January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: (RIN 0938–AT99) Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

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, *Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (CMS-9123-P).* We appreciate the emphasis CMS has placed on addressing prior authorization, what MGMA member practices identify as the leading administrative burden facing their organizations. Our comments and recommendations are aimed at improving these proposals and making the promise of improved healthcare data exchange and a more streamlined prior authorization process a reality.

The Medical Group Management Association (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 58,000 medical practice administrators, executives and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures and specialties that deliver almost half of the healthcare in the United States.

MGMA supports many of the underlying foundations contained in this proposed rule to reduce the administrative burdens faced by physician practices. However, we are concerned with several provisions and assumptions included in the rule. Prior authorization is a transaction challenged by a lack of standardization of health plan-provider request and response formats and plan clinical documentation requirements. This lack of plan standardization was clearly identified by the CMS Document Requirement Lookup Service (DRLS) Work Group and led to a recommendation by the Work Group that CMS consider analyzing federal health plan rules for opportunities to align. As well, the recently released Office of the National Coordinator for Health Information Technology (ONC) Intersection of Clinical and Administrative Data (ICAD) Taskforce recommendations included a call for CMS to work with ONC and other federal actors to establish consistent processes and guidelines for prior authorization rule sets to apply to

federally controlled or contracted plans. This recommendation included simplifying authorization rules and removing rules that have high burden (e.g., those that are frequently approved, frequently overturned on appeal, or otherwise have low utility). We believe that simply automating a broken system will not result in appreciable improvement. Automation is critical, but if the challenge of prior authorization is to be addressed, proprietary health plan formats and requirements must also be standardized.

Key Comments and Recommendations

- Prior authorization is the most burdensome administrative process facing physician practices. We are concerned that, as proposed, this regulation will do little to alleviate these challenges.
- By limiting the applicability of the rule to a small subset of health plans, CMS is almost guaranteeing that widespread industry adoption of these new automated prior authorization solutions will not take place. At a minimum, Medicare Advantage plans should be included, and preferably the regulation should cover all HIPAA-covered health plans should be mandated to support Application Programming Interface (API) requirements and Document Requirement Lookup Service (DRLS) solutions.
- CMS proposes to have health plans respond to practices with 72 hours for an urgent prior authorization and within 7 days for those authorizations deemed "standard." These timeframes are unacceptable and will result in continued administrative burden for practices and delayed care for patients.
- If physician practices are to make the financial investment necessary to adopt FHIR-based API transactions, CMS needs to adopt automation approaches that result in real-time communications that drive efficiency and improve patient care.
- Automating prior authorization communication between physician practices and health plans is not enough. CMS must also standardize health plan prior authorization request and response formats and supporting clinical documentation requirements to substantially improve this process.
- Should CMS make the necessary regulatory modifications, the requirement to have health plans support FHIR-based API solutions has the potential of significantly improving the way that health information is exchanged between patients, physician practices, and health plans and streamlining prior authorization processes.
- Due to the complexity of this proposed regulation and the potential impact on patients, providers, health plans, and supporting vendors, we strongly urge CMS to release the next iteration of this rule as another proposed rule or interim final rule and permit additional public comment.

Comments on Specific Regulatory Provisions

CMS proposal (p. 82594): *We are proposing to require impacted payers to report metrics about patient use of the Patient Access API to CMS. We also seek comment on whether we should consider requiring these data be reported to CMS at the contract level for those payers that have multiple plans administered under a single contract or permit Medicaid managed care plans, CHIP managed care entities, or QHP issuers on the FFEs to aggregate data for the same plan type to higher levels (such as the payer level or all plans of the same type in a program). Specifically, we propose that these payers report quarterly: the total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app; and the number of unique patients whose data are transferred via the Patient Access API*

to a patient designated third-party app more than once. Tracking multiple transfers of data would indicate repeat access showing patients are either using multiple apps or are allowing apps to update their information over the course of the quarter.

MGMA response: We support the requirement that health plans report the names of the unique apps that access the plan's API and recommend that this information be reported on a quarterly basis. We also urge CMS to require plans to make public the answer each app provides to any privacy attestation. However, we urge CMS not to make broad assumptions regarding patient interest in using Patient Access APIs based on these metrics. As proposed, the rule applies only to a limited number of patients whose use and access to technology may not reflect that of the national population. We also note that these metrics could be influenced by regional, demographic, and member specific factors outside the plan's control, such as availability of broadband services, smart phone adoption, socioeconomic status, and a member's desire to adopt and use new technology.

CMS proposal (p. 82595): *We do not intend to publicly report these data at the state, plan, or issuer level at this time, but may reference or publish them at an aggregate, de-identified level. We are proposing that by the end of each calendar quarter, payers would report the previous quarter's data to CMS starting in 2023. In the first quarter the requirement would become applicable, payers would be required to report, by the end of the first calendar quarter of 2023, data for the fourth calendar quarter of 2022. Therefore, beginning March 31, 2023 all impacted payers would need to report to CMS the first set of data, which would be the data for October, November, and December 2022. We request comment on this proposal.*

MGMA response: We disagree with the agency's proposal not to publicly report these data at the state, plan, or issuer level. Keeping these metrics hidden will prevent the industry from assessing the data and leveraging the results when calling for policy changes. Transparency into the data exchange via app process is critical if patients and providers are to have the ability to fully evaluate health plans and for CMS to receive data-driven feedback from the industry.

CMS proposal (p. 82587-8): *We believe aligning these policies across all payers would benefit all payers alike. However, we do not believe our approach to start with state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs will have a negative impact on patients. We believe these policies would provide a net benefit to these patients, bringing these programs closer in alignment with one another. We are aware that these proposals, if finalized, would create misalignments between Medicaid and Medicare that could affect dually eligible individuals enrolled in both a Medicaid managed care plan and an MA plan. While we currently do not believe it is necessary to apply these policies to Medicare Advantage organizations at this time, we intend to further evaluate the implementation of these policies to determine whether they would also be appropriate to apply to Medicare Advantage organizations for future rulemaking.*

MGMA comment: By restricting the applicability of these proposed requirements to a small number of health plans, CMS is virtually guaranteeing that industry implementation of these automated solutions will be limited, do little to alleviate the current level of administrative burden on physician practices, and continue the current level of patient care delays. Therefore, MGMA strongly urges CMS to align the impacted payers in this proposed rule with all health plans deemed covered entities under HIPAA or, at a minimum, align this rule with the impacted health plans in the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564), as this proposed rule is purported to be an extension of that final rule. Including Medicare Advantage plans, for example, will widen the scale of this initiative by increasing the number of patients beyond the proposed impacted health plans, which will further the goals of improving data exchange and reducing the burden of prior authorization.

Without mandating that Medicare Advantage plans support prior authorization APIs it is unlikely that commercial health plans will deploy this API technology. Should Medicare advantage plans not be included in the covered health plans, it is highly doubtful that many EHR and practice management system software vendors will offer their provider clients the supporting technology, not will many practices request it as the health plans covered in this proposed rule typically do not comprise a significant percentage of a practice's patient panel. Further, the proposed covered health plans do not have a substantial number of medical services that require authorization and physician practices will gain little by automating the few services that require prior authorizations.

CMS proposal (p. 82590): *Effective Dates: The rule proposes an effective date of January 1, 2023 for most of the requirements.*

MGMA comment: There are several issues that could impact the January 1, 2023 proposed implementation date. While we concur generally that the referenced Da Vinci and CARIN Implementation Guides (IGs) are the appropriate standards, there is concern in the industry regarding the maturity level of the HL7 IGs cited as references in this regulation to establish the implementation standards. HL7 and other standards bodies are currently supporting trial implementation of the IGs. The experience of those trial implementations and production-level demonstrations over the course of 2021, and the experience of implementing Patient API's associated with the current CMS and ONC Interoperability Rules, will assist in informing modifications to the IGs. Lessons learned from these experiences should lead to a more successful implementation. We recommend CMS provide sufficient time for this IG development process to be completed and to incorporate the experience from early adopters. CMS should consider requiring implementation no earlier than one year following publication of the final IGs.

As well, stakeholders impacted by this proposed rule are still implementing the requirements of the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564). Health plans (with support from their vendors must also comply with the Transparency in Coverage Final Rule (CMS-9915-F) for plan years beginning January 1, 2023. Should the proposed date be finalized, there will be insufficient time to complete that work and implement the requirements proposed in this rule

MGMA recommends CMS reconsider the January 1, 2023 effective date and consider alternative options, such as establishing an effective date one-year after the IGs are finalized by HL7 and/or creating a voluntary, one-year education and testing period between willing trading partners in 2023.

CMS proposal (p. 82591): *Specifically, we are proposing at 431.60(b)(5) for state Medicaid FFS programs, at 438.242(b)(5) for Medicaid managed care plans, at 457.730(b)(5) for state CHIP FFS programs, at 457.1233(d)(2) for CHIP managed care entities, and at 45 CFR 156.221(b)(1)(iv) for QHP issuers on the FFEs to require these payers to make available to patients information about any pending and active prior authorization decisions (and related clinical documentation and forms) for items and services via the Patient Access API conformant with the HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG no later than one (1) business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization. We believe one (1) business day is appropriate because in order for patients to have true transparency into the process, they need to see the information timely.*

MGMA comment: We agree with CMS that patients should play a central role in the care delivery process. Providing them access to prior authorization information could be helpful during some communications with health plans. While we support this proposal in theory, we do have the following comments: (i) Patients may not fully understand what is expected of them or be able to follow or manage their pending prior authorizations via their apps. It will be critical for the health plan to present the

information via the app in a manner that makes it easier for the patients to understand; (ii) While providing the patient access to information that a prior authorization request has been submitted on their behalf could be helpful, the focus of this CMS rule should be on notifying the provider of the response to the prior authorization request; and (iii) We are concerned that the PDex IG was developed with minimal input from a number of key stakeholder groups, including physician practices. As a result, there is a need for more time to understand and implement the standard.

CMS proposal (p. 82591): *If a patient can see the supporting documentation shared with their payer they might better understand what is being evaluated and even potentially help providers get the best and most accurate information to payers to facilitate a successful prior authorization request, thus potentially avoiding unnecessary delays in care and reducing burden on providers and payers.*

MGMA comment: Patients should play an important role in the care delivery process and increasing patient engagement is a goal we all share. However, with this provision CMS could unintentionally be adding additional burden and delays in care. Should health plans, for example, require the involvement of the patient in a prior authorization it would insert patients into already burdensome administrative workflows. Most concerning, a health plan could require the patient to contribute information as another condition for approval of a service or medication, further delaying the approval process. Should the health plan work directly with the patient and not include the practice, it could lead to discrepancies in information submitted by both parties and again lead to delays in care. We recommend the agency clarify that health plans are not to require that patients contribute or review information as part of the prior authorization process.

CMS proposal (p. 82591): …*we propose that payers would be allowed to conform with either the US Core IG or the PDex IG to facilitate making the required USCDI data available via the Patient Access API.*

MGMA comment: We are concerned that CMS is proposing that impacted health plans be permitted to conform with either the US Core IG or the PDex IG to facilitate making the required United States Core Data for Interoperability (USCDI) data available via the Patient Access API. Providing these health plans the option to select which IG to support could have a detrimental impact on practices. Physicians are already required to use EHRs certified to the US Core IG. Since the Patient Access API and Provider Access API are linked, practices could be forced to incur additional costs if IGs that overlap with the requirements of the Provider Access API are used inconsistently. We question why CMS would propose a health plan IG policy that could result in incompatibility with practice EHRs---potentially negating the usefulness of the Physician Access API. Selecting one IG will decrease costs and encourage adoption by practices.

CMS proposal (p. 82592): *We did not include information about prescription drugs and/or covered outpatient drugs in any of the proposals in this rule. However, we are interested in better understanding the benefits and challenges of potentially including drug information in future rulemaking. For example, what specific considerations should we take into account? Are there unique considerations related to the role Pharmacy Benefit Managers (PBMs) play in this process? Overall, we do think it would be very valuable to payers, providers, and patients to have information about a patient's prescription drug and/or covered outpatient drug pending and active prior authorization decisions, and we would like to better understand how to most efficiently and effectively consider including this information in these API provisions in the future.*

MGMA comment: When integrated into a pharmacy management system, electronic prior authorization streamlines the approval process and patients can start their medications sooner. The result is increased patient satisfaction, adherence to medication regimens, and fewer visits the emergency room. This more

automated process improves patient care, reduces provider burden, and even saves plan resources. Additionally, per the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses final rule (CMS-4180-P), Medicare Part D plans have to offer a real-time pharmacy benefit tool showing physicians patient-specific drug coverage information, including alternatives, effective January 1, 2021.

We support the work undertaken by the National Council for Prescription Drug Programs (NCPDP) to develop the SCRIPT Standard electronic prior authorization transactions. It is anticipated that these automated transactions will significantly reduce the approval time of prescription benefit prior authorizations, leading to expedited access to drug therapy for improved continuity of care. As well, the NCPDP real-time prescription benefit (RTPB) transactions can provide clinicians point-of-care information to support clinical decision-making for prescribing drugs, thereby negating the need to obtain a prior authorization and reducing the overall administrative burden. We urge CMS to work with NCPDP, provider associations, and other stakeholders to identify opportunities to include prescription drug information and RTPB in the proposed APIs.

CMS proposal (p.82593-4): *We propose that impacted payers must request the third-party app developer's attestation at the time the third-party app engages the API. Under our proposal, the payer must inform the patient within 24 hours of requesting the attestation from the app developer of the status of the attestation—positive, negative, or no response, with a clear explanation of what each means. The patient would then have 24 hours to respond to this information… We also request comment on whether the request for the app developer to attest to certain privacy provisions should be an attestation that all provisions are in place, as it is currently proposed, or if the app developer should have to attest to each provision independently*

MGMA comment: We understand the importance of finding the appropriate balance between facilitating patient access to health information and ensuring the confidentiality of that information. We agree that health plans should have the ability to ensure that patient-directed third-party apps deploy a designated level of privacy and security functionality. An attestation response from the app developer seeking to access the Patient Access API would be a helpful guide for the patient to determine if the app would maintain the confidentiality of their information.

MGMA also supports the provision in the regulation that third-party app vendors must attest to health plans during an application registration process. This attestation includes certain facts about how they manage and protect the privacy and security of patient information both upon receipt and in an ongoing fashion. All patient rights regarding an app's stewardship of the patient's information should be made clear to the patient when they act to download their information into the app and patients clearly need to have the right to rescind rights of access by app vendors in real-time upon learning of the status of third-party app attestation.

CMS should provide clear and consistent guidelines regarding to what third-party app vendors must attest to (e.g., CARIN Code of Conduct, third-party use or sale of data, etc.). This description should also align with the HIPAA privacy and security requirements. As well, CMS should develop a sample workflow for third-party app vendors and health plans to follow regarding the app registration and attestation process. This sample workflow should reference a scalable approach in which standards can support the real-time access to attestation information that can be shared in a federated manner. The ONC FHIR at Scale Taskforce (FAST) group has proposed such methods and CMS should work with ONC to incorporate that work into the subsequent rulemaking.

Absent clear guidance, we are concerned that any stipulations regarding timeframes (i.e., the proposed rule's requirement that the plan inform the patient of the status of the attestation within 24 hours from the request by the app developer) may be unworkable. Similarly, the 24-hour period that the patient has to respond to this information may not be sufficient. We recommend extending the 24-hour requirement to a minimum of two business days for each of the timeframes. In addition, we recommend the development of a transparent approach could reduce the need for the back and forth between patients and plans regarding app attestations and serve as a market driver to encourage app developers to meet minimum privacy and security standards.

Additional comments are requested by CMS on:
The proposal of the payer's obligation to send the data regardless of whether or not the patient responds to the payer after notification of the app's attestation results, specifically notification if the app does not attest to meeting the above privacy provisions.

Although there is concern that inappropriate disclosures will be made to third-party apps, if these apps are designated by the patient, the health cannot refuse to share the data. However, to reduce the chance of inappropriate disclosures, we urge CMS to work with stakeholders groups, include those representing patients, to educate them on the privacy and security concerns related to sharing health information with third-party apps and the importance of having those apps attest to meeting a standardized set of privacy and security requirements.

Whether the request for the app developer to attest to certain privacy provisions should be an attestation that all provisions are in place, as it is currently proposed, or if the app developer should have to attest to each provision independently.

We continue to be concerned that patients will have their health information inappropriately disclosed If they are not fully informed and aware of the potential dangers associated with sharing their information with third-party apps. We recommend the app developer should attest that all provisions are in place and not be required to attest to each provision independently. The process of all-in-one attestation and patient communication of the results will be challenging enough in its own right. Adding nuance to the attestation may result in a protracted process and could be confusing to patients. CMS should be prescriptive with regard to the minimum set of requirements to which a third-party app developer should attest to. Giving a third-party app a privacy and security "score" could be an effective way of communicating to patients how well their designated app will protect their information.

CMS proposal (82594): *Specifically, we propose that these payers report quarterly: (1) The total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app; and (2) The number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app more than once. Tracking multiple transfers of data would indicate repeat access showing patients are either using multiple apps or are allowing apps to update their information over the course of the quarter.*

MGMA comment: We urge CMS to provide additional information on what constitutes a "unique patient" so that patients can be identified in the same manner. As well, clarification is required on the issue of what happens when a patient leaves a health plan and then returns, such as occurs frequently with Medicaid beneficiaries. For example, CMS should stipulate whether a health plan is required to assign a new patient identifier and would the patient be considered new or existing.

CMS proposal (82594): *We are proposing to require impacted payers to report metrics about patient use*

of the Patient Access API to CMS.13 We believe this is necessary to better understand whether the Patient Access API requirement is efficiently and effectively ensuring that patients have the required information and are being provided that information in a transparent and timely way.

MGMA comment: These metrics are important for CMS to collect. Understanding the impact that these new policies have both on health plans and patients is critical to establishing whether the policies are successful and if any additional modifications are required. Proposing these metrics also raises the issue of whether the initial stage of the implementation should be voluntary on the part of health plans. Following collection of these metrics, and prior to making the policy mandatory for all health plans, CMS could then potentially use this time to modify policies to better ensure success.

We also recommend that CMS collect metrics on the communications between health plans and app developers regarding privacy and security attestations. It will be important to determine how many app developers are willing to attest to meeting the privacy and security criteria, how many agree to participate in the attestation process, but are unable to attest to meeting the criteria, and how many app developers refuse to participate in the attestation process. As well, it would be helpful to collect metrics on health plan and patient communications regarding these privacy and security attestations. How successful were health plans in reaching out to the patient regarding the app developer attestation and what was the result of the health plan-patient communication (i.e., did the patient continue to request that their information be supplied to the app developer, or did they decide not to have their information shared with the app developer).

CMS proposal (p. 82600): *Therefore, our proposal does not permit a payer to deny use of or access to the Provider Access API based on whether the provider using the API is under contract with the payer. A provider that is not in network would need to demonstrate to the patient's payer that they do have a care relationship with the patient.*

MGMA comment: We urge CMS to clarify what it would expect a practice to provide to a health plan to demonstrate a "care relationship" with a patient. In today's environment, health plans leverage demands for prior authorization, complex documentation requirements, hidden plan guidelines, delayed responses to practice requests, denials without clear explanation, and inefficient workflow requirements including driving practices to proprietary online portals to slow administrative transactions. Permitting health plans to establish the requirement for a practice to demonstrate care relationships inevitably will result in another unnecessary, time-consuming, and burdensome process that will delay patient care.

We recommend that practices not be expected to demonstrate a care relationship using approaches that are beyond what in-network providers would need to take to demonstrate a relationship with a patient or that take practices out of their normal workflows. Typically, this is accomplished now by simply supplying the health plan the patient's insurance plan member ID, first and last name, and date of birth. CMS should also consider leveraging the existing companion guide on the HIPAA-mandated X12 270/271 electronic eligibility transaction supporting Medicare Beneficiary Matching as a template for what should be required to facilitate beneficiary matching.

Further, the rule as proposed does not appear to provide sufficient time to develop a process to administer out-of-network provider requests. In addition to complexity associated with verification of a care relationship, technical logic to automate out-of-network provider access API would significantly escalate the cost of compliance, and manual administration would increase administrative costs. Generally, there are no user identifiers and password credentialing security for most non-participating providers. To avoid industry confusion, we support CMS implementing a staged approach that begins by including plan participating providers. Out-of-network providers should be added at a later date.

CMS proposal (p. 82601): *We believe that the benefits of data sharing would be greatly enhanced if other payers were sharing health information about their patients with health care providers for multiple patients at once, as CMS is now beginning to do under BCDA and as we are also further testing through the DPC pilot, for instance. As a result, we are proposing a second approach to require impacted payers to implement payer-to-provider data sharing using the HL7 FHIR Bulk Data Access (Flat FHIR) specification—a Bulk Data Provider Access API.*

MGMA comment: We concur that there are potential benefits of data sharing would be greatly enhanced if other health plans were sharing health information with physician practices for multiple patients at once. We note, however, that the HL7 FHIR Bulk Data Access specification is designed to "periodically retrieve updated clinical data" and not for daily bulk claims and clinical transactions among changing enrollees or providers as discussed in the CMS proposed rule. Sufficient implementation has not occurred to assess if it will meet industry needs and the proposed timeframes. The Provider Access API application should be limited to individual enrollee data requests, and testing continue for the FHIR Bulk Data Access specification. CMS should not require this Bulk Data Access specification until the standard can be applied to this use case and has been thoroughly tested.

Once the standards specifications are established, CMS should work with ONC on establishing specific requirements for EHR developers to include in their technologies for clinical data as part of the ONC Certified EHR Technology (CEHRT) program. In addition, CMS should consider including incentives to use the Provider Access API in their workflows within the Improvement Activities component of Merit-based Incentive Payment System (MIPS) program.

CMS should also focus efforts on exchange of data from patients to practices. As patients now will have access to all their information captured by their health plans via the Patient Access API, the patient should also be considered a potential conduit for the data. The patient can choose to share their health plan data records with any provider of their choosing if and when third-party apps and EHRs implement a Bulk Data transfer capability. For practices to incorporate actionable data, they will need EHR vendors to support a "curation function" to permit clinicians and patients to selectively incorporate data into the patient record. Without this capability, there will be a significant amount of duplicate and non-essential data and practices will not realize the benefits. As development of the standard continues, CMS should work with practices to ensure the Provider Access API returns accurate and useable information.

CMS proposal (p. 82602): *We are proposing that impacted payers would be permitted to put a process in place for patients to opt-in to use of the Provider Access API for data sharing between their payer and their providers. As with the attribution process discussed above, we did not want to be overly prescriptive regarding how this opt-in process might be implemented. However, we are considering whether to suggest a specific process for all payers who choose to implement this opt-in. One possible approach might be for CMS to have all payers engaging in an opt-in approach to include information about the ability to opt-in to this data sharing as part of their annual notice or regular communication with patients—such as when they communicate with patients about claims, and to permit opt-in via a variety of options, including by phone, via a website, or using an app, for instance.*

MGMA comment: MGMA supports the proposal that requires health plans to implement a process that has patients opt-in to the use of the Provider Access API for data sharing between their provider and plan. An opt-in approach is preferable to an opt-out approach, as the opt-out approach brings a likelihood of added burden for physician practices to manage questions and concerns from patients once they become aware that they were opted-in to the API. In addition, we recommend that the health plan be required provide understandable information for their enrollees on how to opt-in, what the Provider Access API

involves, how their data is shared, details on the privacy and security safeguards, how to subsequently opt-out, and who the patient can contact for additional information.

CMS proposal (p. 82603): *We are proposing that payers make educational resources available to providers that describe how a provider can request patient data using the payer's Provider Access APIs in nontechnical, simple, and easy-to-understand language.*

MGMA comment: MGMA strongly supports the requirement that health plans make clearly understandable educational resources easily available for providers to learn how they can request patient health data using the plan's Patient Access API. We also urge CMS to work with MGMA and other professional societies on API education.

CMS proposal (p. 82608): *The proposed PAS API could support increased use of the HIPAA standard through its capability to integrate with a provider's system directly, automation, and improved timeliness for obtaining a response to a prior authorization request, particularly when paired with the DRLS API. However, we are interested in hearing from commenters if there are other steps CMS could take to further implementation of the X12 278 standard and what challenges would remain if the standard was more widely utilized.*

MGMA comment: The 2019 CAQH Index Report, released in 2020, suggests that industry adoption of the electronic prior authorization transaction lags significantly behind the other HIPAA-mandated electronic transactions (see below). Electronic claim submission (96 percent in 2019), coordination of benefits/crossover claim (86 percent in 2019), eligibility & benefit verification (84 percent in 2019), claim status inquiry (70 percent in 2019), claim payment (70 percent in 2019), and remittance advice (51 percent in 2019) are all higher than prior authorization transaction (13 percent in 2019).

Increased use of the prior authorization electronic transaction would result in significant savings to both plans and providers. Data taken from the 2019 CAQH Index Report suggests that moving from manual to electronic prior authorizations would net the health plans a savings of $3.27 per transaction. For providers, moving from manual to electronic prior authorization transactions would net a savings of $9.04 per transaction. CAQH estimates that the combined net savings for the industry would be $12.31 per prior authorization transaction.

The most significant barrier to widespread use of the X12 278 transaction is the lack of a supporting standard for electronic attachments. Without an attachment standard, health plans have developed web-based portals to provide a mechanism in which to submit documentation to support the prior authorization request. A mandated attachments standard is imperative for the prior authorization process regardless of which transactions are used to send and respond to requests. Additionally, using an API to simply automate the initial prior authorization request and response does not address need to transmit supporting clinical documentation nor does it necessarily address burdensome workflow issues for practices.

We do have concerns with the reference in the proposed rule to the continued use of the X12 278 in tandem with the Da Vinci PAS API. It appears the only value of using the X12 278 in this model is to ensure HIPAA compliance. However, establishing a workflow where a transaction starts as a PAS API, is converted to an X12 278, transmitted to the health plan, where it is then translated back to a PAS API adds nothing to the process other than translation costs for both practices and health plans. We expect that if this approach is adopted, practices will be forced to engage clearinghouses and other third-party intermediaries to submit these transactions and the benefits of automation benefits would be lost. To solve this, we urge CMS to aggressively promote HIPAA waivers, permitting practices, health plans and supporting vendors to adopt a PAS API workflow that does not require mapping to the X12 278.

CMS proposal (p. 82608-9): …_we propose to require that, beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023), state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs, implement and maintain a FHIR-based DRLS API… populated with their list of covered items and services, not including prescription drugs and/or covered outpatient drugs, for which prior authorization is required, and with the organization's documentation requirements for submitting a prior authorization request, including a description of the required documentation._

We also request input on a potential short-term solution to address the challenge of accessing payer requirements for prior authorizations. We solicit feedback on how payers currently communicate prior authorization requirements, and on the potential for payers to post, on a public-facing website, their list of items and services for which prior authorization is required, populate the website with their associated documentation rules as in interim step while they implement the DRLS. This is not intended to harmonize prior authorization requests, but rather to quickly address the issue identified by stakeholders regarding access to prior authorization information. If payers could post their prior authorization requirements on a website, how could that information be presented and organized for providers to easily identify the services and items which require prior authorization? Finally, we request comments on how the posting of this information on payer websites would provide a satisfactory interim solution to the challenge of accessing payer requirements for prior authorizations in advance of implementing the DRLS API.

MGMA comment: MGMA and many provider organizations, health plans, and vendors participated in the CMS workgroup that developed the DRLS initiative. DRLS shows tremendous promise to streamline and automate prior authorization communications between health plans and providers. Coverage Requirements Determination provides an automated way for provider EHR systems to contact health plan systems in order to determine requirements for prior authorization, specific documentation, prior treatments, appropriate use criteria and potentially gaps in care.

We note that on the CMS [DRLS webpage](#) the agency states: "How will this benefit providers? Providers will be able to discover Medicare FFS prior authorization and documentation requirements: At the time of service." Thus, even CMS recognizes that one of the most important components of the DRLS initiative was its "real-time" approach that would provide critical information to the clinician at the time of the patient encounter. While DRLS focused on communicating whether a prior authorization weas required and giving the physician practice the necessary clinical template, we assert that this same approach be applied more broadly to the prior authorization determination API requirements for health plans.

The rule also seeks comment on provider access to health plan prior authorization requirements. Full transparency and easy access to prior authorization requirements would significantly decrease provider burden and streamline the prior authorization process. Health plan burden would also be decreased as they must answer provider prior authorization requests for medications and medical services that do not require authorizations. Reducing these call center communications would save health plan resources.

We note that in today's physician practice environment, typically prior authorization policies and requirements are communicated by health plans to providers via plan websites, written and electronic bulletins, and sent to providers in emails. With practices often having contracts with dozens of different health plans, these types of communications are often lost or overlooked. The wide variation between health plans in their prior authorization policies, the ever-changing nature of these policies, and the proprietary approach taken by individual health plans in how they describe their policies makes tracking and implementing these policies extremely challenging for practices.

A solution to this issue would be to standardize the way that health plan requirements for prior authorizations are presented to providers. For example, health plans could be required follow a template that would list all the medications and medical services that require an authorization. This template could also include the clinical documentation required by the health plan to support the authorization. These templates could then be posted in a standardized area on the health plan's public-facing website. This standardized and transparent approach, while not automating prior authorization, would significantly improve the ability of practices to understand and meet plan authorization requirements.

CMS proposal (p. 82609-10): *To help address this issue, we are proposing that impacted payers implement a Prior Authorization Support (PAS) API that facilitates a HIPAA compliant prior authorization request and response, including any forms or medical record documentation required by the payer for items or services for which the provider is seeking authorization.*

MGMA comment: MGMA strongly supports an end-to-end automated PA process that integrates with a practice's EHR workflow. We are supportive of the proposed rule's requirement on health plans to implement a PAS API to facilitate HIPAA compliant prior authorization request and responses, including any forms or medical record documentation required by the plan for items or services for which the provider is seeking authorization. However, we do have some concerns with the provisions as proposed in the rule.

For example, we urge CMS to clarify the issue of which transaction standard is to be followed. We note in the preamble that health plans are required to support the PAS API HL7 FHIR standard while later in the rule it specifically requires compliance with the X12 278 HIPAA transaction standard.

Further, the industry is facing the challenge that while some physician practices, EHR/practice management system vendors, and health plans are ready or will be ready shortly to support FHIR-based transactions, many are not. We are particularly worried that small and medium-sized practices will not be able to easily discard their X12-based technologies and workflows. We are also concerned about the ability of physician practices to implement the software required to support the PAS API HL7 FHIR and DRLS API proposals. With no mandate on software vendors to develop supporting products, we believe it is unlikely that practices will be able to support these standards by 2023.

CMS proposal (p. 82610): *Specifically, we propose to require that Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs implement and maintain a PAS API conformant with the HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023)…We request comment on steps that HHS could take to educate providers on the benefits of these APIs and incentive their use. We also request comment on opportunities to encourage health IT developers to implement these functions within EHRs, including the potential future addition of certification criteria in the ONC Health IT Certification Program.*

MGMA comment: As we state above, one of the impediments to practices moving forward with the proposed automated API approaches is the lack of vendor support. EHR and practice management system software vendors are not HIPAA covered entities and this proposed rule does not require the vendors to support these new standards. The proposed rule does, however, allude to the ONC certification program when it asks for comment on the potential future addition of certification criteria in the ONC Health IT. In ONC's May 2020 final rule, it outlines the next iteration of its certification program (to go into effect at the end of 2022) and does not include any requirements on the software to support the CMS PAS API HL7 FHIR and DRLS API proposals. It would likely take a minimum of five additional years for ONC to include PAS API HL7 FHIR and DRLS API requirements in the software. Further adding to the challenge, only

providers participating in the Medicare/Medicaid Promoting Interoperability program or the Promoting Interoperability component of MIPS are required to deploy CEHRT, potentially leaving out many physician practices.

As we have stated previously, we believe the assumption that mandating a small subset of health plans to implement the untested PAS API HL7 FHIR and DRLS API requirements will incentivize health IT developers to develop and physician practices to adopt the technologies necessary to support API interfaces is incorrect. Even assuming the vendors produce the necessary technology, physician practices will be reluctant to invest resources and move forward with APIs when only a small number of their health plans support them.

In addition, health plans using different prior authorization processes, as in today's environment, must be avoided as it increases administrative burdens. Permitting multiple PAS APIs would be costly and burdensome for practices to support and add unnecessary complexity to EHR vendor integration. Because of this, we recommend the agency require health plans to utilize a single PAS API that would house PAS exchange for all participating plans. Further, practices have concern that the PAS API could provide health plans unfettered access into the practice EHR and lead to unauthorized access to patient information. To avoid this, we recommend CMS establish appropriate protections to ensure that health plans are only able to access EHR data relevant to a specific prior authorization request and ensure that the practice has the opportunity to review any patient information prior to it being transmitted to the plan.

Further, we assert that the best approach for the industry to move forward a with prior authorization solution is to improve the X12 278 transaction, move forward with the X12 275 electronic attachment standard, and permit physician practices and health plans to continue to use these transactions. At the same time, CMS should require health plans to support the PAS API HL7 FHIR standard, streamline the HIPAA waiver process, permit willing trading partners to transact prior authorizations leveraging this standard, gather and report data on the return on investment (ROI) of this approach, and appropriately incentive physician practices adoption should an ROI be clearly established.

CMS proposal (p. 82611): *To improve the timeliness, clarity, and consistency of information for providers regarding prior authorization status, specifically denials, we are proposing that impacted payers send certain response information regarding the reason for denying a prior authorization request.*

MGMA comment: We believe including a requirement for a denial to be issued to the provider from the health plan would improve the current prior authorization process. With these denial codes in place, practices would better understand a health plan's prior authorization requirements and it could lead to decreased call volumes between providers and health plans. However, to be an effective communication tool and to decrease the cost and burden of implementation for health plans, providers, and their vendor partners, these denial codes must be standardized. We urge CMS to work directly with appropriate industry stakeholders in the development of this important code set.

CMS proposal (p. 82612): *We wish to learn how new policies could help improve this process, and therefore request input from payers and other industry stakeholders, on the issues that could inform a future proposal to prohibit impacted payers from denying claims for covered items and services for which a prior authorization has been approved.*

MGMA comment: We have concerns that as the prior authorization process becomes increasingly automated, some health plans may seek to gain advantage by approving the service or medication and then denying the practice's claim either once it has been submitted or demand repayment later after a plan audit has determined the service or medication did not meet the plan's arbitrary medical necessity

requirements. This approach puts the practice in the middle between the patient and the health plan and would force the provider to potentially seek repayment from the patient themselves. We urge CMS to take action to prevent a health plan from denying payment for a claim or repayment for a claim that has been paid if the provider has received a prior authorization from the health plan and has met all of its published clinical requirements.

Further, CMS is urged to clarify that an approved prior authorization applies in clinical scenarios such as during the course of a procedure or surgery when a clinician decides that a different but related service to the one approved is more appropriate for a patient. Plans should be required to offer flexibility in their claims adjudication systems so that approved codes can be transferred to related procedures to prevent claim denial. Similarly, a changing clinical situation during an invasive procedure may require a clinician to perform an additional or different service than that originally approved by the plan. Requiring a clinician to stop the procedure simply to obtain PA for the new/additional service is unrealistic and could even endanger the patient's health. We recommend CMS mandate that health plans establish protocols for such scenarios (e.g., allowing retrospective approvals) to prevent unnecessary claim denials and unfair financial risk for practices and patients.

CMS proposal (p. 82613): *We are not proposing that a prior authorization would be automatically approved should the impacted payer fail to meet the required timeframe. If the deadline is missed, providers may need to contact the payer to determine the status of the request and whether additional information is needed.*

MGMA comment: Without a mandate to make decisions within the required timeframes, there will be no incentive for the health plan to comply with the law. Health plans could simply wait for the practice to contact them, thus delaying the process further and at the same time, delaying patient care. Placing the burden on the provider to follow up once the health plan has failed to meet the regulatory deadline is unfair and runs contrary to the intent of the overall regulation, which is to reduce provider administrative burden and speed up the prior authorization process. We urge CMS to include in the final rule a provision that deems a prior authorization request (that includes all of the specific documentation required in the DRLS API) approved by the health plan if the determination is not made in accordance with required deadlines.

CMS proposal (p. 82613): *Given our interest in patient health outcomes, we are proposing to require that state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities provide notice of prior authorization decisions as expeditiously as a beneficiary's health condition requires and under any circumstances not later than 72 hours of receiving a request for expedited decisions. Notice should be provided no later than 7 calendar days after receiving a request for standard decisions. For Medicaid managed care plans, we are also proposing to maintain that an extension of 14 days is authorized if the enrollee requests it or a health plan determines additional information is needed.*

MGMA comment: While we understand CMS is seeking to find the balance between accelerating the timing of a health plan communication of prior authorization determinations to providers while not imposing unreasonable expectations on health plans, this proposal falls far short of that balance.

In this rule, CMS has proposed that health plans provide notice of prior authorization decisions not later than 72 hours of receiving a request for expedited decisions and no later than 7 calendar days after receiving a request for standard decisions. Medicaid managed care plans are allowed an extension of 14 days if the enrollee requests it or a health plan determines additional information is needed. These time frames are simply unacceptable and will result in unintended consequences. In some cases, the 72 hour and 7 day requirement are actually longer than the current timeframes offered by some health plans.

Thus, it would be a step backward if those plans were permitted to lengthen their response times to meet the maximum allowed under the regulation. As well, these protracted proposed response times will act as a disincentive for physician practices to invest resources in these new standards and technologies.

We agree that physician practice and health plan adoption of electronic prior authorization could result in significant saving to both stakeholder groups and improve the care delivered to patients. However, to have wide physician practice adoption of API-based technologies, the transactions being automated must also be offered in real-time or near real-time. Real-time electronic prior authorization transactions will reduce cost for practices and health plans by eliminating manual (fax, phone, proprietary plan web portal) communications with plans.

It is important to note that the vast majority of prior authorization requests by physician practices are ultimately approved by health plans. The goal in establishing regulations in the area should be to streamline those "routine" medical services and medications that are approved by health plans at an extremely high rate. While a small number of complex medical situations require exchange of documentation and even clinical discussions, a significant number of medical services and medications do not require the submission of supporting documentation from the provider these could have determinations communicated between health plans and practices in real-time.

These real-time decisions for routine medical services and medications could mirror the current approach that practices and health plans leverage for verifying insurance eligibility and benefits. Under the 2011 CMS interim final rule, plans are required to support a real-time eligibility and benefits verification transaction with the supporting operating rule stipulating a maximum response time when processing in real-time mode of 20 seconds or less.

CMS also proposes to permit an extension of 14 days if certain health plans determine additional information is needed. We oppose this provision, as we believe that permitting health plans to issue multiple requests for clinical documentation will result in further patient care delays and practice burdens. Additionally, health plan prior authorization documentation requirements should be sufficiently transparent—especially with implementation of the DRLS API—to prevent these repetitive information requests.

CAQH CORE Operating Rules

The issue of how quickly a health plan should be required to communicate prior authorization determinations was comprehensively addressed during a lengthy and vigorous debate during the development of the prior authorization operating rules. CAQH CORE, a multi-stakeholder organization representing a broad spectrum of health plans, providers, vendors, and government entities, and the operating rules authoring entity, voted in 2020 to set time limits on when health plans must request additional supporting information from providers and communicate final determinations to providers on prior authorization requests.

With approval of this operating rule, CAQH CORE participating organizations agreed to update requirements in the CAQH CORE 278 Prior Authorization Infrastructure Rule. We note that the new requirements set national expectations for prior authorization turnaround times using the HIPAA-mandated X12 278 standard to move the industry toward greater automation. The operating rule establishes maximum timeframes at the two different stages in the prior authorization process: (i) Two-Day Additional Information Request: A health plan, plan or its agent has two business days to review a prior authorization request from a provider and respond with additional documentation needed to

complete the request; and (ii) Two-Day Final Determination: Once all requested information has been received from a provider, the health plan, plan or its agent has two business days to send a response containing a final determination.

Under this operating rule, the timeframe requirements must be met 90 percent of the time in a calendar month. This updated rule, coupled with the release of the CAQH CORE 278 Prior Authorization Data Content Rule in May 2019, enhance the information sent in the HIPAA-mandated standard electronic transaction and allow for faster responses. We note that the CORE Certification is now available for entities to demonstrate conformance with the CAQH CORE Prior Authorization Operating Rules and show commitment to greater prior authorization automation.

We strongly recommend that CMS leverage API technology and support real-time prior authorization processes for routine medical services and medications. For non-automated urgent authorizations, health plans should have a maximum of 24 hours to provide a determination and for those small number of medical services and medications that require more extensive communications between practices and health plans, we recommend the agency follow the timeframes established by the CAQH CORE prior authorization operating rules.

CMS proposal (p. 82618-9): *We propose that these metrics would include, at a minimum, the following: A list of all items and services that require prior authorization; the percentage of standard prior authorization requests that were approved, reported separately for items and services; the percentage of standard prior authorization requests that were denied, reported separately for items and services; the percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services; the percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services; the percentage of expedited prior authorization requests that were approved, reported separately for items and services; the average and median time that elapsed between the submission of a request and a decision by the payer, plan or issuer, for standard prior authorizations, reported separately for items and services.*

MGMA comment: These metrics are important for CMS to collect and we agree with each of the proposed items to collect. Understanding the impact that these new policies have both on health plans and patients is critical to establishing whether the policies are successful and if any additional policy modifications are required. As well, capturing these metrics, especially those identifying the items and services that require prior authorization and the number that were approved, could serve as a guide for eliminating authorization requirements for a subset of these items and services.

We also recommend that CMS collect metrics on the communications between health plans and app developers regarding privacy and security attestations. It will be important to determine how many app developers are willing to attest to meeting the privacy and security criteria, how many agree to the attestation process, but are unable to attest to meeting the criteria, and how many app developers refuse to participate in the attestation process. As well, it would be helpful to collect metrics on health plan and patient communications regarding these privacy and security attestations. How successful were health plans in reaching out to the patient regarding the app developer attestation and what was the result of the health plan-patient communication (i.e., did the patient continue to request that their information be supplied to the app developer, or did they decide not to have their information shared with the app developer).

Proposing collection of these metrics also raises the issue of whether the initial stage of the implementation should be voluntary for the industry for one year or more. Following collection of these

metrics, and prior to making the policy mandatory, CMS could then potentially use this time to modify policies to better ensure success.

CMS proposal (p. 82619): *We seek comment for potential future rulemaking on the incorporation of gold-carding into star ratings for QHP issuers on the FFEs. We also considered proposing gold-carding as a requirement in payer's prior authorization policies and seek comment on how such programs could be structured to meet such a potential requirement.*

MGMA response: While we oppose prior authorization requirements on physicians treating Medicare beneficiaries, if they are to be imposed for certain covered services, we strongly urge the Agency to develop a streamlined process that does not distract from patient care and does not add to practice burden. There are a number of opportunities to achieve these goals, including deployment of a gold-carding program. The optimum gold card program would exempt a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS would elect to withdraw the exemption. CMS would then exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. By achieving this percentage of provisional affirmations, the provider would be demonstrating an understanding of the requirements for submitting accurate claims. Further, it would not be necessary for a provider to achieve 100 percent compliance to qualify for an exemption because innocent and sporadic errors could occur that are not deliberate or systematic attempts to submit claims that are not payable*.*

Should Medicare move forward with expanding the number of beneficiary services subject to prior authorization, we believe that this approach should be used as the policy template. By implementing this type of exemption program, the Agency achieves several policy goals. First, it reduces the administrative burden on those clinicians who have shown themselves to adhere to Medicare's medical necessity guidelines. Second, it permits CMS to identify those clinicians who are not adhering to Medicare medical necessity guidelines and requires them to receive an authorization prior to performing the service. This also affords the Agency an opportunity to educate these clinicians on appropriate use of these medical services. Finally, by rewarding clinicians who adhere to Medicare's medical necessity requirements, the Agency is incentivizing adherence which will lead to an increase in appropriate use of services.

CMS proposal (p. 82620): *We seek comment on whether there should be certain restrictions regarding requirements for repeat prior authorizations for items and services for chronic conditions, or whether there can be approvals for long term authorizations. What alternative programs are in place or could be considered to provide long-term authorizations for terminal or chronic conditions?*

Patients expressed concern about being able to continue a specific course of care where, for example, they might be in the middle of an approved course of care requiring physical therapy, but then change health plans (payer). We seek comments on whether a prior authorization decision should follow a patient when they change from one qualified health plan on the Exchange to another, or to another health plan impacted by this proposed rule, and under what circumstances that prior authorization could follow a patient from payer to payer.

We also seek comment for potential future rulemaking on other prior authorization topics, such as whether prior authorizations should be valid and accepted for a specified amount of time. We are interested in comments on who should determine how long an existing approved prior authorization from a previous payer should last and whether prior authorization should be regulated by amount of time and/or by condition.

The lack of standard forms and requirements from payers is considered burdensome and time consuming for both patients and providers. We request input on solutions to standardizing prior authorization forms, including the possibility of developing an HL7 FHIR based questionnaire for prior authorization requests. Finally, we request comments on how to potentially phase out the use of fax technology to request and send information for prior authorization decisions.

MGMA comment: We appreciate CMS recognizing the concern raised by patients and physician practices regarding prior authorizations and specific situations. We offer the following responses to the issues raised in this section of the proposed rule.

Prior authorizations and chronic illnesses. We strongly encourage the agency to place restrictions on repetitive authorizations for treatment for chronic conditions, as these duplicative requirements are not only administratively burdensome for physician practices but can often interfere with continuity of care and place patients at risk for dangerous interruptions in therapy. We note that the 2018 Consensus Statement signed by MGMA, the American Medical Association, the American Hospital Association, American Pharmacists Association, America's Health Insurance Plans and the Blue Cross Blue Shield Association included the provision "[s]upport continuity of care for medical services and prescription medications for patients on appropriate, chronic, stable therapy through minimizing repetitive prior authorization requirements." We contend that prior authorization approvals should extend for the duration of therapy to prevent avoidable interruptions in care and unnecessary practice hassles.

Plan to plan movement. The 2018 Consensus Statement also included the statement supporting "[s]ufficient protections for patients undergoing an active course of treatment when there is a formulary or treatment coverage change or change of health plan that may disrupt their current course of treatment." CMS should require health plans to create protections for new members on chronic treatment to prevent harmful care disruptions and require plans to accept a previous plan's approval for a minimum of a 60-day grace period. Similarly, with the Plan-to-Plan API permitting the new plan to review the supporting clinical documentation used by the previous plan for approval, CMS should require plans (i) to honor a previous plan's prior authorization approval for at least 60 days, (ii) request and obtain the prior authorization supporting clinical documentation from the previous plan to establish the approval in the new plan's system, and (iii) only request additional information from the practice if it is not included in the Plan-to-Plan API data exchange and is necessary to make the determination.

Standardized forms and requirements. Developing the technology to support highly variable prior authorization documentation requirements across many different health plans for medical services will be extremely challenging for health plans, clearinghouses, other intermediaries, and EHR vendors. To decrease this burden and facilitate a streamlined prior authorization process, we recommend standardizing the data elements needed to support prior authorization decisions for specific services. It is important to note that the HL7 Uniform Structure and Coding Elements for Prior Authorization workgroup is currently undertaking this effort. Once developed and fully tested, CMS should require health plan adherence. Harmonization of prior authorization data sets will be critical if the PAS API model is to be scalable across all health plans, medical services, and criteria.

Fax technology. CMS solicits input on how to potentially phase out use of fax machines for exchanging PA-related data. For healthcare, the fax machine is a symptom, not a cause. EHR and other HIT technology in use by practices offer significant promise for adopting processes that will eliminate the need for faxes. However, the replacement process must share similar characteristics with the fax machine and the alternative must offer many of the same advantages. The alternative solution must be universally adopted

by all the practice trading partners (thus avoid the current problem of multiple workflows). It must be reasonably priced and not require complex staff training. It must be fast and easy to operate. We also need to recognize that small and rural practices may need to continue to rely on fax machines for the foreseeable future. These providers lack the current infrastructure and resources to implement FHIR-based technology and will need additional support and time to reach end-to-end automation.

CMS proposal (p. 82640): *We believe answers to the following questions would be beneficial in obtaining additional information on the overall electronic prior authorization process, the impact of this process on patient health and safety issues, and whether the hospital (and other providers and suppliers) CoP requirements are a good vehicle to achieve nearly universal adoption and use of electronic prior authorization requests and receipts*

MGMA comment: Physician practices report that prior authorization requirements from health plans represent the most burdensome administrative process the encounter. Practices are eager to adopt technology and workflows that streamline prior authorization, reduce their costs, and improve the care they deliver to their patients. The assumption behind this question from CMS, that practices will need the threat of being excluded from the Medicare program to adopt standards that reduce prior authorization burdens is false. If there is reluctance on the part of practices to move forward with a FHIR-based API solution it is due to the fact that not all health plans will support it, thus forcing practices to support multiple workflows.

CMS proposal (p. 82672): *A State [Medicaid agency] must establish, implement, and maintain a process to facilitate generating each provider's current beneficiary roster to enable this payer-to-provider data sharing via the Provider Access API.*

MGMA comment: MGMA believes that additional clarification is needed on the intended level of attribution for access to a member's data and how health plans should address attribution for providers who do not participate in their network. More standardization of the attribution requirements would also be beneficial. Additionally, the requirements outlined in the proposed rule seems arduous and will require two separate processes for new versus established patients. A lack of a standard for attribution will create confusion for providers as the data requirements and processes may potentially vary for every health plan and this added burden on providers will likely result in reduced adoption. An electronic standard should be developed for verifying a patient relationship and confirming a patient has an upcoming appointment. As written, there is no electronic, automated method for such confirmation, putting burden on stakeholders to confirm the relationship and potentially requiring complicated patient consent management protocols in order to establish patient relationships.

REQUESTS FOR INFORMATION

CMS RFI: *Reducing Burden and Improving Electronic Information Exchange of Prior Authorization: This RFI seeks feedback on 1) barriers that exist for hospitals (and other providers and suppliers) to electronically transmit prior authorization requests and receive prior authorization decisions for patients receiving care and services by the applicable provider and 2) the addition of a MIPS improvement activity, and if this area will be appropriate to encourage clinicians to make certain improvements.*

MGMA response: The current practice for providers is to fax, mail, or upload to proprietary websites prior authorization requests and submit the clinical documentation necessary to conduct prior authorizations. At the same time, the vast majority of inpatient and outpatient facilities have implemented electronic

health records (EHRs), giving them unprecedented opportunities to automate the collection and transmission of clinical data in support of a prior authorization. To encourage providers to invest the resources necessary to implement electronic prior authorization, the solution must go beyond the initial communication to the health plan and include the ability to transmit supporting clinical documentation, reduce the variability of health plan requirements, be incorporated into the clinician workflow, include provider education, and have a clear return on investment (ROI).

Electronic Attachments

We believe that the low adoption rate of the X12 278 is not a sign that providers are unwilling to implement an automated solution to prior authorization but is due primarily to the fact that there is no standardized approach to transmitting the necessary clinical documentation to the health plan to support claims and prior authorizations. The electronic attachment standard (X12 275) was mandated by Congress in HIPAA (1996) and re-mandated in section 1104 of the Affordable Care Act in 2010. However, CMS has not yet issued a final regulation naming the standard. Creating a national standard for electronic attachments would streamline the prior authorization process and decrease administrative burden and cost by:

- Eliminating lost health plan requests for additional documentation and provider responses;
- Reducing cost associated with staff manual collection of supporting documentation and the cost of paper and postage;
- Decreasing health plan documentation requests as there would be improved predictability of plan content needs (plans could be specific in what they required in order to render an authorization decision), thus eliminating the "back and forth" that currently exists in the system; and
- Reducing pends, denials, appeals, all resulting in faster treatment approvals.

A national standard for the electronic attachment also opens the door for additional functionality that would have a direct impact on the delivery of patient care. For example, care coordination/care management, patient transitions of care, quality reporting, support for alternative payment models such as patient-centered medical homes and accountable care organizations, all will benefit from standardized and automated clinical data exchange.

Reduce Proprietary Approaches

Another incentive for providers to adopt electronic prior authorization solutions would be to reduce the ability of health plans to require proprietary approaches. The current proposal from CMS applies only to Medicaid and CHIP managed care plans, state Medicaid and CHIP fee-for-service programs, and Qualified Health Plans issuers on the Federally-facilitated Exchanges. With no mandated attachments standard, all other health plans would continue being permitted to have their providers submit prior authorization requests via fax, phone, or online web portal. Should only a small percentage of a provider's patient base be comprised of those covered health plans outlined in the NPRM, it is highly unlikely that providers would invest resources in a technology solution to address only a small fraction of their prior authorization volume.

Integrate Real-Time Solutions Directly into Provider Workflows

Real-time electronic prior authorization transactions have the potential of reducing cost for health plans and providers by eliminating manual (fax, phone, proprietary plan web portal) provider communications with the plan. These real-time decisions would be primarily for routine medical services and medications that are approved at an extremely high rate. These are medical services and medications that would not typically require the submission of a large amount of supporting documentation from the provider to the plan.

These real-time decisions for routine medical services and medications could mirror the current approach that providers and health plans leverage for verifying insurance eligibility and benefits. Under the 2011 CMS interim final rule, plans are required to support a real-time eligibility and benefits verification transaction with the rule stipulating that "The maximum response time when processing in real time mode must be 20 seconds or less."

In the ONC November 2018 report "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs," recommendations are identified for improving prior authorization processes. On page 19 of the report ONC signals its clear support for real-time electronic prior authorization transactions when it makes the following recommendation: "Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers and plans."

<u>Establish Return on Investment</u>

Ultimately, the most effective way to incentivize providers to adopt electronic prior authorization solutions is to establish a clear ROI. Absent that ROI, especially in times of economic uncertainty, providers will be very unlikely to invest resources in untried and untested technologies. We note that data reported in from the 2019 CAQH Index Report has started to quality that ROI. The Index Report suggests that moving from manual to electronic prior authorizations would net the health plans a savings of $3.27 per transaction. For providers, moving from manual to electronic prior authorization transactions would net a savings of $9.04 per transaction. CAQH estimates that the combined net savings for the industry would be $12.31 per prior authorization transaction. Promoting these savings opportunities via an all-plan single solution will be critical in any effort to encourage providers to implement automation solutions.

<u>Provider Education</u>

Educating the provider community on the advantages associated with adoption of electronic attachments and electronic prior authorization would jump start the national implementation. Once automation solutions have been established, we encourage CMS to work directly with MGMA and the national provider associations to conduct outreach on the value proposition for adoption these new solutions and implementation guidance.

<u>Market Demand</u>

EHR and practice management system software vendors are not covered entities under the law. For them to offer automation solutions they need to hear clearly from their customer base that this functionality is being requested by their customers. Establishing the ROI for these solutions will arm providers with the information they need to request that their vendor partners support automated prior authorization.

<u>MIPS Improvement Activity</u>

The Improvement Activity component of MIPS could be one lever to encourage eligible clinicians and group practices to adopt electronic prior authorization solutions, but we believe it would offer only a modest incentive at best. The Improvement Activity component is currently worth just 15% of the total MIPS score. We would recommend that if adoption of a CMS-recognized electronic prior authorization solution is included in the list of qualified Improvement Activities, it should be assigned a high weight as further encouragement for eligible clinicians and group practices to implement these solutions.

<u>Additional Recommendations</u>

- Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.

- Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.
- Seek provider, health plan, and vendor input in the standards development process. It is critical that FHIR-focused initiatives include the perspectives of every impacted stakeholder group, including health plans, vendors, and providers from a variety of care settings.
- Integrate FHIR into the current standards environment. While FHIR-based standards show great promise, there has been considerable investment made 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 mandated replacement.
- Identify administrative use cases. We urge that the developers of FHIR-based standards close 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.
- Work with health plans and other stakeholders to support pilots for standardized electronic ordering of services.
- Avoid costly mandates on the industry. Adopting the technology and workflow modifications necessary to support any new standard requires considerable investment by stakeholders. New standards need to be fully tested and EHR, practice management system, and other software vendors must incorporate them fully prior to any requirement to use them. The cost for stakeholders to implement any new standard must be considered prior to any mandate.

CMS RFI: *Reducing the Use of Fax Machines: This RFI seeks feedback on how electronic data exchange could replace fax technology.*

MGMA response: The biggest single issue with the fax machine in healthcare (other than that it takes a significant amount of time on both the sender's and receiver's part to collect, organize, document, and convey the requisite information relevant to the care process in question), is that it is still perceived by many practices as the most efficient method to accomplish the task at hand. A fax machine continues to be easy to incorporate into the office workflows and they are inexpensive and dependable. Fax machines are also ubiquitous-every care delivery site, and every health plan has a fax machine and accepts fax transmissions. Fax machines all work exactly the same way and there are no technology standards to meet other than knowing the correct number to dial. Importantly, fax machines require no specialized training to operate and putting pen to paper is still the fastest way to collect, organize, document and convey a concise body of rich narrative clinical text.

As we stated above, for healthcare, the fax machine is a symptom, not a cause. EHR and other HIT technology in use by practices offer significant promise for adopting processes that will eliminate the need for faxes. However, the replacement process must share similar characteristics with the fax machine and the alternative must offer many of the same advantages. The alternative solution must be universally adopted by all the practice trading partners (thus avoid the current problem of multiple workflows). It must be reasonably priced and not require complex staff training. It must be fast and easy to operate. We also need to recognize that small and rural practices may need to continue to rely on fax machines for the foreseeable future. These providers lack the current infrastructure and resources to implement FHIR-based technology and will need additional support and time to reach end-to-end automation.

RFI: *Accelerating the Adoption of Standards Related to Social Risk Data: This RFI seeks feedback on barriers the health care industry faces to using industry standards and opportunities to accelerate adoption of standards related to social risk data.*

MGMA response: The health inequities experienced by individuals at risk for the social determinants of health (SDoH) during the COVID-19 national pandemic highlighted the growing need for improved cross-sector sharing of social and medical care information. Common social determinants domains include collecting information about food, housing, education, utility assistance, employment, stress, anxiety, and depression. Several of these domains may be considered behavioral health conditions, raising confidentiality issues.

SDoH services exists outside the traditional health care delivery domain as defined by HIPAA's treatment, payment, and operations definition. For example, these services can include food banks, community support services, faith-based organizations, and social work organizations. These entities are not routinely included in the chain of trust associated with HIPAA covered entities and their business associates. Therefore, what constitutes treatment, payment, and operations for practices when determining to include these social services into the healthcare plan is often unclear. Physician practices generally must obtain a patient's authorization before sharing protected health information with non-health care providers (which are, by default, non-covered entities) for non-treatment purposes and, under current law, must limit such disclosures to the minimum necessary.

Patients should have notice of and understanding regarding how their healthcare information is used and should have a say in whether their data is shared by practices and other covered entities with parties outside of the traditional healthcare system, particularly for purposes beyond treatment. At the same time, we recognize that social service and community-based support programs often provide significant assistance to individuals who may not otherwise receive it and understands why access to a patient's PHI can be beneficial to an individual, particularly when the individual is unhoused, has limited access to health care services, or receives multiple supports across a spectrum of services and organizations.

We note that the Office for Civil Rights (OCR) recently issued an NPRM focused on removing barriers to care coordination. To avoid situations where practices, concerned about HIPAA compliance, are reluctant to leverage SDoH data and solutions offered by non-covered entities to help their patients, we urge CMS to work directly with OCR to develop regulation and guidance to assist patients and providers understand their rights and responsibilities. In concert with OCR, CMS should establish options for data sharing agreements between physician practices and social programs to promote information exchange while still maintaining patient confidentiality.

While gathering and acting on SDoH data has the potential of improving patient care, the data are often highly sensitive, can lead to stigma, and can create or worsen inequities. Additionally, these data may not be permanent and an individual's social risks and the SDoH that influence them may fluctuate dramatically over time. Patients must have personal control over their data and each individual should have the right to consent to, and challenge the collection, content, retention, use or disclosure of information relating to them, and they should have the right to have their information corrected or omitted. Any federal effort seeking to collect and exchange SDoH data must incorporate appropriate privacy protections for patients.

Finally, as CMS considers how best to promote the collection and dissemination of SDoH data, it is imperative that provider workflow issues are incorporated. To be practical, useful, and actionable, SDoH data must be presented to the provider in a clear, unambiguous, and concise manner. As well, SDoH data must be directly in the provider's workflow for it to be effectively acted upon. Primary care providers, the clinicians most likely to need and use SDoH data, have only a limited amount of time to spend with each of their patients. Unnecessary time spent searching for SDoH-related information will take time away from direct patient care. Optimally, SDoH data will serve as a prompt for the provider's EHR to identify patient needs and specific solutions (i.e., the address of a local food bank) during the encounter.

Conclusion

In conclusion, we want to commend CMS for taking on the challenge of improving the sharing of health data between patients, providers, and health plans and reducing the burden associated with the prior authorization process. MGMA believes this regulation, if appropriately implemented, has the potential of facilitating automated exchange of health information and streamlining administrative processes. However, significant modifications to the provisions included in this NPRM will be necessary if the industry is to achieve the goals set out in this proposal.

We look forward to continuing to work with CMS to assist physician practices transition to effective and efficient health IT and ensure that the promise of improving the nation's healthcare system through technology 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