November 20, 2019

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

Re: Center for Program Integrity. Request for Information on the Future of Program Integrity

Dear Administrator Verma,

The Medical Group Management Association (MGMA) is pleased to submit the following response to the Centers for Medicare & Medicaid Services' (CMS') Center for Program Integrity *Request for Information on the Future of Program Integrity*. We applaud the Agency for reaching out to the industry to identify opportunities to improve program integrity. We caution CMS, however, that decreasing access to care for Medicare beneficiaries and increasing provider burden through the imposition of challenging prior authorization requirements is not the appropriate pathway to promoting integrity in the Medicare program.

Any application of a prior authorization process undertaken in an effort to decrease utilization must be weighed against its impact on patient care and those who deliver that care. The current prior authorization process is cumbersome, heavily reliant on manual processes, and leads directly to delays and denials of care. Rather than increasing the use of authorizations, CMS should identify opportunities within the Medicare program to promote program integrity and in the broader healthcare environment to reduce the overall volume of prior authorizations and automate the remainder.

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 55,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,500 organizations of all sizes, types, structures and specialties that deliver almost half of the healthcare in the United States.

CMS has established that patient-centered care is at the center of the Medicare program. Empowering patients to play an active role in their care can increase patients' satisfaction with provided services and ultimately improve treatment quality and outcomes. However, prior authorization programs create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. The very manual, time-consuming processes used in these programs burden physician practices and divert valuable resources away from direct patient care.

Overall, a Medicare program integrity effort that requires providers to qualify for payment by obtaining approval before performing a service for a beneficiary would be inefficient and would result in delays in or denials of patient care.

RFI Questions

Question 9
What program integrity activities should CMS consider to ensure that items or services are provided as approved through the prior authorization process?

MGMA Response
Program integrity, ensuring that the "pay it right" approach is maintained, is a critical component of the Medicare program. The challenge is ensuring that the integrity of the program is maintained while not impeding the delivery of care to beneficiaries or increasing administrative burden on physician practices.

We believe this can best be achieved by leveraging the data that CMS already collects. Rather than impose burdensome administrative processes on all providers of Medicare services, the Agency should instead identify outliers and target them for education and only impose prior authorization requirements as a last resort. Should a Medicare beneficiary be prescribed an inappropriate treatment, test, or medication, it is likely the result of one of two issues. First, the clinician may not be aware of the current medical evidence for that particular clinical situation. In these cases, targeted education would be the most effective solution. Second, the patient may present with a unique set of circumstances that warrant the treatment, test, or medication that Medicare deems inappropriate. In this case, the optimum solution would be to have the treating clinician provide the reasoning and documentation to support the alternative approach. This may also require the treating clinician to engage in a peer-to-peer communication where the merits of the treatment, test, or medication can be discussed.

Question 10
Can clinical decision support tools play a role in prior authorization? If yes, how?

MGMA Response
Clinical decision support (CDS) software can be effective tools for clinicians. However, as much promise as CDS tools have, implementation of inappropriate CDS programs can actually serve to increase provider burden. As an example, the requirements of the Appropriate Use Criteria (AUC) program for capturing and reporting AUC data on advanced radiologic imagining tests will +professionals. The outcome of this onerous reporting process will be to identify only 5 percent or less of outlier ordering professionals and subject them to prior authorization requirements in future years. We believe that the intent of the Protecting Access to Medicare Act, passed prior to the enactment of Medicare Access and CHIP Reauthorization Act, can be achieved through alternative approaches.

We recommend a different approach and urge the Agency to make the AUC and any future program that seeks to mandate clinician use of CDS tools voluntary. Offering significant credit through the Improvement Activities component of the Merit-based Incentive Payment System (MIPS) is also an effective method of incentivizing clinicians to adopt the technology. Leveraging MIPS reporting and other types of survey data will permit the Agency to gather data on the types of diagnostic imaging tests that have been identified by CDS software as not appropriate. Once sufficient data has been gathered, CMS can work with the appropriate medical professional associations to educate ordering professionals regarding the ordering of appropriate advanced diagnostic imaging services. Further, we urge CMS to offer comprehensive training prior to any requirement for professionals to consult CDS software for AUC or any other program.

CMS Question 11
How can we apply prior authorization without adding to provider and supplier burden?

MGMA response
Prior authorization continues to be one of the most onerous administrative processes faced by physician practices and we are very supportive of eliminating or streamlining this process. Health plan utilization-management requirements misuse clinician and staff time while interrupting or delaying appropriate care. When required, they need to be developed in a way that ensures they are clinically valid and implemented in a way that is transparent, timely, efficient, flexible and standardized.

This message is the core of a comprehensive set of 21 Principles developed by MGMA and a coalition of 16 other organizations representing clinicians, medical groups, hospitals, pharmacists and patients. Prior to imposing any new Medicare prior authorization requirements on clinicians, we urge CMS to closely review these Principles with the goal of incorporating as many as possible into revised federal policy.

When prior authorization is required, CMS should make every effort to automate the process. While the Principles document was primarily directed to health plans and utilization review entities, there are several that could be addressed by better use of EHRs. For example, in the area of medications, Medicare should provide, and vendors display, accurate, patient-specific, and up-to-date formularies that include any prior authorization requirements and step therapy requirements in EHR systems for purposes that include electronic prescribing and electronic prior authorization.

Question 12

How can we apply prior authorization while maintaining timely and complete access to medically reasonable and necessary covered services for our beneficiaries?

MGMA response

Gold Carding

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 use of real-time or near real-time tools and processes and full transparency regarding what covered services, tests, DME, or medications require a prior authorization and what documentation is needed to support a prior authorization or a post-payment Medicare audit.

On page 985 of the OPPS Final Rule with comment, the Agency outlines a gold card program to exempt certain clinicians from prior authorization requirement:

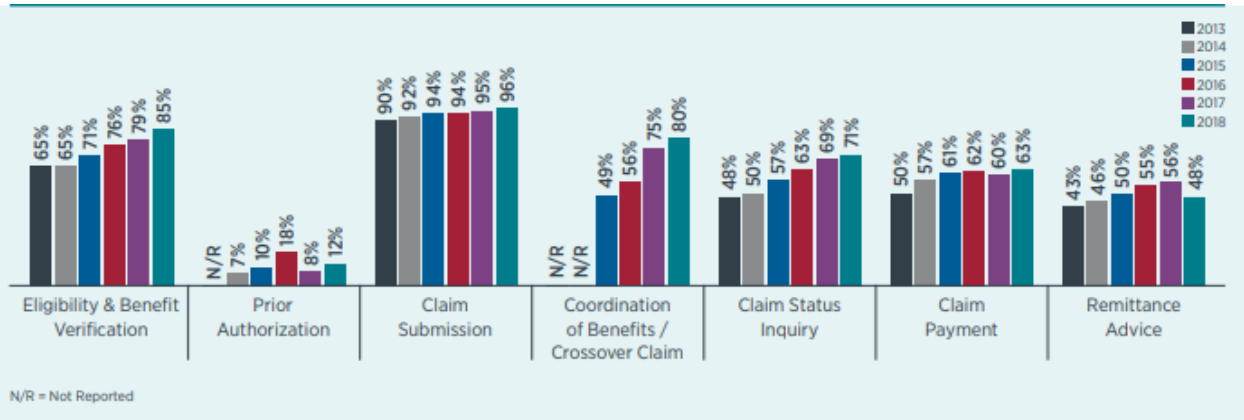
"Also, we proposed that CMS may elect to exempt a provider from the prior authorization process in proposed new § 419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS elects to withdraw the exemption (proposed new § 419.83(c)). We would exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. We anticipate that an exemption will take approximately 90 calendar days to effectuate. We believe that, by achieving this percentage of provisional affirmations, the provider would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is 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. In addition, we propose that we might withdraw an exemption if evidence becomes available based on a review of claims that the provider has begun to submit claims that are not payable based on Medicare's billing, coding, or payment requirements. If the rate of nonpayable claims submitted becomes higher than 10% during a semiannual assessment, we will consider withdrawing the exemption. We anticipate that withdrawing the exemption may also take approximately 90 calendar days to effectuate."

Should Medicare move forward with expanding the number of beneficiary services subject to prior authorization, we believe that this well constructed 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.

Electronic Prior Authorization Standards

Additional opportunities exist to streamline prior authorization by leveraging existing electronic transaction standards and mandating a new standard for clinical documentation transmission. The automation of prior authorization processes will be significantly increased by fully implementing the X12 278 electronic transaction and supporting operating rules, when available. The most recent CAQH Index, released in 2019, 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 2018), eligibility & benefit verification (85 percent in 2018), coordination of benefits/crossover claim (80 percent in 2018), claim status inquiry (71 percent in 2018), claim payment (63 percent in 2018), and remittance advice (48 percent in 2018) are all higher than prior authorization transaction (12 percent in 2018). We urge that CMS, through more aggressive enforcement, ensure that X12 278 electronic transaction and any supporting operating rules are offered and supported by all health plans.



Increased use of the prior authorization electronic transaction would result in significant savings to both plans and providers. Data taken from the 2018 CAQH Index Report, indicates that moving from manual to electronic prior authorizations would net the health plans a savings of $3.47 per transaction. For providers, moving from manual to electronic prior authorization transactions would net a savings of $3.81 per transaction. CAQH estimates that the combined net savings for the industry would be $7.28 per prior authorization transaction (see below).

Transaction	Method	Health Plan Cost	Provider Cost	Industry Cost	Health Plan Savings Opportunity	Provider Savings Opportunity	Industry Savings Opportunity
Eligibility & Benefit Verification	Manual	$4.00	$3.61	$7.61	$3.92	$2.60	**$6.52**
	Electronic	$0.08	$1.01	$1.09			
Prior Authorization	Manual	$3.50	$6.61	$10.11	$3.47	$3.81	**$7.28**
	Electronic	$0.03	$2.80	$2.83			
Claim Submission	Manual	$0.49	$2.37	$2.86	$0.40	$0.92	**$1.32**
	Electronic	$0.09	$1.45	$1.54			
Claim Status Inquiry	Manual	$4.03	$7.12	$11.15	$3.99	$5.23	**$9.22**
	Electronic	$0.04	$1.89	$1.93			
Claim Payment	Manual	$0.50	$2.11	$2.61	$0.41	$0.24	**$0.65**
	Electronic	$0.09	$1.87	$1.96			
Remittance Advice	Manual	$0.54	$2.99	$3.53	$0.48	$1.84	**$2.32**
	Electronic	$0.06	$1.15	$1.21			

4 The CAQH Index cost and saving estimates only account for the labor time required to conduct the transactions. They do not reflect the time and cost associated with gathering information for the transactions. Systems costs are also excluded from the cost and savings estimates.

Electronic Attachments Standards

The current practice for medical groups is to fax, mail, or upload to proprietary websites the clinical data necessary to conduct prior authorizations. By leveraging EHR technology, the electronic attachment standard (X12 275) would automate the collection and transmission of clinical data in support of a prior authorization. Mandated by Congress in HIPAA (1996) and re-mandated in section 1104 of the Affordable Care Act in 2010, CMS has not yet issued a final regulation naming the standard. This standard, in addition to transmitting clinical documentation requirements for prior authorization, can significantly reduce administrative burden by supporting claim submissions, referrals, transitions of care, care coordination documentation requirements, and simplifying other patient data communication needs.

Although CAQH did not collect data regarding the industry use of associated costs of attachments for its 2018 report, it did collect this information for its 2017 report (see below). With no government mandate for health plans to support the electronic attachment standard, as there is with the other HIPAA electronic transaction standards, industry adoption of the electronic attachment was at 6 percent.

Transaction	Method	Health Plan Cost	Provider Cost	Industry Cost	Health Plan Savings Opportunity	Provider Savings Opportunity	Industry Savings Opportunity
Claim Submission	Manual	$0.62	$2.46	$3.08	$0.53	$1.83	$2.35
	Electronic	$0.09	$0.63	$0.73			
Eligibility & Benefit Verification	Manual	$4.36	$2.84	$7.20	$4.29	$2.17	$6.46
	Electronic	$0.07	$0.67	$0.74			
Prior Authorization	Manual	$3.68	$5.75	$9.43	$3.64	$3.20	$6.84
	Electronic	$0.04	$2.55	$2.59			
Claim Status Inquiry	Manual	$4.39	$5.26	$9.65	$4.35	$3.63	$7.98
	Electronic	$0.04	$1.63	$1.67			
Claim Payment	Manual	$0.57	$1.59	$2.16	$0.48	$0.40	$0.88
	Electronic	$0.09	$1.19	$1.28			
Remittance Advice	Manual	$0.50	$4.82	$5.32	$0.45	$3.69	$4.14
	Electronic	$0.05	$1.13	$1.18			
Claim Attachment	Manual	$1.74	$1.68	$3.42	$1.64	$0.51	$2.15
	Electronic	$0.10	$1.17	$1.27			

Health plan cost for a manual attachment is estimated by CAQH to be $1.74. The cost to a health plan for an electronic attachment is $.10 for a total health plan savings per attachment transaction of $1.64. For providers, the cost for a manual attachment is estimated by CAQH to be $1.68,

$1.17 for an electronic attachment, for a savings of $.051 per attachment. Combined, industry savings per attachment transaction would be $2.15.[1]

Creating a national standard for electronic attachments would streamline prior authorization and claim submission processes 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.

Real-Time Prior Authorization Decisions

Adoption of electronic prior authorization will result in significant saving to both health plans and providers. Moving to real-time electronic prior authorization transactions will further reduce cost for health plans and providers by eliminating manual (fax, phone, proprietary payer web portal) provider communications with the plan. More importantly, real-time prior authorization transactions will lead directly to improved patient care by moving the process up front and facilitating physician-patient conversations at the time of service. Combining a prior authorization with cost transparency will permit the physician to discuss treatment options that take into account the expected out-of-pocket expenses to be incurred by the patient.

The initial step will be to create a system, based on established national standards, that enables real-time decisions for routine medical services and medications that do not require extensive supportive clinical documentation and that are approved by health plans at a high rate. 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."

The establishment of real-time prior authorization standards is also referenced in the Office of the National Coordinator for Health Information Technology (ONC) November 2018 report "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs." The report outlines some of the many challenges associated with the current prior authorization processes and offers recommendations on how to improve those processes. On page 14 of the report, ONC recommends the following strategy: "*Leverage health IT to standardize data and processes around ordering services and related prior authorization processes."* Later in the report (page 19) ONC signals its clear support for real-time electronic prior authorization transactions when it makes the following recommendation: "*Support automation of ordering and prior*

[1] Note that CAQH captured data on attachment usage and cost only related to use of the attachment in support of a claim submission, not a prior authorization request. The savings associated with use of the transaction for authorizations would likely be greater as a clinical data submission in support of a claim typically requires less data than what is required to support a prior authorization request.

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 payers."

Fast HealthCare Interoperability Resources (FHIR)

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

- Seek clinician input in the standards development process: The HL7 DaVinci project current list of participants includes some of the nation's largest health plans, EHR developers, and other Health IT vendors. Providers, especially provider associations, are not generally part of the DaVinci process. Without provider involvement, the industry runs the risk of standards being developed that do not meet clinician need and/or do not receive clinician support.

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

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

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

Document Requirement Lookup Service (DRLS)

We are participants in and strongly supportive of the CMS DRLS initiative. DRLS will allow providers to discover prior authorization and documentation requirements at the time of service in their EHR or integrated practice management system through electronic data exchange with a payer system. Once implemented, we believe DRLS will enable practices and payers to achieve three important goals: reduce provider burden, reduce improper payments and appeals, and improve provider-payer communications.

Under DRLS, practices will be able to discover Medicare fee-for-service prior authorization and documentation requirements at the time of service (during the patient encounter) and have the information pushed directly into their EHR or integrated practice management system. Practices will be able to automate the process that answers questions such as "is prior authorization required for the item or service for which I'm about to refer my patient?" and "does the health plan have documentation requirements for the item I'm about to order for my patient?"

As promising as DRLS is, this initiative is currently strictly focused on Medicare Fee-for-Service. To be successful, any automation solution for prior authorization cannot be a "one off" that only supports one or only a few health plans. When limited in scope, these automation solutions force

practices to deploy multiple workflows and adds significant administrative burden to the process. We strongly encourage CMS to expedite the development of DRLS, then take steps to mandate MA plan support of the DRLS process through call letter requirements and work with the Office of the National Coordinator to ensure that DRLS standards are included in the next edition of Certified EHR Technology.

Exploration of Additional Standards

We urge CMS to support and expand on current efforts to identify common data elements and standardize templates that can be implemented by health IT developers to support more automation around prior authorization processes. We also believe that CMS should explore opportunities to incentivize clinicians to adopt technology certified to conduct these electronic transactions according to recognized standards.

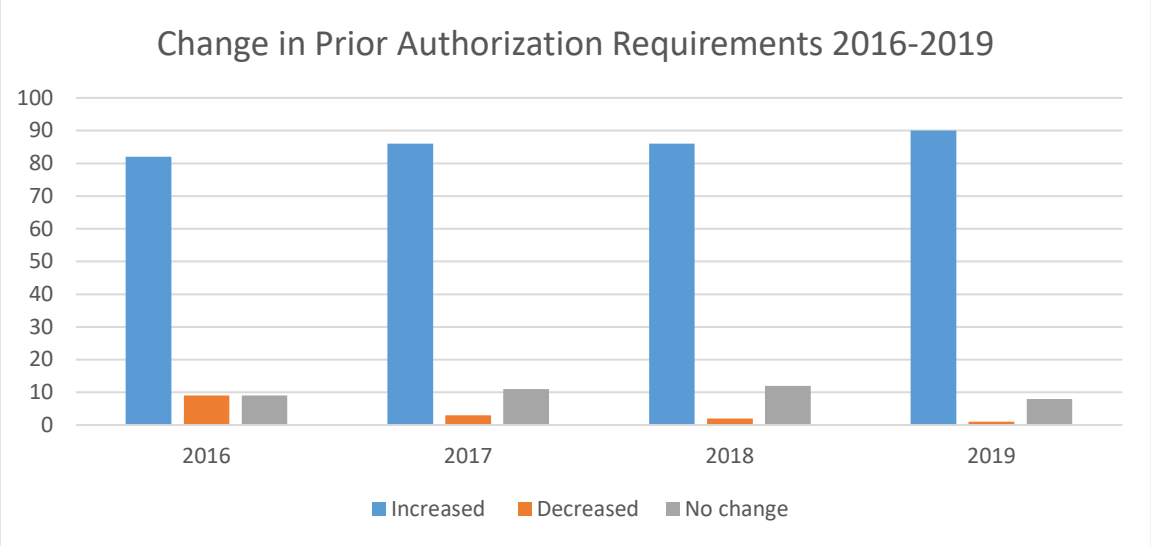
Documentation requirements for items and services associated with prior authorization and ordering for certain medical services are significant sources of administrative burden. We assert that CMS can play an important role in evaluating and addressing administrative processes and clinical workflow factors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

In addition, one of the challenges is getting the healthcare industry to adopt new standards and new technologies. Implementation costs for these upgrades fall directly on the shoulders of physicians. Optimally, practices should receive direct grants or tax breaks that would assist in covering the cost of implementing these new technologies. Alternatively, the Agency could explore innovative opportunities to incentivize practices to move toward more advanced health IT by offering credit through the Promoting Interoperability or Improvement Activities components of MIPS.

Question 14
Are there other issues with respect to prior authorization that CMS should consider?

MGMA Response
Documentation requirements from health plans for items and services associated with prior authorization and ordering for certain medical services are also significant sources of administrative burden. Congress and the Administration can play an important role in evaluating and addressing administrative processes and clinical workflow factors contributing to this burden. While electronic health records, practice management system software vendors and other health IT solutions can also play a role in reducing this burden, prior authorization processes suffer from a lack of standardization and common approaches.

Not only are prior authorization requirements challenging, but MGMA members also report that prior authorization requirements from health plans are actually increasing. In a poll conducted September 17, 2019 with almost 1,000 respondents, 90 percent reported that prior authorization requirements had increased in the past year, 9 percent stated that requirements had stayed the same, and one percent indicated they had decreased. It is important to note that over the past few years, MGMA members have reported through our annual poll a consistent spike in prior authorization requirements (see below).



To put prior authorization into perspective and to compare this task with other administrative burdens facing medical practices, the MGMA regulatory burden survey asked practice executives to rate a number of administrative challenges from not burdensome to extremely burdensome. The survey results were released October 14, 2019 and included responses from executives representing over 400 group practices. Two-thirds of respondents are in practices with less than 20 physicians and 14 percent are in practices with over 100 physicians. Three-fourths of respondents are in independent practices.

Survey respondents identified prior authorization as the leading regulatory burden facing their practice in 2019 (see below).

	Not burdensome	Slightly burdensome	Moderately burdensome	Very burdensome	Extremely burdensome	Very + Extremely
Prior authorization	2%	5%	10%	22%	61%	83%
Medicare quality payment program (MIPS/APMs)	4%	2%	17%	30%	47%	77%
Audits and appeals	1%	9%	23%	35%	32%	67%
Lack of EHR interoperability	5%	10%	20%	33%	32%	65%
Medicare Advantage chart audits	6%	10%	23%	26%	35%	61%
Translation and interpretation requirements	8%	14%	24%	26%	28%	54%
Medicare and Medicaid credentialing	4%	18%	31%	24%	23%	47%
HIPAA privacy and security	8%	15%	35%	28%	14%	42%
Federal fraud and abuse law	17%	22%	37%	18%	6%	24%

Eighty-three percent rated prior authorization as either very or extremely burdensome. Quotes from survey respondents regarding prior authorization included:

- *"We are now staffing 1 Auth coordinator per 3 physicians for MRI, surgery and PT. Millions per year in prior auth staff and other new expenses due to abusive commercial and MA payer rules and regs."*
- *The carry-over of these regs to the private/commercial payers, especially the ones who own Medicare Advantage plans has tremendously increased the admin. burdens for us mostly due to their non-standardization of requests (Prior Auth denials, medical necessity requests, quality/value-based measures and reimbursements, etc.)"*
- " *During the past year we have added 3 new employees to handle just the prior authorization requirements."*
- *" Loss of payments due to the insurance [plan's] inability to take care of their clients should not be the physician's burden to carry."*
- *" Prior authorization has been out of control for years and it is only getting worse. The insurance companies walk away with record profits and no accountability except to their shareholders. All of burden is placed upon the providers/medical offices who continue to see declining reimbursement and increasing overhead costs."*

Prior Authorization and Practice Costs

This lengthy prior authorization process results in significant burden for practice administrative and clinical staff. Practice costs related to prior authorization include:

- Clinical and administrative staff time spent determining if an authorization is necessary for a particular service, test, or medication. Each health plan has their own proprietary medical necessity requirements, thus adding additional burden for practice staff. Some practices report they are forced to have staff assigned to specific health plans to conduct prior authorizations
- Clinical and administrative staff time determining what documentation is required to support the individual plan's medical necessity requirements;
- Administrative staff time transmitting the prior authorization request and support documentation to the health plan (most often via mail, facsimile, or uploaded through a health plan's website);
- Clinical and administrative staff time spent responding to a health plan authorization denial, which may include compiling and transmitting additional clinical documentation; and
- Clinical staff time to engage in a peer-to-peer discussion of the clinical issues.

Conclusion

As CMS looks for opportunities to augment its program integrity efforts, we urge the Agency to avoid the knee-jerk reaction of imposing harsh new prior authorization requirements on clinicians and the beneficiaries they treat. Through leveraging artificial intelligence and capturing utilization data, CMS should be able to identify those small number of clinicians who need additional training or require prior authorization.

As we have emphasized, CMS should seek to reduce the volume of prior authorizations by "gold carding" clinicians who have met cost and quality metrics and by incentivizing the use of CDS software. The remaining prior authorizations should be automated by establishing national standards for electronic prior authorization transactions, electronic attachments, and electronic real-time prior authorization. Finally, CMS should explore new FHIR-based processes for

efficiently moving clinical data from the practice to the health plan. Combined, these approaches will be important steps toward alleviating the crushing administrative burden that practices currently face with prior authorization.

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