



August 12, 2019

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

RE: Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork (CMS-6082-NC)

Dear Administrator Verma:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on how to reduce administrative burden. The agency seeks input regarding opportunities to reduce regulatory burdens on physician practices and make the delivery system less bureaucratic and complex. MGMA has long championed administrative simplification and regulatory relief and strongly supports this Administration's efforts to mitigate or eliminate obsolete and burdensome rules.

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

The agency seeks new recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers. MGMA recommends that CMS carefully review and implement MGMA's detailed recommendations in response to previous requests for information on administrative flexibilities and efficiencies:

- [Comments](#) on 2018 Proposed Quality Payment Program rule (Aug. 21, 2017);
- 2018 Proposed Physician Fee Schedule [comment](#) letter (Sept. 11, 2017);
- Administrative burden [response](#) to CMS and the Office of the National Coordinator for Health Information Technology (ONC) following stakeholder meetings (Feb. 7, 2018); and
- [Response](#) to CMS' RFI on how the Physician Self-Referral (Stark) Law might be improved (Aug. 24, 2018).

In addition to the forgoing comment letters, the following are recommendations to reduce burden on physician practices that we believe could be addressed through regulatory and sub-regulatory action.

Quality Payment Program (QPP)

Repealing the problematic sustainable growth rate and retiring a hodgepodge of quality reporting programs, the Medicare Access and CHIP Reauthorization Act (MACRA) charted a value-based trajectory for the Medicare payment system by valuing innovative, patient-centric and efficient care delivery over check-the-box bureaucracy. However, the Merit-based Incentive Payment System (MIPS) remains an overly complex program that rewards the quantity of reporting rather than the quality of care provided to patients. Additionally, the advanced alternative payment model (APM) pathway is far too narrow. CMS should reset and align the QPP with the original intent of MACRA to support physician practices as they transform the way they deliver care. To further the department's goal to emphasize high-value care and patient outcomes while minimizing burden on eligible clinicians, MGMA offers the following recommendations:

- **Decrease the number of measures across MIPS.** In 2019, group practices' finite resources are spread across at least 16 measures, including a minimum of six quality measures, two cost measures, six promoting interoperability measures, and two improvement activities. CMS should structure MIPS to allow practices to prioritize effective and impactful improvements to patient care, rather than comply with sprawling reporting mandates.
- **Simplify MIPS and reduce redundancies by awarding cross-category credit.** As implemented, MIPS reflects a continuation of the agency's historically siloed approach to quality reporting, consisting of four programs under one umbrella. We appreciate the agency's recent efforts in the 2020 proposed Physician Fee Schedule (PFS) to align reporting efforts through the MIPS Value Pathways participation framework and look forward to more closely reviewing this proposal, as well as providing more detailed comments.
- **Provide clear and actionable feedback regarding MIPS performance at least every calendar quarter,** as recommended by the statute. Without transparent criteria and timely feedback, MIPS is essentially a reporting exercise that enters data into a "black box" only understood by CMS, rather than a useful barometer practices can leverage to drive clinical improvement.
- **Refine the low-volume threshold application to group practices.** CMS should mirror its own policy for non-patient facing eligible clinicians (ECs) and scale the low-volume threshold to the group practice level, exempting a group from MIPS if 75% or more of its ECs individually fall below the low-volume threshold or the group's average Medicare allowed charges or Medicare patient population falls below the threshold.
- **Release critical MIPS information prior to the start of the performance period.** To participate successfully and, more importantly, implement evidence-based actions at the point of care, groups need time to plan and review key program details, such as the quality measure specifications and benchmarks, qualified vendor lists, and clinician and group practice eligibility determinations. Further, if CMS makes changes to measure specifications or benchmarks mid-performance year, MGMA urges the agency to announce these changes when they have the potential to impact MIPS participants.
- **More clearly delineate any changes made mid-year to QPP measure specifications, benchmark files, or other technical documents that may impact current year reporting.** For example, for the 2018 reporting period CMS removed the benchmark for measure 226 from files posted to the QPP website. Since this measure was substantially changed prior to the 2018 performance period, a benchmark should never have been included; however, MIPS reporters should not be expected to reconcile benchmark files with MIPS measure tables

contained in the PFS each year to determine whether files posted to the QPP website are accurate. Going forward, MGMA encourages CMS to be more transparent about inadvertent errors in QPP resources and to more widely publicize these updates through clear communications that explain the policy basis for the change.

- **Continue to improve the QPP website and Resource Library.** We appreciate the efforts CMS has made to improve the QPP website to make it more user-friendly and to create concise guidance documents in the Resource Library. The QPP website and QPP resources constitute a significant improvement over legacy quality reporting program educational materials and webpages, and we commend CMS for these improvements. We encourage the agency to consult with the stakeholder community when making any updates or changes.
- **Prioritize methodological improvements to the MIPS cost performance category before increasing its weight.** We urge CMS to extensively test new episode-based measures, reform the patient attribution methodology, and account for social determinants of health through appropriate risk adjustment. Some strategies that could be used to create a better glide path for new cost measures include the following suggestions for the first year a cost measure is implemented, making them informational; making measures voluntarily and awarding bonus points to those reporters that agree to have them scored, setting higher minimum episode thresholds, and setting a higher reliability standard and increase thresholds if needed to achieve reliability.
- **Improve the actionability of cost measures.** MGMA regularly hears from our members that they are unable to make informed decisions about their cost effectiveness and that their clinicians are unfairly penalized for costs outside of their control, particularly when caring for patients with complex social or medical needs.
- **Stabilize the quality performance category** by maintaining current data completeness thresholds for longer than a single performance year. While we will provide more detailed comments in our response to the 2020 PFS proposal, we urge CMS not to move forward with its proposal to increase the quality measure data completeness threshold to 70% in 2020. Further improvements to the category include eliminating the outcome or high-priority measure requirement, removing the administrative claims measure, and maintaining “topped out” measures. We oppose CMS’ scoring policy to apply a six-point cap to topped-out measures because it adds a layer of complexity; a decile-based system already discourages reporting topped-out measures since a score of 99.99 can equal just 7 or 8 points anyway. Rather than removing measures after 3 years, CMS should be more deliberate about measure removal and ensure the agency is not arbitrarily cutting in half available measures across wide groups of reporters.
- **Avoid adding complexity to the improvement activity performance category** by continuing to allow ECs and groups to attest to completion of activities and not requiring a future minimum participation threshold like the 50% threshold for group practices proposed for 2020 implementation.
- **Further simplify and reduce physician reporting burden in the promoting interoperability category.** For example, CMS should award credit through a yes/no measure attestation and leverage health IT vendors’ reporting on utilization of CEHRT functionality. CMS should propose alternative reporting methodologies, including physician attestation, to simplify and reduce physician burden in future rulemaking. The HITECH Act permits a professional to satisfy the demonstration of meaningful use of CEHRT and information

exchange through attestation. We also believe that HITECH would permit third party-supported physician attestation via “other means specified by the Secretary.”

- **Retain but modify the small practice bonus.** Rather than tweak the bonus on an annual basis, we strongly encourage the agency to codify the small practice bonus for at least three years. Additionally, we urge the agency to apply this bonus to a clinician or group practice’s overall MIPS score, where it would be more impactful, rather than the quality category score.
- **Revise the APM risk standard** to account for the investment and operational risks inherent in moving from fee-for-service to risk-bearing arrangements. CMS has discretion under the MACRA statute to revise the APM risk standard.
- **Work directly with the physician community** to develop new models of care delivery and episode payments and accelerate the APM approval process.
- **Seek opportunities to adopt private sector payment models and patient-centered medical home (PCMH) models as Advanced APMs.** Some of the most innovative and successful APMs are being developed and deployed by the private sector.
- **Make all CMS Innovation Center demonstration projects voluntary.** Gaining experience and support from the physician community for new models is essential to their success. While MGMA is encouraged by recent announcements from CMS creating new APMs such as the Primary Care First, Direct Contracting, and voluntary kidney care models, we do not support mandatory APMs that are untested and lack evidentiary support. While we will be providing more detailed feedback on the proposed Radiation Oncology and End-Stage Renal Disease Treatment Choices models through a forthcoming comment letter, we urge the agency to make these models and any future Innovation Center initiatives voluntary.
- **Create clear and consistent waivers from the Stark and Anti-Kickback Laws for all APMs.** Reducing the burden associated with complying with these regulations is an important incentive for a physician to participate in an APM. The Department of Health & Human Services (HHS) has broad authority to create payment and fraud and abuse waivers, and we encourage CMS to work with the Office of Inspector General to create waivers that allow sufficient flexibility for practices participating in risk-based arrangements.

Prior Authorization

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

Payer utilization-management requirements such as prior authorization require and misappropriate clinician and staff time toward unnecessary administrative requirements, while interrupting or delaying appropriate care. These utilization requirements need to be dramatically reshaped to ensure they are clinically valid and implemented in a way that is transparent, timely, efficient, flexible, and standardized. This message is the crux 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. We urge that CMS closely review these principles with the goal of incorporating as many as possible into revised federal policy. In addition, we offer the following recommendations to improve the current prior authorization process:

- **Curb health plan prior authorization abuses** by fully implementing national standards and operating rules that more effectively automate prior authorization. Ensure that these transactions and operating rules are deployed across all health plans.
- **Explore whether use of clinical decision support (CDS) software** could be used to meet prior authorization requirements. Use by clinicians of CDS software currently approved by CMS for use in the Appropriate Use Criteria (AUC) program could be an alternative to conducting prior authorization requests for advanced imaging tests. CMS should use its authority to require Medicare Advantage to permit CDS consultation, and if the test is deemed to be clinically appropriate, to be a substitute for prior authorization.
- **Leverage and improve existing electronic transaction standards for prior authorization.** The automation of prior authorization processes will be significantly increased by fully implementing the X12 278 electronic transaction and supporting operating rules, when available. According to the most recent CAQH Index, industry use of the 278 transaction in 2018 was only at 12 percent—by far the lowest adoption rate of any of the HIPAA-mandated transactions. We urge that CMS, through more aggressive enforcement, ensure that X12 278 electronic transaction and any supporting operating rules are offered and supported by all health plans.
- **Release the electronic attachments regulation.** Mandated in HIPAA, and re-mandated in section 1104 of the Affordable Care Act, the electronic attachments transaction regulation has the potential to reduce burden by supporting claim submissions; meeting clinical documentation requirements for prior authorization transactions; supporting referrals, transitions of care, and care coordination documentation requirements; and other clinical and administrative situations where patient data needs to be shared efficiently and securely.
- **While continuing to support the current X12 standards, explore the new Fast Healthcare Interoperability Resources (FHIR)-based standards to address prior authorization.** FHIR has the potential to reduce the burden of prior authorization and other administrative tasks. However, we urge CMS to ensure the following issues are considered as FHIR standards and administrative and clinical use cases are being developed:
 - **Seek clinician input throughout the standards development process.** The HL7 Da Vinci project (seeking to implement FHIR-based solutions) current list of participants includes some of the nation’s largest health plans, EHR developers, and other Health IT vendors. Healthcare practitioners, especially associations that represent them, are generally not part of the Da Vinci process. Without involvement from the clinician community, the industry runs the risk of developing standards that do not meet clinician need and/or do not receive clinician support.
 - **Integrate FHIR into the current standards environment.** While these FHIR standards show great promise, there has been considerable investment made by physician group 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 mandatory replacement. For those entities granted a waiver permitting them to pilot use of non-standard transactions such as FHIR to conduct prior authorizations, they should be required to submit a comprehensive report to CMS outlining their implementation process, challenges and costs encountered, and results of the pilot (i.e., return on investment).
 - **Identify administrative use cases.** We believe the Da Vinci project and the Document

Requirement Lookup Service initiative from CMS hold great promise for addressing some critical administrative issues facing practices, not least of all the burdens associated with prior authorization. We urge that the developers of FHIR-based standards closely align their work with those engaged in alleviating clinician administrative burdens.

- **Promulgate standards for Real-Time Benefit Transactions (RTBTs).** RTBT technology for medications presents prescribers, at the point of care, with specific cost and benefit coverage information within their EHR, as well as signaling when a prior authorization is required by the health plan. In addition, therapeutic alternatives along with patient out-of-pocket costs are presented to the prescriber. Armed with this information and working directly with the patient, the best, most affordable medication can be selected during the office visit. This replaces the onerous manual process of retrospective prescription drug cost comparison, which all too often involves back-and-forth phone calls between the pharmacist, prescriber, and patient and can lead to treatment abandonment or higher costs for the patient. It was encouraging to see on May 16 CMS issue its final rule, Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F), which included a requirement that MA plans support at least one pharmacy RTBT product by Jan. 2021. While this is a positive step, we are concerned that none of the RTBT products currently on the market support all health plans and pharmacy benefit managers (PBMs). This lack of standardization will result in practices either not adopting this new technology or being forced into a separate workflow process to access information for a health plan or PBM not included in their RTBT module. In the short term, CMS should encourage the RTBT product developers to work together to create solutions that work with all health plans and PBMs. Longer term, the agency should expeditiously release a national standard for medication RTBT once developed and tested by NCPDP and work with stakeholders to develop an RTBT standard for medical services.
- **Require full transparency of health plan clinical template and prior authorization requirements.** Transparency of health plan clinical documentation requirement templates and plan coverage rules as use cases will result in a significant reduction in administrative burden. CMS, in concert with ONC, should also support and expand on current efforts to identify common data elements and standardized templates that can be implemented by health IT developers to support more automation around prior authorization processes.
- **Reinstate CMS' 2012 policy prohibiting MA plans from utilizing step therapy protocols for Part B physician administered medications.** Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision-making process. We recognize the importance of reducing drug prices for both patients and the healthcare system, however we do not agree with punitive approaches that create barriers to appropriate and timely treatment.

Additional Administrative Simplification Issues

By some accounts, administrative costs in the U.S. healthcare system total in excess of \$300 billion annually, or nearly 15 percent of all healthcare expenditures in the nation. Further, these administrative costs add to clinician frustrations and serve, as in the case of health plan prior authorization mandates and other requirements, as a clear impediment to patient care. When HIPAA was passed in 1996, one of its goals was decreasing the burdensome and costly administrative overhead experienced when clinicians and health plans interact. While the law required the development of a wide range of national standards for critical electronic transactions including verifying patient insurance eligibility, claim submission, prior authorization, attachments,

and remittance advice, for various reasons the industry has still not reaped the full benefit of these standards.

More than twenty years after the passage of HIPAA, several critical standards have yet to be promulgated by the government, while others have not been updated or are simply not enforced. This has led to a continuation of manual administrative processes that, if corrected, could save the healthcare industry billions of dollars. **MGMA urges CMS to engage directly with the leaders of medical groups on the frontlines of the complex healthcare system to identify appropriate administrative standards to reduce excessive costs in the healthcare system and improve coordination among providers and health plans.** To achieve administrative simplification, MGMA offers the following recommendations:

- **Reinstitute the CMS guidance prohibiting electronic payments (e-payments) abuses and unfair business practices.** CMS issued sub-regulatory guidance in 2017 to address several important payment abuse issues. Four critical FAQs that were posted publicly online (22281, 22285, 22297, 22385), now removed from the agency's website, provided critical industry guidance prohibiting unfair business practices such as charging fees for e-payments and forcing practices to accept "virtual" credit cards that carry per-transaction fees. Reinstating this guidance will encourage the widespread adoption of cost-saving Electronic Funds Transfer (EFT) payments and deter health plans and payment vendors from engaging in unfair business practices.
- **Make the AUC program voluntary in 2020 and beyond.** We recommend the agency make the AUC program voluntary and continue offering credit through the Improvement Activities component of MIPS. Extending the voluntary reporting period will permit CMS to gather data on the types of diagnostic imaging services that have been identified by CDSM software as not appropriate. Once sufficient data has been gathered, CMS can work with the appropriate medical associations to educate professionals regarding the ordering of appropriate advanced diagnostic imaging services. This achieves the goal set out in the Protecting Access to Medicare Act of 2014 of reducing the volume of inappropriate services while at the same time not burdening physician practices.
- **Support opportunities for single capture of all HIPAA electronic transaction enrollment information** for all health plans, thus removing the burdensome requirement that clinicians be required to enroll separately with each health plan for each of the HIPAA transactions.
- **Standardize the provider credentialing process across all payers, including Medicare, federal programs, and all state Medicaid programs.** This approach would simplify the enrollment and reenrollment process for all clinicians. By leveraging existing private sector credentialing databases (i.e., CAQH ProView), redundant data input requirements would be eliminated.
- **Streamline the data collection process and improve the accuracy of provider directory information** for Medicare Advantage plans by collecting this information centrally and disseminating it to the plans.
- **Do not require the unique device identifier (UDI) to be reported on the CMS 1500 paper claim form or the X12 837 P or X12 837 I claim forms.** Rather, require that certified EHRs have the ability to capture and query UDIs.
- **Lift the prohibition on HHS working with the private sector on the national patient identifier and/or patient matching approaches.** Effective and safe interoperability is made significantly more difficult without the establishment of an accurate method of identifying

patients and matching medical records. Absent a standardized identifier, false positive matches (records where patients have the same name but are different individuals) and false negative matches (records not matched up as the matching data differs but belongs to the same patient) can lead directly to patient safety issues and negative clinical outcomes.

- **Establish national standards for the use of electronic acknowledgements.** Standards already exist with some health plans supporting them currently. Requiring all plans to support them would decrease administrative burden by signaling to a practice when a health plan or clearinghouse has received a submitted claim and if that claim contains errors.
- **Deem appropriate third-party accreditations or certifications as meeting the HIPAA Security Risk Analysis.** Data security concerns are growing and deeming third-party HIPAA security accreditations or certifications would encourage providers to take a proactive approach to conducting a comprehensive risk analysis and would better protect patient data.
- **Make business associates, such as practice management system vendors, subject to the HIPAA standard electronic transactions requirements,** in addition to their current responsibilities under the HIPAA privacy and security rules. Adoption of the HIPAA transactions would be increased if practice management system vendors were required to support the standards.
- **Support private sector efforts to certify practice management system software.** With PMS software that facilitates use of the HIPAA transactions, practices will achieve increased levels of automation and paper-based burdens will be reduced.
- **Establish a process to certify health plan compliance** with all applicable national electronic data interchange standards and operating rules. To date, CMS has not levied any fines on health plans for non-compliance with the HIPAA electronic transactions, operating rules, or code sets. In the absence of a federal health plan certification process, we urge the deployment of a random audit process to help ensure health plan compliance.
- **Move forward with administrative simplification enforcement.** With no administrative simplification enforcement fines to date levied against a covered entity for non-compliance, there is little reason to submit a complaint on the part of a provider and little incentive to be compliant on the part of a health plan. We urge the agency to:
 - **Initiate random audits of health plans and clearinghouses,** starting with those who have had a formal complaint previously lodged against them for non-compliance with electronic transactions, operating rules, national identifiers, or code sets; and
 - **Publish the names of every covered entity** who either failed a CMS audit, entered into a corrective action plan with CMS, or is levied a fine or reached a settlement agreement with CMS regarding non-compliance with the administrative simplification standards.
- **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.

Physician Reimbursement Policies

In addition to calls for reduced administrative burden and improvements to the QPP, MGMA makes the following recommendations around physician reimbursement:

- **Release sub-regulatory guidance on the communications-based technology services established in the 2019 PFS.** MGMA is pleased that CMS finalized payment for virtual visits (G2012), evaluation of patient-submitted images/videos (G2010), remote patient monitoring (99453, 99454, 99457), and interprofessional consultations (99451, 99452, 99446, 99447, 99448, and 99449) through the 2019 PFS. We support the agency's policy to recognize clinicians and staff for the work they do outside of the traditional office visit and appreciate that the agency took a flexible approach to implementing these codes rather than being overly prescriptive. We request, however, that the agency promulgate sub-regulatory guidance around particular elements of these codes, as the agency indicated it would provide clarification when needed but has declined to do so in sub-regulatory guidance or through the 2020 proposed PFS.¹ For example, MGMA members have reported they are hesitant to use new remote patient monitoring codes because they are unaware of what technological devices would qualify when collecting and transmitting physiological data. Moreover, concerns around patient privacy, a lack of guidance around billing requirements, and fear of being audited have served as a barrier to implementation. While we encourage CMS to maintain a flexible approach to implementation of these codes, we also submit that further guidance around the new communications-based technology codes would be useful for physician group practices that want to change the way they care for patients and work more closely with care teams to achieve better outcomes. MGMA members have pointed out the following concerns in relation to the new remote codes:
 - **Collecting beneficiary co-insurance amounts**
 - MGMA members report that the cost to create, transmit, and collect patient co-insurance amounts associated with new communications-based technology codes exceed the amount being collected.
 - Medicare beneficiaries may recognize the utility of receiving these services yet decline them due to the costs.
 - While CMS has indicated in the past that it lacks the statutory authority to waive or eliminate the beneficiary's co-insurance obligation, we request that the agency work with the Office of Inspector General on a waiver policy or seek congressional authority to waive nominal co-insurance amounts.
 - **Interprofessional consultations**
 - Consulting physicians have expressed concerns that it is difficult to obtain consent from patients who they have not previously seen.
 - Given that the CPT descriptor of these codes include modalities for communication between providers (i.e., telephone/internet assessment), these codes may prohibit two clinicians from the same group practice billing for these services.
 - **Remote Patient Monitoring**
 - There remains confusion over what technologies qualify for remote patient monitoring services.

¹ 83 FR 59452, 59576 (Nov. 23, 2018).

- **Improve utilization of chronic care management (CCM) services.** Services such as CCM are a step in the right direction for enhancing Medicare beneficiary care management and preventing adverse events, such as unnecessary hospital readmissions. A Nov. 2018 report commissioned by CMS’ Innovation Center indicated that utilizing CCM services reduced costs by \$74 per beneficiary per month relative to a comparison group over the 18-month period studied. The report found "clear support that CCM is having a positive effect on lowering the growth in Medicare expenditures on those that received CCM services" and that beneficiaries in the CCM program had lower hospital, emergency department, and nursing home costs.² This data tends to show that CCM services have the potential to decrease costs for both the program and beneficiaries, while improving quality of care. Many practices, however, provide this type of care coordination without receiving reimbursement as a result of burdensome administrative requirements. MGMA members cite the requirement to collect beneficiary co-insurance as the most significant barrier; for example, one primary care practice in Alabama reported: “When we try to gain consent from the patient, they decline the service based on copay. In our MSSP, we had a big push to increase CCM – it was unsuccessful for this reason. Any code changes to CCM will only work if we can eliminate the amount the patient is responsible for.” While CMS has indicated that it lacks the authority to waive the 20% co-insurance, MGMA recommends that the agency designate CCM services as “additional preventive services” available under Medicare Part B through its waiver authority outlined in Section 1115A(d)(1) of the Social Security Act. Alternatively, like co-insurance amounts for communications-based technology services, we urge CMS to work with OIG and/or Congress on solutions to eliminate this requirement.

Modernizing the Stark Law

Few, if any, federal regulations affect the structure and operation of physician group practices to the extent of the Stark Law. MGMA has worked with Congress and CMS for almost 30 years in repeated efforts to reduce burden associated with this law. Unfortunately, those efforts have been highly frustrating; with each successive CMS rulemaking under the Stark Law, the regulatory scheme has become more complex, to the point where it is now virtually unfathomable to all but the most specialized attorneys and compliance consultants. Many smaller group practices simply cannot afford these resources, and in any group practice, each dollar devoted to them is a dollar diverted away from efforts to provide better patient care. Specifically, CMS should develop policy to:

- **Protect value-based payment arrangements.** MGMA recommends CMS create a single, overarching compensation exception for APMs and innovative clinical and financial arrangements. We encourage CMS to work with OIG to create a companion safe harbor under the Anti-Kickback Statute. We do not recommend changes to the regulations implementing the Stark Law’s ownership ban.
- **Remove regulatory barriers.** To provide effective regulatory relief, CMS must standardize compliance requirements and eliminate the numerous conflicting requirements placed on healthcare providers. Though existing exceptions to the Stark Law’s prohibitions are numerous, they contain complex criteria and esoteric terminology that are subject to regulatory interpretation and factual determinations that open the door to inadvertent noncompliance, particularly in the context of innovative arrangements. Any action must be

² Evaluation of the Diffusion and Impact of the Chronic Care Management (CCM) Services: Final [Report](#) (Nov. 2017).

guided by administrative simplification, in line with CMS’—indeed, this Administration’s—repeatedly trumpeted focus on burden reduction and regulatory relief.

- **Support the group practice model.** In addition to changes in Stark Law regulations, it is important that the Administration maintain the flexibility needed to deliver care in the new healthcare system’s delivery environment. In particular, preservation of the Stark Law in-office ancillary services exception is crucial to ensuring physicians can continue to provide coordination of care for patients. We seek assurance from CMS that any reform will account for physician group practices of all sizes and specialties and offer protection to all medical groups that participate in or contribute to innovative payment arrangements as a component of a larger entity.

Conclusion

We appreciate the opportunity to share our comments regarding opportunities to relieve regulatory burden and to offer our recommendations to improve and simplify CMS programs to support groups practices as they transform their organizations. Should you have any questions, please contact Mollie Gelburd at mgelburd@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs