to this burden. While EHRs, practice management system software vendors and other health IT solutions can also play a role in reducing this burden, prior authorization processes suffer from a lack of standardization and common approaches.

Industry consensus statement

In January 2018, a coalition of stakeholders, including MGMA, the American Hospital Association, American Medical Association, American Pharmacists Association, America's Health Insurance Plans, and the Blue Cross Blue Shield Association, released a consensus statement on how to improve the prior authorization process. Included in the statement was the following:

Automation to Improve Transparency and Efficiency.

Moving toward industry-wide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. Additionally, making prior authorization requirements and other formulary information electronically accessible to health care providers at the point-of-care in electronic health records (EHRs) and pharmacy systems will improve process efficiencies, reduce time to treatment, and potentially result in fewer prior authorization requests because health care providers will have the coverage information they need when making treatment decisions. Technology adoption by all involved stakeholders, including health care providers, health plans, and their trading partners/vendors, is key to achieving widespread industry utilization of standard electronic prior authorization processes.

We agree to:

- *Encourage health care providers, health systems, health plans, and pharmacy benefit managers to accelerate use of existing national standard transactions for electronic prior authorization (i.e., National Council for Prescription Drug Programs [NCPDP] ePA transactions and X12 278)*
- *Advocate for adoption of national standards for the electronic exchange of clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with prior authorization*
- *Advocate that health care provider and health plan trading partners, such as intermediaries, clearinghouses, and EHR and practice management system vendors, develop and deploy software and processes that facilitate prior authorization automation using standard electronic transactions*
- *Encourage the communication of up-to-date prior authorization and step therapy requirements, coverage criteria and restrictions, drug tiers, relative costs, and covered alternatives (1) to EHR, pharmacy system, and other vendors to promote the accessibility of this information to health care providers at the point-of-care via integration into ordering and dispensing technology interfaces; and (2) via websites easily accessible to contracted health care providers*

It is important to note that in signing this consensus statement, the largest national associations representing health plans signaled their support for increased automation of prior authorization, including support of the NCPDP standards for medication ePA.

Comments on Specific Provisions of the Proposed Rule

CMS Statement (Page 28452-3)

In our review of the standard, CMS found that the X12 278 standard is by nature a batch standard which cannot support real-time consideration of prescriptions. For example if a PA were to be submitted using the X12 278 standard, the PA would not be submitted to the plan until the following day, the plan would review it in the second day and, if all the information were correct, the approval would be conveyed back to the physician 3 days after the prescription was captured in the batching process. The reason for this is because the X12 278 is designed to batch the transactions, since this is what is optimal in the DME context. However, this is not optimal in the ePA context, since it would

result in ePA transactions taking days to process. Resolution of the ePA would be further delayed if the plan needed additional information on the PA request.

Finally, there is an inconsistency between the types of information that are required to be submitted on a DME claim, which is what the X12 278 transaction was designed to support, and the type of information that is required to be submitted for medications. For example, the X12 278 standard requires the diagnosis to be submitted, which is not required on prescription claims, but it does not accommodate a field for National Drug Codes (NDCs) and dosage information fields that are integral when evaluating medication requests. Because the X12 278 transaction is not specifically created to process medications, prescribers would have to find a place to insert NDCs and look up the codes using another source. In contrast, the SCRIPT ePA standard is prepopulated with all NDCs and dosage information so the prescriber can choose among appropriate options.

MGMA Response

While we do not disagree with the agency that X12 278 transaction is not the appropriate standard to convey electronic prescription prior authorization requests, we disagree with the characterization that the X12 278 is strictly a batch transaction used "in the DME context." The X12 278 has the ability to conduct batch and real-time transactions. Both the X12 278 TR3 Guide and the CORE Phase IV operating rule (existing and new draft) address both real-time and batch processing. While the X12 and CORE rules currently do not require health plans to support real-time transactions, health plans are required to support one or the other processing modes. Some health plans (i.e. Harvard Pilgrim), currently do support real-time X12 278 transactions.

CMS Proposal (page 28458)

(7) Electronic prior authorization. Beginning January 1, 2021, Part D sponsors and prescribers must comply with the National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following transactions: (i) PAInitiationRequest and PAInitiationResponse (ii) PARequest and PAResponse (iii) PAAppealRequest and PAAppealResponse (iv) PACancelRequest and PACancelResponse.

MGMA Response

While the regulatory preamble references several times that Part D plans will have to support the NCPDP ePA transactions, but prescribers will only be required to use the transactions if doing PA electronically, the actual language at the end is not clear on this point. The regulation states on page 28458 that ". . . Part D sponsors **and prescribers must comply** with the NCPDP standard." We urge the agency in the final rule to be clear that the requirement is strictly on health plans and is not an ePA mandate on prescribers. We recommend the final rule language mirror that in the proposed rule's background preamble (on page 28451) where the agency states: "Under this proposal, Part D plan sponsors would be required to support version 2017071 of the [NCPDP] SCRIPT standard for four ePA transactions, and **prescribers would be required to use that standard when performing an ePA transaction** for Part D-covered drugs they wish to prescribe to Part D-eligible individuals."

CMS Proposal (page 28451)

A facsimile, a proprietary payer portal that does not meet standards specified by the Secretary or an electronic form are not treated as electronic transmissions for the purposes of ePA requests.

(Page 28454)
The PA process has historically been handled via facsimile exchange of information or telephone call, and only recently via payer-specific web portals. However, there is an overall consensus among stakeholders testifying to NCVHS that there is a need for real time PA at the prescriber level for electronic prescribing

MGMA Response

Throughout the proposed rule, CMS repeatedly references leveraging EHR and eRX technologies to generate ePAs. For true automation to occur, it is critical that the ePA process be fully integrated in the EHR workflow. We urge the agency to explicitly state that computer to computer facsimiles and proprietary health plan web portals (even if they purport to mimic the NCPDP Script standard version 2017071) are not acceptable methods of meeting the requirements of the rule.

CMS Proposal (page 28451)

An ePA transaction standard would allow a prescriber using an electronic prescribing (eRx) system or an electronic health record (EHR) with eRx capability to determine whether the beneficiary's plan requires a PA for a given medication.

MGMA Response

For physician practices to take full advantage of ePA functionality, their EHRs must have the capability of generating the transactions. The lack of availability of the transaction in EHRs is a significant barrier to physician practice adoption. While EHR software vendors will be required support the 2017071 version of the eRX SCRIPT standard effective Jan. 1, 2020, they will not be required to support the ePA transaction. One method of ensuring that EHRs will support the ePA transaction will be to incorporate this functionality into future certification editions from the Office of the National Coordinator for Health Information Technology.

CMS Proposal (page 28455)

Therefore, we propose to add §423.160(b)(7) which would require that Part D plans be able to support the NCPDP SCRIPT ePA standard transactions included within version 2017071 beginning on January 1, 2021, and that prescribers use that standard when conducting ePA by the same date. The proposed ePA standard applies to the following list of ePA transactions: • PAInitiationRequest and PAInitiationResponse • PARequest and PAResponse • PAAppealRequest and PAAppealResponse • PACancelRequest and PACancelResponse.

We welcome comments on the proposed adoption of the NCPDP SCRIPT standard version 2017071 eRx for these ePA transactions for Part D- covered drugs prescribed to Part D eligible individuals.

MGMA Response

MGMA supports the naming of the 2017071 version of the SCRIPT standard for ePA. However, we note that the ePA mandate does not go into effect until Jan. 1, 2021, and some states already have adopted prescription drug ePA mandates and name earlier versions of SCRIPT ePA as the standard. We urge the agency to work with those impacted states – particularly those states with legislative language that does not include defaulting to later version of SCRIPT if it was federally mandated.

Conclusion

In conclusion, MGMA supports the objective of deploying HIT and standards in physician practices to improve the sharing of clinical data and decrease administrative burdens. While we would urge CMS to avoid mandating prior authorization requirements for Part D medications or for any other Medicare program, in the cases when clinicians are required to conduct a prior authorization, we support an automated approach using established national standards. In the case of Medicare Part D prescribing, we support the agency's proposal to establish as the national standard the NCPDP ePA standard transactions included within version 2017071 beginning on Jan. 1, 2021.

Physician practices and their vendor partners will require education regarding this standard and the potential to streamline Part D medication prior authorization. We recommend CMS aggressively communicate to both constituencies the implementation specifications of the NCPDP Script standard version 2017071 and the administrative simplification opportunities associated with use of these transactions.

We look forward to continuing to work with CMS and other federal agencies to facilitate physician practice transition to effective and efficient health IT and ensure that the promise of improving the nation's healthcare administrative and clinical transactions through automation and the use of national standards becomes a reality. Should you have any questions regarding these comments, please contact Robert Tennant, Director, Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs