September 11, 2017

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule (Federal Register Vol. 82, No. 139, July 21, 2017)

Dear Administrator Verma:

The Medical Group Management Association (MGMA) appreciates the opportunity to submit comments on the rule, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program," released on July 21, 2017 with file code CMS-1676-P. We look forward to continuing to work with the Centers for Medicare & Medicaid Services (CMS) on the issues in this proposed rule.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, advocacy and education, MGMA empowers medical group practices to create meaningful change in healthcare. With a membership of more than 40,000 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.

In summary, we urge CMS to:

- **Remove administrative barriers to billing care management services** by aligning the codes with the CPT Editorial Panel guidelines, eliminating certification requirements for use of electronic health records, and seeking opportunities to waive patient cost-sharing.

- **Verify the accuracy of data collected during the initial data collection period under the Clinical Laboratory Fee Schedule before applying it to payment** and, moving

forward, notify applicable physician office laboratories in advance of the data collection period.

- **Finalize the proposed implementation delay of appropriate use criteria** (AUC) and extend the education and testing year through at least 2019.

- **Hold clinicians harmless from 2018 penalties under the largely obsolete PQRS, Value-Based Payment Modifier (VM) and EHR Incentive Program (Meaningful Use) programs** if they demonstrated a clear attempt to participate in these programs in 2016 by successfully reporting at least one measure.

- **Clarify eligibility requirements for furnishing care under the expanded Medicare Diabetes Prevention Program** and allow physician group practices to furnish these services virtually.

- **Implement MGMA's detailed recommendations in response to the Request for Information on CMS Flexibilities and Efficiencies** to significantly decrease unnecessary regulatory paperwork and improve the quality and efficiency of healthcare delivery in this country.

- **Use the results of MGMA's regulatory burdens survey as a tool to help provide regulatory relief for medical group practices** (see attached).

Misvalued code target

CMS proposal: Due to laws passed in recent years, CMS must meet annual targets for reductions in PFS expenditures by adjusting the RVUs of codes identified as misvalued. For 2018, the annual target is 0.5%. CMS estimates the net readjustment to misvalued codes in 2018 would be 0.31%, falling below the 2018 annual target and triggering a requirement to lower the conversion factor by the difference between the net adjustment and the target. If finalized, the conversion factor would be reduced by 0.19%.

MGMA comment: We recognize the challenge of meeting the 0.5% misvalued code threshold established by Congress and were disappointed the agency missed the targets in 2016 and 2017 due to its narrow approach, thus decreasing overall Medicare physician payments. MGMA continues to suggest a broad approach that fully and accurately accounts for payment changes due to misvalued codes under the PFS and allows the agency to more easily meet the target. It would be unfortunate if CMS diminished the 0.5% update under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for the third year in a row by taking a narrow approach to the misvalued code target.

Evaluation and management (E/M) guidelines

CMS proposal: CMS believes the E/M guidelines are outdated and proposes a multi-year effort to update the guidelines, reduce administrative burden on physician practices and better align E/M coding and documentation with the current practice of medicine. The agency seeks input

regarding reducing or eliminating guidelines for documenting history and medical exam and placing greater importance on medical decision making and time to determine the appropriate level of E/M visit code.

MGMA comment: MGMA agrees there is significant opportunity to eliminate needless documentation requirements for billing an E/M visit code and to reduce ambiguity about the appropriate level of E/M service. We believe CMS should simplify and clarify the coding guidelines for these physician services so that they transfer into clinical practice. Both the 1995 and 1997 guidelines leave significant room for interpretation, resulting in disagreements among coding experts and physicians about the appropriate code in certain circumstances. Not only are the guidelines overly complex, but they were also established prior to physician practices' adoption and use of electronic health records and other health information technology platforms. We encourage CMS to engage stakeholders, including physician practice administrators, in a transparent process to realize our shared goal of reducing ambiguity in and modernizing the E/M guidelines.

During this process, CMS should heed MGMA member concerns about moving to a time-based approach to billing E/M services, as it may fail to capture the nuances of many of the physician-patient counseling and interactions reflected in the wide array of office visits billed as an E/M code. This approach would not properly reflect the complexity and medical decision-making inherent to providing these services. Although there is ample room to reduce paperwork that does not move the needle on high-quality health care and reduce the administrative complexity of billing these services, we caution against using this initiative simply as a disguised means to reduce reimbursement for physicians. As Medicare transitions from fee-for-service toward a value-based system and physicians take on more accountability for their resource utilization, the cognitive care furnished during these services – often the bedrock for the physician-patient relationship – has increasing importance. Therefore, this effort should be part of a broader initiative to accurately reimburse physicians and other health professionals for the work furnished during E/M visits.

Care management services

CMS proposal: CMS proposes to adopt CPT codes for 2018 to replace the G-codes it established for several of the care management services finalized last year. The agency also seeks input about how to further reduce burden on reporting practitioners for care management services, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes.

MGMA comment: MGMA continues to support CMS' efforts to support delivery reforms requiring centralized management of patient needs and extensive care coordination among providers, often on a non-face-to-face basis across an extended period of time. We believe these payments are particularly vital in the context of the forthcoming transition to the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs), as both programs rely on physician fee schedule payment as their foundation. Unfortunately, however, many practices have been prevented from receiving reimbursement for them as a result of burdensome administrative requirements to be eligible to furnish these services. We were pleased CMS

revised a number of requirements for these services in the 2017 Physician Fee Schedule final rule to allow more practices to provide these services to Medicare beneficiaries.

To further improve access to these services and remove barriers to billing care management services, such as chronic care management (CCM), MGMA urges CMS to make three additional modifications to the CCM scope of service requirements. First, the agency should provide additional flexibility to obtain beneficiary consent by removing the requirement to obtain consent as part of a face-to-face visit, including an Annual Wellness Visit, Initial Preventive Physical Examination or face-to-face E/M service. While CMS proposes to remove the required initiating visit for patients who have been seen within the last year, we believe the agency should expand upon this proposal by removing this requirement for all patients. The conversation initiating CCM and discussing beneficiary consent could easily be done over the phone where a care coordinator would walk the patient through the beneficiary consent form, after which the patient could either mail a signed copy of the form, or log into an online patient portal to provide their consent. Ultimately, there could be a variety of ways in which medical group practices could adequately explain the service and discuss beneficiary consent. CMS should provide flexibility to those who may have creative ideas for how to engage patients and begin furnishing CCM. Consequently, we urge CMS to remove the face-to-face requirement for obtaining beneficiary consent.

Second, CMS should remove the requirement that CCM services be furnished using, at a minimum, the edition(s) of certification criteria acceptable for the EHR Incentive (meaningful use) Program as of December 31 of the calendar year preceding each CCM payment year. Purchasing and implementing an EHR demands considerable financial and administrative resources, and a high-quality EHR may serve an organization's needs for many years, even if it is not certified to the most recent government certification criteria. While an EHR can be an asset to furnishing this service, it is unfortunate to prevent beneficiaries whose providers do not meet specific EHR certification requirements from accessing CCM services. We urge CMS to remove the requirement for a specific level of EHR certification.

Third, CMS should use its demonstration authority to test a similar service without the cost-sharing element, evaluate patient satisfaction and access, and if successful, bring the data to Congress for a legislative remedy to allow for expansion of the model that removes any patient cost-sharing element. Assuming an average national reimbursement rate of $42, the patient copays amount to approximately $8 per month. Billing this co-payment creates confusion as beneficiaries are not accustomed to paying for services without a face-to-face component, and it is difficult to explain the return on investment through timely care interventions that may prevent more costly hospital or emergency department visits down the road. In addition, the administrative costs of monthly collections may deter some practices from billing this service altogether. Further, CMS will largely reap the financial savings of the service through reduced reimbursement for avoidable complications, readmissions, and emergency department visits. We urge CMS to explore avenues within its statutory authority and seek expanded authority to eliminate the patient cost-sharing element of CCM and similar care management services.

MGMA also supports alignment of the CMS requirements and CPT billing guidelines, and we urge CMS to finalize its proposal to adopt the same scope of service requirements as CPT. Use

of CPT codes creates consistency across the industry and reduces inadvertent billing inaccuracies.

Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule (CLFS)

CMS proposal: CMS solicits feedback from applicable laboratories on experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods established by the Medicare Clinical Diagnostic Laboratory Tests (CDLT) Payment System Final Rule on June 23, 2016.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) required CMS to revise the Medicare reimbursement methodology for services furnished under the CLFS, based on data submitted by applicable laboratories that report commercial payer pricing data. CMS finalized a data collection period of Jan. 1 through June 30, 2016 and a corresponding reporting period from Jan. 1 through March 31, 2017. Under the final rule, beginning on Jan. 1, 2018, the payment amount for a test on the new CLFS will be equal to the weighted median private payer rate for each test.

MGMA comment: Physician office laboratories (POLs) reported significant difficulty in determining who qualified as an applicable laboratory required to collect and report data, what pricing data needed to be reported, and how the revised CLFS would impact business. Challenges resulting from this new mandate were exacerbated by the fact that CMS finalized a retrospective data collection period, declined to notify reporting entities of their obligations, did not provide adequate outreach and education, and did not allow enough time for reporting entities to verify and validate collected information.

CMS finalized that, while an applicable laboratory would be defined at the national provider identifier (NPI) level and revenue thresholds would apply to a laboratory's NPI, reporting would be performed by the TIN level entity (42 CFR 414.502). Although CMS estimated that only 5% of POLs would be responsible for reporting, the number of POLs that had to collect and analyze data was much larger because group practices needed to determine whether they were subject to reporting requirements. Unfortunately, CMS did not notify POLs whether they were responsible for reporting and the agency gave ambiguous definitions of an "applicable laboratory," which left many laboratories in doubt as to their status.

In particular, in a CMS FAQ document revised as late as March 9, 2017 (just 22 days before the finalized reporting deadline), CMS provides: "although a laboratory must have its own NPI, the group practice could also be assigned the same NPI as the laboratory. In other words, the laboratory's NPI doesn't have to be unique to the laboratory. If the laboratory and group practice are both assigned the same NPI and the group practice bills for its laboratory's services, then in essence, the laboratory's services are being billed under its own NPI" (FAQ 2.12). This is in apparent contrast to FAQ 2.14: "if the laboratory has not been assigned an NPI, the laboratory does not qualify to be an applicable laboratory. In other words, in order to qualify to be an applicable laboratory, the CLIA certified laboratory must be assigned an NPI and have its services billed to Medicare Part B under that NPI."

MGMA members with POLs reported they "could not even make it through the first step of determining whether or not [they needed] to report" and that CMS guidance was "extremely confusing" with "multiple ambiguous criteria related to Medicare revenue, NPI#, tax ID#, etc." One member said: "I have listened to the webinar and have read all of the CMS published materials on this topic. I am still struggling to understand if we have to report this information and how to report it." The consequences of arriving at an incorrect determination were significant: failing to report or misrepresenting data could result in civil monetary fines of up to $10,000 per day, per omission, but voluntary reporting was prohibited.

POLs that determined they were subject to reporting requirements informed MGMA that collecting and reporting accurate private payer pricing data proved to be exceptionally difficult, despite expending substantial resources, due to a compressed timeframe and retroactive data collection period, insufficient guidance on what data to report and how to submit it, and issues extrapolating tremendous amounts of pricing data. There were reports that partial payments were inadvertently reported to CMS as a total payment. For example, one POL submitted only the allowed amount of all lab tests, irrespective of any cost-sharing amounts, as the final payment rate. Other members reported difficulty determining whether to report once per CPT code per payer; how to account for tests covered by a primary, secondary, or even tertiary payer; and whether to report applicable information based on the data of service or date of payment. MGMA emphasizes that we are not asserting that applicable laboratories failed to utilize best efforts to submit accurate data; instead, based on what we have learned, for most applicable laboratories, the retrospective data collection constituted an impossibility.

In consideration of member and industry feedback, MGMA has strong concerns that the integrity of the data for calculating payment rates is not accurate given that the data collection period was retrospective, pricing data is incomplete and excludes all hospital labs and virtually all POLs, and the methodology to aggregate each clinical test payment is not clear or transparent. The lack of data integrity does not reasonably reflect congressional intent to establish a correct weighted median for each test on the CLFS and moreover, may result in many clinical laboratories being forced to close. The foregoing underscores the importance of validating data to ascertain whether payment calculation is correct, and to do so in a transparent manner. Building a new payment structure from flawed materials will only result in inaccurate payment rates for clinical laboratories, which undermines the very intent of PAMA and impairs the infrastructure of point-of-care testing.

Laboratory testing furnished at the point-of-care, such as in a physician's office, enhances patient-centered care and outcomes while also decreasing the costs of care coordination and administrative processes in the health care system. Particularly in light of HHS' goal to move toward value-based delivery of healthcare, it is in the agency's interest to continue to support the group practice model, including point-of-care lab testing, which complements a wide range of physician services under one roof in a manner that is seamless to patients. Moreover, point-of-care testing is far more than just a convenience to patients; it has the potential to save lives.

Without immediate action, CMS will implement a new payment system on Jan. 1, 2018, potentially based on flawed and incomplete data, that is likely to impact the availability of

essential laboratory services in communities across the country. We recommend CMS implement the following steps:

1. Publish preliminary CLFS rates for CY 2018 as soon as possible, as the agency indicated it would do in September, in order to provide medical groups and component laboratories time to prepare for any potential disruptions to care delivery resulting from potential significant cuts.
2. Issue an interim final rule to:
    a. Modify existing regulation and provide that CMS will conduct market segment surveys (on reference laboratories, POLs, independent laboratories, and hospital community laboratories) to validate and adjust the final amount calculated based on the data collection to ensure congressional intent achieved that payments reflect private market payments.
    b. Allow pricing to proceed as planned on Jan. 1, 2018, based on data collection and submission under the existing rule **only for**:
        i. Sole source clinical tests since the data submissions are reasonably expected to be accurate given the limited test menus and the final amount calculated easily validated by the sole source clinical laboratory.
        ii. Any additional clinical tests where factors establish high data integrity and transparency of private payer payment calculation.
    c. Delay pricing updates for all other clinical tests until market segment surveys conclude and final amounts calculated based on the current data collection are either validated or adjusted based on the market surveys.
3. For future data collection periods, which must occur every three years, MGMA strongly urges CMS to modify its approach to collecting private payer pricing information. The agency should utilize the least burdensome option to identify private payer rates across all labs, which might include sampling a geographically diverse set of POLs, requesting contracted rates for the most common Medicare lab services, or surveying private payers about the rates paid to labs. At the very least, the agency must take steps to clarify the definition of an applicable laboratory and permit excluded laboratories to voluntarily report to improve accuracy of the agency's calculation of the prices paid for lab services across various settings.

Appropriate use criteria (AUC) for advanced diagnostic imaging services

CMS proposal: Under PAMA, CMS must establish a program that denies payment for advanced diagnostic imaging services unless the ordering professional adheres to AUC using a qualified clinical decision support mechanism (CDSM). CMS proposes to delay the start date until Jan. 1, 2019. This first year would be an educational and testing year, during which professionals must consult AUC using a qualified CDSM when ordering applicable imaging services and furnishing professionals must report consultation on the Medicare claim, but claims denial would not begin until 2020. CMS expects a voluntary reporting period to begin in July 2018 and would incentivize early adoption by providing improvement activities credit under MIPS.

To implement AUC reporting requirements, CMS proposes claims processing instructions. Namely, the agency plans to establish a set of G-codes to describe which qualified CDSM was used by the ordering professional, as well as a series of modifiers to identify adherence to AUC

or exceptions, including for professionals who qualify for a significant hardship. CMS seeks comment on how to include this information on claim forms.

The agency proposes to modify its policy on hardship exceptions for ordering professionals to align with the ACI component of MIPS. CMS proposes to exempt from AUC any professional who is not required to report for ACI in MIPS, but would continue to maintain a separate hardship process under the AUC program for those who report for ACI.

MGMA comment: We continue to have ongoing concerns about the administrative and financial burdens practices will face when trying to comply with new AUC requirements. First and foremost, the authorizing legislation was passed prior to the Medicare Access and CHIP Reauthorization Act of 2015 and does not account for the duplicative work of AUC and the Quality Payment Program (QPP). For instance, CMS discusses the identification of outliers who order and furnish imaging services that may not be medically necessary and appropriate, yet the agency is simultaneously identifying and penalizing outliers in Medicare in MIPS and APMs. In MIPS, physicians and non-physician practitioners will be assessed on the total costs of their care under the cost performance category, and those participating in an APM who exceed their financial benchmarks must either forego shared savings or repay the difference. Why implement this onerous new requirement if the agency is already penalizing high utilization in MIPS and APMs? We urge CMS to delay implementation of the AUC program until after it can study the overlap with the QPP and best determine how to avoid duplicities and burden on providers during a period of massive transition.

Second, this proposal will allow CDSMs to either be incorporated into EHRs or be stand-alone applications. Stand-alone applications could pose both workflow and interoperability issues for practices. These stand-alone applications will create an enormous administrative burden on practices, as duplicative data entry would be required. Additionally, we have concerns that the supporting vendors and applications will not be ready in time to begin this program, especially because EHR vendors will be focusing their efforts on preparing for the new requirements under MIPS. In addition, the industry continues to face challenges related to effective and efficient data interoperability. These new CDSMs will pose a significant financial burden on practices to update EHRs or implement stand-alone applications at the same time they are preparing and upgrading systems to interoperate with other care settings, as well as meet the numerous technology requirements under the QPP.

The agency's proposal to require AUC for all advanced diagnostic imaging, including those not in the priority clinical areas, will require practices to attain CDSMs for all advanced diagnostic imaging services, even as CDSMs are not required to have any AUC other than those in the priority clinical areas. This will lead to practices having to purchase and use more than one CDSM to ensure that all bases are covered. In addition to the financial burden, this will increase administrative burden as clinicians will be required to consult multiple CDSMs.

In conclusion, we support a delay of the AUC program and an education and testing period in 2018. However, we do not believe this will provide sufficient time for medical groups and their vendor partners to prepare, especially in light of the concurrent transition to MIPS and APMs, and we urge the agency to extend the educational and testing year through at least 2019.

PQRS and Meaningful Use Reporting Requirements

CMS proposal: PQRS and EHR Incentive Program (Meaningful Use) quality measure reporting requirements would be retroactively reduced to six measures with no additional NQS domain or cross-cutting measure stipulations. CMS would also relax the previously-mandated requirement that groups of 100 or more eligible professionals (EPs) administer the CAHPS for PQRS survey. Instead, the agency proposes to award PQRS credit to groups that did administer the survey, but would not penalize groups that did not. These proposed changes would not impact the qualified registry measures groups option and would also not apply to the 2015 reporting year, with one exception for groups participating in the Accountable Care Organization (ACO) Secondary Reporting Period if their ACO failed to report on their behalf. CMS notes that if less than six measures were reported, the measure application validity process would still apply.

MGMA comment: Congress recognized when it passed MACRA in an overwhelming bipartisan vote that the existing Medicare value-based purchasing programs affecting physicians—Meaningful Use (MU), PQRS, and Value-Based Payment Modifier (VM) – needed to be streamlined and aligned. We recognize that this Administration has shown an appreciation for reducing administrative burden on practices imposed by government regulations and agree with the agency's logic expressed in this proposed rule that the unnecessary complexity of these programs lead to "difficulty in understanding the requirements to be a satisfactory reporter for PQRS" (82 Fed. Reg. 34099). We appreciate the agency taking an important step in the right direction toward this goal by reducing PQRS and Meaningful Use reporting requirements to better align them with the current MIPS requirements and urge CMS to consider further reducing the regulatory burden on physician practices by holding all group practices and EPs that attempted to report in 2016 harmless from any penalty in 2018. We contend that reducing the requirements after the performance period has already concluded has the potential to create even more confusion for practices struggling to navigate the rules and payment implications of these retired programs, while simultaneously familiarizing themselves with and executing new MIPS reporting protocols. To be successful in MIPS, practices need to have their full attention committed towards meeting this end, and juggling current MIPS requirements while processing retroactive reporting requirements and how they impact their practice may create needless frustration and significant confusion.

Further, the stringent criteria under these past programs stand in stark contrast to the sliding scale scoring approach adopted under MIPS, and additional flexibilities CMS created specifically for the 2017 transition year. One of the critical design improvements Congress included in the originating statute for MIPS was the concept of a "sliding scale" scoring methodology, which diverged from the all-or-nothing approach of the old quality reporting programs under which practices who fell just short of even one requirement would face the maximum penalty and even potentially two penalties simultaneously, as was the case with PQRS and the VM. Recognizing the massive regulatory burden and immense learning curve that switching to MIPS would present, CMS implemented additional, much-needed flexibilities for the 2017 transition year, including setting the MIPS performance threshold at three points and generally instituting a three-point scoring "floor" for quality measures, even those that fall short of data completeness criteria. Because of this, a clinician could report the same amount of data, and would fare very differently under the PQRS and MU as they would under MIPS, even assuming these new

proposals are finalized. For instance, a clinician who successfully reports one quality measure this year would avoid a 2019 MIPS penalty, but that same exact level of reporting a year earlier would incur an automatic 2% penalty under PQRS and an additional penalty under the VM. This strains logic and undercuts the agency's purported goals of reducing administrative burden on practices and easing the transition to MIPS.

For these reasons, we urge CMS to hold harmless from PQRS and MU penalties those clinicians who attempted to report in 2016, i.e., were successful in reporting at least one measure, but were ultimately fell short due to the complexity and magnitude of the reporting requirements. This would align more with the current MIPS requirements for the 2017 performance year and enable practices to devote their resources and energy towards maximizing their success and MIPS, a common goal shared between CMS and physician practices. If the Administration is truly seeking ways to reduce the administrative burden on practices, certainly one of the simplest and most impactful ways CMS can accomplish this is by recognizing the outdated requirements of those programs as inconsistent with the current direction of Medicare physician payment and holding harmless those group practices who attempted to participate but were unsuccessful for any number of reasons.

Value-Based Payment Modifier (VM)

CMS proposal: CMS would reduce the overall scope and size of VM penalties in 2018 based on 2016 performance. For practices who fell short of PQRS criteria, the automatic VM penalty would be cut in half, from 4% to 2% for groups of 10 or more EPs, and from 2% to 1% for group practices of nine or fewer EPs or those consisting of only non-physician EPs. CMS would also hold harmless any practices who fully satisfied the modified PQRS reporting requirements (e.g., six measures).

MGMA comment: MGMA supports CMS' general policy goals of "better alignment and ensuring a smooth transition from the final year of the VM to the first year of MIPS as well as continuing to align the VM with the policies established for the PQRS" (82 Fed. Reg. 34126). We also support the proposal that any EP who avoids a PQRS penalty should be exempt from VM penalties. We reiterate our earlier point that any clinician who made a reasonable attempt to participate in PQRS but fell short due to the onerous requirements should be exempt from both PQRS and VM automatic penalties.

MGMA appreciates CMS' recognition that VM penalties are too steep and supports reducing them. However, we contend this policy does not go far enough in supporting the agency's stated goals of ensuring a smoother transition to MIPS. The VM uses different methodologies for evaluating performance and levying payment adjustments than MIPS. Accordingly, the same performance could yield different scores and payment adjustments under the VM as under the cost and quality categories of MIPS. This difference is even more exaggerated by the fact that CMS instituted a general three-point floor for quality measures (which avoids a MIPS penalty) and chose not to weigh the cost category in MIPS for 2017 and proposed to do so again for 2018 due to the fundamental flaws in methodologies and measures, nearly all of which were carried over in some capacity from the VM. In the 2018 QPP proposed rule (82 Fed. Reg. 30049), CMS states its intention to start over and develop a new set of episode-based cost measures due to the

concerns raised over the accuracy of the previous measures. If these measures and methodologies do not meet the agency's standards for MIPS, practices should not continue to be arbitrarily penalized based on similar, and in many cases identical, measures under the VM. The VM is in the past.

Rather than penalizing practices based on outdated and flawed methodologies, CMS should hold groups harmless from quality-tiering VM penalties so they can focus on maximizing future success under MIPS. Importantly, under this proposal, practices who did perform well on cost and quality metrics under quality-tiering would also still have an opportunity to be rewarded and earn a bonus based on the revenue collected from the automatic penalties levied on practices that did not attempt to participate in PQRS.

Physician Compare

CMS proposal: Due to proposed VM policy changes, CMS proposes not to move forward with reporting practice-specific 2016 VM performance and payment adjustment information, including whether a clinician or group was eligible to but did not report PQRS data, to the Physician Compare website as previously finalized. However, the agency would proceed with publishing public files containing non-practice-specific VM data and publicly reporting 2016 PQRS quality data.

MGMA comment: MGMA supports CMS' proposal not to add practice-specific 2016 performance data given the reasoning cited that the data would "only be available for one year," "may not reflect an EP or group's actual performance or payment adjustment" given the proposed PQRS reporting requirement changes and the fact that "this data could be confusing for the public" (82 Fed. Reg. 34103). MGMA has repeatedly emphasized the potentially damaging implications on practices' reputation of publishing performance information from quality reporting programs without proper context patients can understand. Moving forward, we urge the agency to keep in mind these same concerns when it comes to posting MIPS data. Those in the medical industry already have a difficult enough time understanding the nebulous MIPS requirements. It is unreasonable to expect Medicare patients to properly decipher and interpret what this performance data means.

Moreover, we seek to emphasize the importance of providing context for performance data, particularly cases where there may be no data to report because the clinician is excluded from MIPS or a particular performance category, so that it does not reflect poorly on the clinician. We also urge the Agency to prioritize correcting existing misinformation as has been known to be a common issue for the Physician Compare website before adding new functionalities and information to the website.

Medicare Shared Savings Program (MSSP)

CMS proposal: Several new complex chronic care management codes (99847, 99489, and G0506) and behavioral health service codes (G0502, G0503, G0504, and G0507) would be added to the list of primary care services. To reduce administrative burden, CMS would eliminate some of the up-front documentation required during the MSSP initial application and

skilled nursing facility (SNF) 3-day waiver application processes. Additionally, all services reported by rural health clinics (RHCs) and federally-qualified health centers (FQHCs) would be automatically counted as primary care services furnished by primary care physicians and would no longer require attestations.

TINs who violate exclusivity requirements would be allowed to remain on multiple participation lists for the remainder of the performance year, but any services furnished by that TIN would be excluded from beneficiary assignment for any ACO for that year and the ACO would be required to correct any overlap for the subsequent performance year and be subject to additional compliance actions. Finally, the agency proposes two changes to the audit process, including lowering the minimum match rate that would trigger an audit from 90% to 80% (the median match rate in 2016) and affording itself more flexibility in designating measures as pay-for-reporting outside of the formal rulemaking process.

MGMA comment: MGMA supports the regular updating of new codes to the list of applicable primary care service codes. In general, MGMA appreciates CMS' desire to reduce administrative burden where possible by removing certain upfront documentation and attestation requirements and encourages the agency to continue seeking out ways to reduce burdensome paperwork on the front end that would otherwise potentially disincentivize participant TINs or even entire ACOs from joining the MSSP.

While we appreciate CMS' intention to similarly reduce administrative burden on FQHCs and RHCs by automatically designating these services as primary care services furnished by primary care providers rather than requiring an attestation, we have concerns over potential adverse implications in terms of patient attribution. A simple solution would be to establish primary care as the default designation for these services, but allow FQHCs and RHCs to attest otherwise on a case-by-case basis. This would allow for the ability to distinguish specialty services when appropriate without imposing undue administrative burden. A similar solution would also resolve exclusivity issues for specialty practices that employ non-physician providers (NPPs). Because these types of providers do not have an additional specialty designation they are not specifically excluded from patient attribution, even if their practice is focused on non-primary specialty care. As a result, specialty practices may be required to be exclusive to one ACO based strictly on its NPPs.

CMS addressed this concern in the 2015 MSSP final rule (80 Fed. Reg. 32749) but ultimately decides not establish special procedures for establishing that NPPs are performing primary care services and not specialty services. MGMA contends this is a missed opportunity and inhibits specialty TINs' ability to maximize their participation in the MSSP by contracting with multiple ACOs. Instituting an optional attestation process similar to the one we suggest for FQHCs and RHCs in which NPPs could voluntarily attest they furnish specialty services for purposes of beneficiary assignment and exclusivity within the MSSP would be a simple solution to this problem. Alternatively, CMS could extend its policy pertaining to beneficiary assignment and not allow a TIN to trigger the exclusivity requirement solely based on services furnished by NPPs. Providing advanced notice of exclusivity determinations for TINs similar to MIPS eligibility verifications would be another effective and simple way to resolve exclusivity issues for specialty practices and ultimately lead to less ACO exclusivity violations down the road.

Finally, MGMA supports CMS' proposal to lower the match rate that would trigger an audit. However, we believe a match rate of 70% or below would be more appropriate. Further, we encourage the agency to take a more proactive approach toward remedying this problem by providing more frequent assessment of match rates throughout the year so ACOs have an opportunity to correct any reporting issues early on, as well as provide ACOs with an opportunity to correct any reporting errors at year-end if feasible. More often than not, mismatch rates are the result of inadvertent reporting mistakes or coding misunderstandings that could be easily resolved and there is little reason well-intentioned ACOs should not have an opportunity to correct and resubmit data if it is possible.

MGMA generally supports releasing measures and scoring information as soon as possible, and appreciates the agency's case for allowing more discretion to make necessary changes outside of the formal rulemaking process but also cautions the agency that this should only be exercised in rare and necessary circumstances with upmost transparency to the public, ideally with impartial criteria for when a measure would be switched to evaluation on a pay for reporting basis.

MACRA patient relationship categories and codes

CMS proposal: In MACRA, Section 101(f) amended section 1848 of the Social Security Act (the Act) to create a new subsection (r) entitled "Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement." Section 1848(r) of the Act requires the establishment and use of classification code sets: care episode and patient condition groups and codes, and patient relationship categories and codes. The purpose of patient relationship categories and codes is to facilitate the attribution of patients and care episodes to clinicians who serve patients in different roles as part of the assessment of the cost of care. Section 1848(r)(3) of the Act also required an interactive and collaborative process with the clinician community and other stakeholders where CMS posts a draft list of patient relationship categories and codes, solicits comments and then posts an operational list of patient relationship categories and codes on the CMS website.

Based on two rounds of CMS-issued patient relationship codes and solicitation of public feedback, the current proposed set of codes and accompanying modifiers are the following:

Proposed HCPCS modifier	Patient relationship category
X1	Continuous/broad services
X2	Continuous/focused services
X3	Episodic/broad services
X4	Episodic/focused services
X5	Only as ordered by another clinician

CMS proposes to instruct clinicians to include new Level II Healthcare Common Procedure Coding System (HCPCS) modifiers on claims to indicate the physician's relationship with the patient beginning Jan. 1, 2018, but it would not be a condition of payment. In the proposed rule (82 Fed. Reg. 34129), CMS states, "We anticipate there will be a learning curve with the use of the modifiers to report patient relationships, and believe that time would be needed to work with clinicians to ensure they gain experience in using these modifiers. Therefore, for at least an

initial period while clinicians gain familiarity, we are proposing that the HCPCS modifiers may be voluntarily reported on Medicare claims, and the use and selection of the modifiers would not be a condition of payment. Claims would be paid regardless of whether and how the modifiers are included. We would work with clinicians to educate them about the proper use of the modifiers."

MGMA Comment: We appreciate the agency's willingness to solicit industry input to previous iterations of these patient relationship codes. Continued collaboration, however, will be critical if the agency is to achieve optimum efficiency and value from this new code set.

We agree with the agency that there will be a "learning curve" associated with use of these new codes and also agree that their use for 2018 be voluntary and that Medicare claims that do not contain patient relationship codes continue to be paid. We do not believe, however, that this new code set should be mandatory in 2019. As use of the code set will be voluntary in 2018, there may not be sufficient use by the physician community to appropriately determine if the patient relationship codes accurately assign tasks and costs. As well, practice management system vendors, the critical lynchpin for submission of these new codes, may not have their software updated in time to meet a Jan. 1, 2019 start date. We urge the agency to extend the glide path for these codes for a minimum of one additional year to better determine if the new code set is appropriate and to better educate providers and their vendors.

In terms of deployment timing, it is critical that providers and their vendor partners be given adequate time to update and install practice management system software, incorporate patient relationship categories into practice workflow, and conduct training for clinical and coding staff. Once the final patient relationship categories are established, we urge the agency to conduct a rigorous outreach campaign to educate providers, their vendor partners, and others impacted by patient relationship categories, regarding these modifiers and the steps necessary to successfully incorporate them in their revenue cycle workflow.

Reporting the patient relationship categories using modifiers

CMS proposal: CMS proposes that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after Jan. 1, 2018, should include the applicable HCPCS modifiers indicating the physician's relationship to the patient, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). "The use of modifiers to report patient relationships would not change the meaning of the procedure codes used to report items and services and guidelines associated with use of such procedure codes. The modifiers would also not be tied or related to intensity of services (evaluation and management services)" (82 Fed. Reg. 34129).

MGMA comment: While MGMA is generally supportive of the proposed approach to use HCPCS modifiers for identifying the relationship of the clinician to the patient, additional clarification is needed to address expected claims processing issues.

It is imperative that CMS clarify a number of the specifics of how to report the Patient Relationship Code HCPCS modifiers on both the CMS 1500 claim form (paper) and the X12 837 professional claim (electronic). Critical issues include:

- The specific position in the claim where the patient relationship category modifier is to be reported (i.e., first modifier or last modifier reported on the service line).
- How the patient relationship category modifier can be reported if there are more than four modifiers that need to be reported for a single service line.
- On claims that contain multiple line items (i.e., multiple procedure codes), is a patient relationship category modifier required for each service line? Further, should a patient relationship category modifier be required to be included on each service line, there could be a need to include different patient relationship category modifiers on a single claim form. How will CMS handle this issue?
- We strongly recommend the agency establish a threshold for patient relationship category modifier inclusion. We are concerned that if the modifier inclusion threshold is 100 percent and an eligible clinician (EC) participating in MIPS inadvertently fails to submit a patient relationship category modifier for a single line item in one claim, they could receive a score of zero for the cost component of MIPS. We recommend this threshold be no higher than 50 percent.

Use of the patient relationship categories in MIPS

CMS proposal: In MACRA, Congress directed CMS to develop patient relationship categories to more accurately attribute patients for purposes of holding clinicians responsible for the cost of care in MIPS. The cost performance component of the MIPS composite score is scheduled to increase from zero percent for the 2017 and 2018 reporting years to 30 percent in 2019 and beyond. Although CMS would not use the patient relationship category information in MIPS in 2018, the agency does not rule out the possibility of considering this data when calculating the cost performance category of MIPS in the future.

MGMA comment: This is an untried code set with no guarantee that use of the codes will result in accurate assignment of cost responsibility. In our comments to the agency on the earlier patient relationship category proposal, we strongly recommended that a pilot test be implemented to determine if the codes would achieve the desired effect and to guide the industry in how best to assign the codes during the claim development (revenue cycle) process. This type of pilot would be critical if the industry is to gauge the impact of these codes on workflow, coding and technology. The pilot should include participants from a variety of medical specialties, different practice sizes, and various care delivery settings. We also strongly advocate for CMS to consider a transition period for use of these codes for purposes of establishing an EC's MIPS score. This transition period, of at least two years, would consist of calculating the cost performance category of MIPS using both patient relationship categories and the cost attribution approach currently used by CMS. Establishment of an appropriate transition period would help to ensure that costs would be accurately attributed to an EC while building in a contingency process should the codes fail to accurately attribute cost. During this transition period, for purposes of calculating the cost performance category of MIPS, the methodology that generated the most advantageous score for the EC would be applied. Adopting this transition period would be highly beneficial to the industry, providing much-needed time for CMS to

conduct pilots, engage stakeholders and ensure that the most accurate cost attribution model would be utilized.

Finally, implementation of any untested and untried code set could lead to challenges associated with cost calculation accuracy. With the cost performance category of MIPS being so significant, the implications of an incorrect cost calculation will be substantial. We therefore urge CMS to establish a lengthy examination period for providers to review the cost data produced by the agency and a robust appeals process that would permit providers to contest data CMS used to calculate the cost performance category of MIPS. Sufficient time should be afforded to allow ECs and groups to present evidence that counters the agency's determination.

Medicare Diabetes Prevention Program (DPP)

CMS proposal: CMS expanded the DPP, a model aimed at preventing type 2 diabetes in prediabetic individuals, and finalized several components of the program in the 2017 PFS final rule. In this rule, CMS proposes refinements and additional model details, including a maximum payment rate of $810 over three years for furnishing educational sessions designed to change behavior for weight control and on-going maintenance classes, as well as demonstrating sustained weight loss by the beneficiary. CMS also proposes a two-year time limit on Medicare coverage of ongoing maintenance sessions. The agency would delay the start of the model until April 1, 2018. Finally, CMS seeks input regarding a separate demonstration project testing a virtual DPP delivery system.

MGMA comment: MGMA supports expanding the DPP in an effort to enhance beneficiary care and outcomes related to pre-diabetes and particularly urges CMS to allow these services to be furnished on a virtual basis to ensure beneficiaries who may have difficulty driving or finding transportation to the practice are able to benefit from these services. However, CMS must provide additional details regarding how these services would be furnished in a physician office setting to allow stakeholders to properly comment prior to expansion in 2018. For instance, it is unclear whether physicians and group practices who undergo an in-depth Medicare enrollment process to participate in and bill Medicare for services they furnish would be expected to achieve the same Centers for Disease Control and Prevention certification as non-Medicare entities. MGMA would strongly oppose this requirement as duplicative of Medicare's stringent program integrity efforts.

The proposed DPP reimbursement schedule is too low as group practices will incur distinct costs in furnishing these services, such as finding an appropriate setting to host classes and adding and training staff educators. MGMA recommends increasing reimbursement rates. We also urge CMS to limit documentation and billing requirements, which are often a hindrance to providers participating in similar programs, such as CCM.

In addition to a modified and expanded DPP applicable to Medicare providers, we urge CMS to align pre-diabetes education codes and billing requirements with established Medicare diabetes self-management education and training services and increase reimbursement for these services. CMS must also expediently issue guidance regarding participation in the DPP and the Quality Payment Program, including whether the model qualifies as an alternative payment model. We

urge CMS to recognize the collective group practice efforts necessary to successfully implement a program aimed at reducing diabetes among a practice's patient population. At a minimum, group practices participating in the DPP should be recognized in full in the improvement activity performance category of MIPS. CMS must also address how the delayed start date will impact physicians and group practices in the QPP.

REQUEST FOR INFORMATION ON CMS FLEXIBILITIES AND EFFICIENCIES

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. In addition to the following detailed recommendations to significantly decrease unnecessary paperwork and improve the quality and efficiency of healthcare delivery in this country, we are attaching the results of our 2017 Group Practice Regulatory Burden Survey with findings from 750 medical practices.

Simplify the Merit-Based Incentive Payment System (MIPS)

Repealing the problematic sustainable growth rate and retiring a hodgepodge of quality reporting programs, 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, as implemented, MIPS is an overly complex program that focuses on the quantity of reporting rather than the quality of care provided to patients. MIPS continues to take a siloed approach to reporting, as it consists of four distinct components under one broad umbrella. This approach is extremely burdensome and incompatible with Congress's goal of reducing the cost of healthcare. At this critical juncture in Medicare's transition from fee-for-service toward value-based reimbursement, CMS has a chance to align the program more closely with the original intent of MACRA.

We offer the following recommendations to reduce the complexity and burden in MIPS:

1. Maintain a 90-day reporting minimum for all MIPS categories

Ask: Reduce all MIPS data collection requirements to a minimum of 90 consecutive days and permit eligible clinicians (ECs) and group practices to report more data as necessary.

Rationale: In the Quality Payment Program Year 2 proposed rule, CMS proposed to increase the data collection period for the quality category of MIPS from a minimum of 90 consecutive days to one calendar year, significantly increasing the reporting burden on clinicians and groups. As MIPS requires participants electing to submit quality data via registry, qualified clinical data registry, or electronic health record on all patients, including those with commercial insurance coverage, a minimum 90-consecutive day window should provide a reliable data set. Claims-based reporting, which is limited to Medicare beneficiaries, may require a longer data collection window, such as six months. Medical group practices trying to participate beyond simply avoiding a MIPS penalty are struggling to comply with the 90-day data collection and reporting

requirement. Needlessly increasing the reporting requirement does not help translate a higher quality of care, but rather a greater quantity of data reporting. A shorter quality measure reporting period would not only reduce the burden but also allow CMS to shrink the problematic two-year lag between performance in MIPS and the payment adjustment year, increase the timeliness of feedback, and set benchmarks on more current data.

2. Establish quarterly feedback

Ask: Provide feedback about MIPS performance at least every calendar quarter.

Rationale: Although MACRA instructs CMS to provide quarterly feedback to MIPS participants, the agency has yet to implement this critical feature of MIPS. Instead, the agency provides feedback once per year, six months after the close of the performance period. Without 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 quality improvement. MGMA's long-standing position is that CMS should provide ongoing, real-time quality and cost feedback to all impacted physicians and group practices. Equipped with this data, practices would be able to understand their performance, rapidly identify potential areas to improve patient care and make necessary adjustments to successfully participate in MIPS.

3. Delay prematurely measuring cost

Ask: Delay measurement of clinicians and groups on cost until it is operationally feasible to provide regular resource use and attribution feedback on at least a quarterly basis.

Rationale: At this time, many features of the cost performance category are unfinished. Notably, episode-based measures are still being developed, while new patient attribution mechanisms will only begin to be tested in 2018. It is crucial for CMS to understand the complexities of patient attribution and take this opportunity to fully test any new code set to ensure the agency achieves the desired outcome of appropriately assigning costs to providers who have control over the care. There are also several significant barriers to successful implementation of the patient relationship codes, including the need for a nation-wide provider outreach and education effort and the requirement that practice management system software be upgraded and deployed to all physician practices. Moreover, CMS needs additional time to finetune methodological aspects of cost, such as risk and specialty adjustment. Thus, an appropriate ramp-up period is necessary to ensure a smooth roll out of the cost component of MIPS.

4. Increase flexibility in the MIPS scoring system by awarding cross-category credit

Ask: Increase flexibility in the MIPS scoring methodology so reporting one data point counts across MIPS categories.

Rationale: One of the principal goals of MACRA was to consolidate three disparate and complex federal quality reporting programs into one. Yet MIPS continues to take a siloed approach to reporting, as it consists of four distinct components under one broad umbrella. We believe CMS should recognize high-value behavior with cross-category MIPS credit. For

instance, reporting quality measures via EHR should count toward fully meeting the advancing care information (ACI) category, rather than merely toward bonus points. Additionally, there are significant obstacles to measuring performance improvement at this time. Group practices operate in a fluid environment of recruitment, acquisition, expansion and reduction. Even if the group composition remains identical between performance years, CMS would not advise how the group can improve for up to 18 months– a gap that does not allow adequate time to implement actionable changes to drive improvements. Further, the agency has just one year of data to judge improvement.

5. Pause new Certified EHR Technology (CEHRT) mandates

Ask: Permit MIPS and APM participants to continue using EHR products meeting the 2014 Edition certification standards in 2019 and develop a more user-centric certification as outlined in the 21st Century Cures legislation.

Rationale: Although the 2018 Quality Payment Program (QPP) proposed rule would allow use of 2014 Edition CEHRT in 2018, CMS is expected to mandate all QPP participants move to a newer CEHRT product in 2019. Compared to more than 3,000 products certified as meeting the 2014 Edition requirements, less than 100 are currently certified to the new standard, raising concerns about the feasibility of moving every medical group practice in the country to a new technology platform without the prerequisite vendor readiness. Additionally, as discussed later in this letter, the current Office of the National Coordinator for Health Information Technology (ONC) certification is undergoing an overhaul, as Congress recognized in the 21st Century Cures Act that the certification program must incorporate user-centered design and focus more on facilitating interoperability. It is therefore appropriate to pause the anticipated government mandate requiring group practices move to a new ONC-certified product until HHS has established a more sustainable, end user-focused certification approach.

6. Add hardship exceptions for uncontrollable circumstances

Ask: Establish MIPS hardship exception categories for circumstances outside the control of a group practice or EC that hinder performance, such as third-party vendor submission problems.

Rationale: CMS has made minor improvements to the definition of qualifying hardships so physicians and group practices are, through no fault of their own, unable to successfully participate in MIPS, such as when their EHR product becomes decertified. Despite this progress, CMS has not recognized similar circumstances where a third-party intermediary is unable to submit data to CMS through no fault of the physician or group practice. It is unfair to penalize a physician or group for the behavior or failure of a vendor.

Expand advanced alternative payment model (APM) opportunities

MGMA supports CMS' goal of driving more clinicians and practices into Advanced APMs as a more dynamic approach to value-based reimbursement compared to the one-size-fits-all approach of MIPS. However, we feel participation in APMs is currently stifled by a number of unnecessary qualifying restrictions in current models, overly stringent risk criteria, and a less

than effective onboarding policy for establishing new Other Payer APMs. We believe there are a few immediate steps the agency should take to expand the Advanced APM pathway, including counting Medicare Advantage APMs as Advanced APMs, setting a more appropriate revenue-based nominal amount standard and formalizing a process and timeline by which HHS would test and approve new Physician-Focused Payment Models (PFPMs). We look forward to continuing to work with the agency to achieve our shared goal of supporting physician group practices as they transform their care delivery from volume-based to value-based in the least administratively burdensome way possible. Specific recommendations are provided below.

1. Lower the nominal (risk) amount standard

Ask: Lower the nominal (risk) amount standard, particularly the revenue-based standard which is currently set at 8% of revenues, and consider other types of financial risk toward this calculation.

Rationale: CMS has not provided sufficient methodology to defend the 8% nominal (risk) amount standard, and we believe this definition far exceeds the "more than nominal" requirement set forth in MACRA and sets an unnecessarily high barrier to Advanced APM participation. In 2017, just six models qualify as Advanced APMs, and two are not currently accepting new applicants next year. Lowering this minimum standard is the most effective way to generate increased Advanced APM opportunities. Practices that would not have been able to participate in an Advanced APM could join new, lower risk models, while more sophisticated practices could continue to join higher risk models which also feature higher levels of reward. Additionally, costs inherent to launching an APM including startup costs, staff training and investment in new technologies can easily exceed millions of dollars by CMS' own estimates, and should be counted towards an APM's nominal (risk) amount standard. Incorporating these risks could lead to many more APM Entities entering this track of MACRA and additional APMs, such as MSSP Track 1 participants, finally being recognized for the very tangible risk they are already assuming.

2. Calculate the nominal (risk) amount standard at the APM Entity level

Ask: Calculate the nominal (risk) amount standard at the APM Entity level, as opposed to the APM level.

Rationale: For APMs that do not expressly define total risk in terms of revenue, CMS proposes to average the Medicare Parts A and B revenue at risk for all APM Entities within the APM and determine whether that amount meets the 8% nominal (risk) amount standard in the 2018 QPP proposed rule (82 Fed. Reg. 30173). This approach could disadvantage smaller APM Entities as setting a universal standard based on average collective revenues would be much higher for smaller APM Entities proportionate to their separate revenues and could be financially untenable. This adverse selection could also lead to the average growing even higher, causing a slippery slope that would drive larger and larger APM Entities from being able to participate.

3. Remove advanced APM restrictions

Ask: Remove unnecessary restrictions that prevent APMs from qualifying as Advanced APMs. Specifically, remove the clinician size limit and primary care focus requirement on Medical Home Models (MHMs).

Rationale: In MACRA, Congress supported the expansion of medical homes as a cornerstone of value-based payment reform. To date, CMS has not created any medical home alternatives outside of MHMs that would qualify as Advanced APMs and restricts MHMs to those with a primary care focus and fewer than 50 clinicians. These restrictions unnecessarily prevent specialty-focused and larger models that have been successful in driving down costs from qualifying as Advanced APMs and instead force them into MIPS.

4. Count Medicare Advantage (MA) towards the Participation Threshold Medicare Option

Ask: Exercise statutory authority to count MA payment arrangements toward the Medicare Option for the Advanced APM Participation Threshold beginning with the 2019 performance period.

Rationale: Nowhere in MACRA did Congress specifically limit the beneficiary count standard to Medicare fee for service patients. Today, one out of every three Medicare beneficiaries is enrolled in an MA plan. APM Entities serving these patients as part of their Medicare population should be able to count these beneficiaries toward their Advanced APM participation under the Medicare Option through the beneficiary count alternative.

5. Add flexibility to the Other Payer Advanced APM determination process

Ask: Establish an open-ended Other Payer Advanced APM determination process starting with the 2019 performance year during which previously-approved APM determinations would remain in effect if there are no changes, and changes and new requests may be submitted during an annual open submission period.

Rationale: In the 2018 QPP proposed rule (82 Fed. Reg. 30183), CMS proposes to require payers to resubmit Advanced APM determination requests for the same APM every year, even if there are no changes. Instituting open-ended determinations and requiring submitters to notify CMS of any changes would ensure accurate records while reducing unnecessary burden on submitters and CMS itself. Delaying determinations for private payer APMs until 2020 as proposed would prevent clinicians participating in private payer APMs from achieving qualified participant status and sharing in the 5% lump sum bonus which is only available for a short time, potentially undermining participation in Advanced APMs.

6. Permit appeals for Other Payer Advanced APM determinations

Ask: Establish a formal appeals process that provides Other Payer APM submitters at least one opportunity to appeal rejected determinations to a separate branch of CMS.

Rationale: Payers, clinicians and APM Entities invest a significant amount of time, energy and resources to build an APM from the ground up. It would be counter to CMS' goal of driving medicine toward value-based reimbursement for CMS to reject APMs without recourse, potentially for a trivial reason, and not provide another opportunity to resubmit for an entire year. These first few years are particularly critical, given the inevitable learning curve and limited window to earn 5% incentive payments. A wave of rejections may also stymie future development of new APMs.

7. Align Qualified Participant (QP) determinations

Ask: Align the All-Payer QP determination period with the current Medicare determination period and allow potential QPs to indicate to CMS which level to make the determination (NPI, TIN, or APM Entity).

Rationale: Syncing the All-Payer QP determination period with the current Medicare determination period would drastically cut down on the complexity within the QPP and ensure consistency between QP determinations made under the Medicare Option and All-Payer Option. CMS is currently proposing to make QP determinations only at the individual clinician level, which is unnecessarily restrictive and would lead to duplicative calculations and a waste of the agency's time when in many cases participation in private payer models is contracted at the TIN-level. This approach would in fact mirror the established approach to MIPS, where CMS makes determinations at all three levels depending on certain circumstances.

8. Expand PFPMs

Ask: Count the Children's Health Insurance Program (CHIP), Medicaid, and MA APMs toward the definition of PFPMs.

Rationale*:* Expanding the definition of a PFPM to include models with these payers would allow greater opportunities for practices to participate in Advanced APMs, particularly specialties that treat patients outside the traditional Medicare population.

9. Better harness the PFPM Technical Advisory Committee (PTAC)

Ask: Assist PFPM developers, and establish a formal process for testing and implementing PFPMs recommended by PTAC, requiring a response to all PTAC recommendations within 60 days.

Rationale: As pointed out in the 2018 QPP proposed rule (82 Fed. Reg. 30209), HHS is under no statutory obligation to test PFPMs. To date, two proposals were recommended by PTAC for limited-scale testing and more than 60 days has passed without a response from the Secretary. Additionally, CMS retains the unique ability to collect clinical and payment data across payers and, up to this point, has offered limited support in providing PFPM developers with this vital data. Without formal assurances that PFPM developers will receive the data they need to develop these models, or that models recommended by PTAC will ever be tested or implemented by HHS, PTAC will not have the necessary credibility and could eventually cease to serve a

practical purpose as developers grow tired of continuing to invest resources with nothing concrete to show for it.

Enact administrative simplification

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.[1] Further, these administrative costs add to clinician frustration and serve, as in the case of health plan prior authorization mandates and other requirements, as a clear impediment to patient care. When the Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996, one of its goals was decreasing the burdensome and costly administrative overhead experienced when providers 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.

We urge CMS to consider the following opportunities to simplify the administration of health care in the United States:

1. Improve patient identification

Ask: Provide technical assistance to private-sector initiatives in support of a coordinated national strategy for industry and the federal government that promote patient safety by accurately identifying patients to their health information.

Rationale: The absence of a consistent approach to accurately identifying patients has resulted in significant costs to hospitals, health systems, physician practices, and post-acute care facilities, as well as hindered efforts to facilitate health information exchange. Patient identification errors often begin during the registration process and can initiate a cascade of errors, including wrong site surgery, delayed or lost diagnoses, and wrong patient orders, among others. These errors not only impact care in medical practices and other healthcare organizations, but incorrect or ineffective patient matching can have ramifications well beyond a healthcare organization's four walls. As data exchange increases among providers, patient identification and data matching errors will become exponentially more problematic and dangerous. Precision medicine and disease research will continue to be hindered if records are incomplete or duplicative. Accurately identifying patients and matching them to their data is essential to coordination of care and is a requirement for health system transformation and the continuation of our substantial progress towards nationwide interoperability, a

[1] Wikler E, Basch P, Cutler D,"Paper Cuts—Reducing Health Care Administrative Costs," Center for American Progress (2012); Health Costs: Health Spending Explorer, *Kaiser Family Foundation* (2015); Casalino, L. P., Nicholson, S., Gans, D. N., Hammons, T., Morra, D., Karrison, T., & Levinson, W., "What does it cost physician practices to interact with health insurance plans?" *Health Affairs*, 28(4) (2009).

goal of the landmark 21st Century Cures Act.

2. *Standardize electronic attachments*

Ask: Expedite release of an electronic attachments regulation.

Rationale: Transmitting clinical data using administrative transactions is commonplace in today's healthcare environment. Often this data is required to support claim submission and prior authorization requests. Yet even when the claim or prior authorization transaction itself is sent electronically, the supporting clinical documentation must be sent manually, often via fax or mail. The result is costly and inefficient movement of data that can delay payment for medical services and even delay the care patients need. The adoption of these standards for electronic attachments would greatly improve and streamline administrative transactions and improve clinical data exchange. Transitions of care, care coordination and care management, as well as clinical quality reporting would be enhanced with a standard for electronic attachments. Significant stakeholder savings would result from reduction in phone calls, mailings, claim denials and claim appeals. Further, by simplifying and standardizing the movement of clinical data, electronic attachments would serve to support the nation's move to APMs.

3. Prohibit electronic funds transfer (EFT) fees

Ask: Prohibit health plans or their contracted payment vendors from charging fees for the basic EFT transaction.

Rationale: Typically, physician practices in the past would receive a paper check from a health plan for payment of a medical service. In 2012, CMS established a standard for EFT and supporting operating rules. Contrary to the spirit of the 2012 rules and arguably contrary to the law itself, some health plans and their contracted payment vendors have sought to take advantage of practices by forcing the payment of EFT transaction fees typically ranging from 2-5% of the total medical services payment. A recent MGMA poll found that 17% of respondents indicated that their EFT payments from health plans came with a fee. The survey also found that of those who responded yes to receiving fees for EFT payments, almost 60% stated that these health plans were using a third-party payment vendor. Providers are forced to pay these EFT fees as there is currently no explicit prohibition against health plans and payment vendors charging these tolls.

The savings and benefits related to use of EFT for business and consumer payments are well established. For practices, the most common savings are in the ability to automate the reassociation of the payment with the remittance advice, as well as savings in staff time to manually process and deposit paper checks. Health plans are required to offer EFT payments when requested by providers and achieve operational efficiencies themselves by eliminating printing and mailing costs. Beyond the material and administrative time savings for all sides, the time and resources that physician practices spend on billing and related tasks are better spent on delivering health care to patients.

Recently, CMS did issue guidance and included a prohibition against health plans or their contracted vendor charging fees for the basic EFT service. However, after just a few days, the agency removed

this guidance from the CMS website. MGMA is strongly advocating for this guidance to be reissued as soon as possible.

Modernize the EHR certification process

Initial incentives associated with the Medicare and Medicaid Meaningful Use EHR Incentive Program were helpful in facilitating the adoption of EHR technology in physician practices, but excessive regulatory requirements and the subsequent punitive nature of Meaningful Use have caused extreme frustration for physicians caring for patients. ONC implemented an EHR certification process that required software vendors to divert research and development resources away from implementing physician-friendly design to meeting seemingly arbitrary government requirements. This regulatory environment has resulted in reduced physician productivity and additional cost associated with meeting the current CEHRT requirements. Further, despite widespread use of EHR technology, and the outlay or almost $40 billion dollars in federal incentives, the industry has also not yet achieved the level of interoperability that would result in significant clinical and administrative improvements promised at the outset of the federal incentive programs.

We offer the following recommendations to provide greater flexibility in the certification standards to match the health information technology needs of physician practices:

1. Improve health information technology (HIT) certification

Ask: Develop a public-private initiative to improve HIT certification process in line with 21st Century Cures Act and increase provider representation on federal HIT advisory bodies, including practice administrators. HHS should also take the opportunity to improve the alignment of technology with clinical practice and better support the delivery of high-quality care.

Rationale: The current EHR certification does not meet the needs of physician practices, as it is overly focused on meeting reporting requirements. In fact, in the MGMA 2017 Regulatory Burden survey, 87% of respondents reported they have at least a moderate level of concern with federally-mandated EHR certification requirements. To further laudable and achievable industry interoperability goals, ONC needs to significantly overhaul its certification program. Most importantly, ONC should modify its certification program to validate that EHR software not only meets established interoperable standards and quality reporting program requirements, but more importantly, contains the functionality necessary to support the real-world needs of clinicians.

2. Prioritize EHR usability

Ask: Include in any new HIT certification effort developer requirements for enhanced provider usability and user-centered design. To help facilitate this, HHS should engage with smaller physician practices to determine best approaches and field test options.

Rationale: The focus of EHR vendors appears to have been on meeting reporting program requirements, not on developing physician-centric EHR interfaces. This regulatory-focused software

certification environment has resulted in lost productivity, additional cost for practices to retool software to better meet their clinical and administrative needs and arguably had a negative impact on patient interactions. Additionally, there is a high level of physician practice frustration with the lack of usability built in to these systems.

Align the Medicare and Medicaid (Meaningful Use) EHR Incentive Program with MIPS

Ask: Align to the greatest degree possible the three sets of EHR reporting requirements – Medicare Meaningful Use, Medicaid Meaningful Use and ACI under MIPS.

Rationale: The federal government has invested nearly $40 billion to spur the implementation and adoption of EHRs across the nation. While there has been widespread implementation of the technology, significant opportunity remains to retool Meaningful Use to support patient care. We have grown increasingly concerned regarding the government overreach with respect to Meaningful Use. The previous Administration produced a regulatory environment that is clearly contrary to the intent of the originating statute and served to distract clinicians from patient care and stifle vendor innovation.

In particular, there is a growing amount of complexity under three sets of program requirements: one for Medicare hospitals, an even greater set of thresholds for Medicaid providers, and finally an entirely different set of requirements for Medicare clinicians participating in MIPS. Many medical groups include clinicians that participate in their state's Medicaid Meaningful Use Incentive Program, while at the same time other clinicians in the group will be participating in MIPS. CMS should not require these groups to develop and implement two entirely separate data capture workflows. Requiring separate workflows requires the practice to incur the cost of additional software upgrades, staff training, and ongoing administrative overhead. It also creates a disincentive to continuing to participate in the Medicaid Meaningful Use program through to its 2021 end point.

Aligning these programs would go a long way toward reducing the regulatory burden on medical group practices. To this end, HHS should permanently establish a 90-day reporting period, of the provider's choosing, for the Meaningful Use program and the ACI performance category of MIPS. The measures, including electronic clinical quality measures, should also be consistent across programs, and providers should receive credit toward for partial performance, rather than have to comply with all-or-nothing, pass/fail approaches in both Meaningful Use and ACI. Finally, we believe HHS should undertake a systematic review of all Meaningful Use and quality measurement programs, soliciting provider and other stakeholder feedback on what is leading to better care and lowering costs.

Reform the Stark Physician Self-Referral Law

Ask: Pursue legislative authority to repeal the outdated physician self-referral law in its entirety, or at least the compensation "prong" of the prohibition on self-referral, which needlessly interferes with the types of incentive based compensation relationships that can drive quality and reduce cost in Medicare's post fee-for-service environment.

Rationale: No serious effort to reduce regulatory burden in the Medicare program would be complete without consideration of the Federal Physician Self-Referral Law. This statute has become, over twenty-five years and through innumerable CMS rule-makings, a regulatory monster of mind-numbing complexity. Even large health systems with in-house counsel and compliance resources far beyond those available to most physician group practices in MGMA's membership have difficulty understanding every nuance of the regulations, leaving them in a position of regulatory uncertainty and risk. The original Stark law was developed to deal with potential over-utilization of health services in a predominantly fee-for-service environment. Medicare's payment environment today is radically different, and with successful implementation of MACRA, will resemble even less the world for which the Stark law was designed. The Stark law was also intended to be a "bright line" alternative to the intent-based Anti-Kickback statute, but it has never provided the desired clarity and certainty. Repeal of all, or substantial parts, of the Stark law would still leave truly abusive referral relationships subject to the anti-kickback law which, in combination with the False Claims Act, has proven to be a much more effective enforcement tool than it was perceived to be 25 years ago. Even the law's original Sponsor, Congressman Fortney "Pete" Stark of California, observed in recent years that had he known it would turn into a regulatory nightmare and classic "lawyers and accountants relief act," he would never have proposed it in the first place.

We doubt, however, that there are adequate regulatory "fixes" to this problem. Thus, we encourage you to pursue significant legislative relief on this topic in the context of the new value-based payment landscape.

We appreciate your consideration of these comments. If you have any questions, please contact me at agilberg@mgma.org or 202.293.3450.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs

MGMA Regulatory Burden Survey

August 2017

Total respondents: The survey includes responses from 750 group practices with the largest representation in independent medical practices and in groups with 6 to 20 physicians.

1. Rate your level of agreement with the following statement: A reduction in Medicare's regulatory complexity would allow our practice to reallocate resources toward patient care.

Strongly disagree	Disagree	Neutral	Agree	**Strongly Agree**
12%	1%	4%	20%	**64%**

2. Approximately how much did you spend, directly and indirectly, per full-time equivalent (FTE) physician last year to comply with new and existing federal regulations? (e.g., loss of physician productivity, staff training regarding regulations, IT implementation and upgrade costs, consulting and attorney fees, etc.)

Less than $10,000	$10,001 - $40,000	$40,001 - $70,000	$70,001 - $100,000	More than $100,000
13%	38%	22%	13%	14%

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3. How burdensome would you rate each of the following applicable regulatory issues?

	Not burdensome	Slightly burdensome	Moderately burdensome	Very Burdensome	Extremely Burdensome	Very + Extremely
Medicare Quality Payment Program	1%	3%	15%	32%	49%	**82%**
Lack of electronic attachments for claims and prior authorization	3%	7%	16%	25%	50%	**74%**
Payer audits and appeals	1%	9%	21%	29%	40%	**69%**
Lack of EHR interoperability	4%	8%	20%	29%	40%	**68%**
Payer use of virtual credit cards	8%	17%	17%	19%	40%	**59%**
Accessing information via Medicare web portals	5%	15%	27%	24%	29%	**53%**
Translation and interpretation services	9%	18%	21%	21%	32%	**53%**
Payer fees for electronic payments	7%	19%	27%	23%	25%	**48%**
Medicare credentialing	6%	24%	29%	24%	17%	**41%**
Fraud and abuse issues	13%	23%	34%	17%	13%	**30%**

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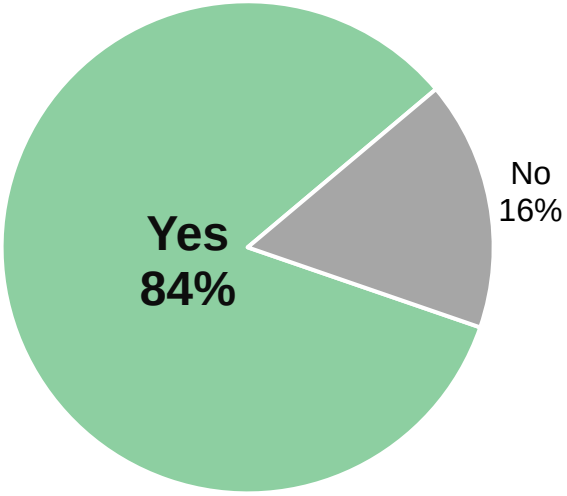
4. Is your practice participating in the Merit-Based Incentive Payment System (MIPS) in 2017?



5. At what "pace" do you plan to participate in MIPS in 2017?

Report the minimum information to avoid a penalty in 2019	20%
Report some data to aim for a modest payment adjustment in 2019	31%
Report the full set of MIPS data to aim for a positive payment adjustment and qualification for an exceptional performance bonus in 2019	**41%**
Not sure	8%

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6. For the following issues, please rate your degree of concern regarding your practice's ability to successfully participate in MIPS.

	Not at all concerned	Slightly concerned	Moderately concerned	Very Concerned	Extremely Concerned	Very + Extremely
Clinical relevance to patient care	2%	6%	13%	29%	51%	**80%**
Relevance to specialty care	4%	6%	12%	23%	54%	**78%**
Overall implementation costs	1%	8%	20%	32%	39%	**71%**
Unclear program guidance	2%	9%	20%	32%	36%	**69%**
Timely feedback	3%	9%	21%	34%	33%	**67%**
Conflicting program requirements	4%	14%	23%	29%	30%	**59%**
Unattainable program requirements	5%	13%	25%	31%	25%	**56%**
Inadequate time for our practice to prepare	5%	15%	30%	29%	22%	**50%**
Vendor readiness	11%	20%	29%	24%	16%	**40%**

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7. How would you rate the complexity of the MIPS scoring system?

Not complex	Slightly complex	Moderately complex	**Very Complex**	Extremely Complex
1%	5%	22%	**38%**	35%

8. Is your practice planning to participate in an Advanced APM in 2017?

Yes, we are participating in an MSSP Track 2 or 3 ACO	6%
Yes, we are participating in a Next Gen ACO	4%
Yes, we are participating in an ESRD model	2%
Yes, we are participating in Comprehensive Primary Care Plus (CPC+)	13%
Yes, we are participating in an Oncology Care model	0.0%
Yes, we are collaborating with a hospital in the Comprehensive Care for Joint Replacement model	0.0%
Not Sure	**40%**
Other	36%

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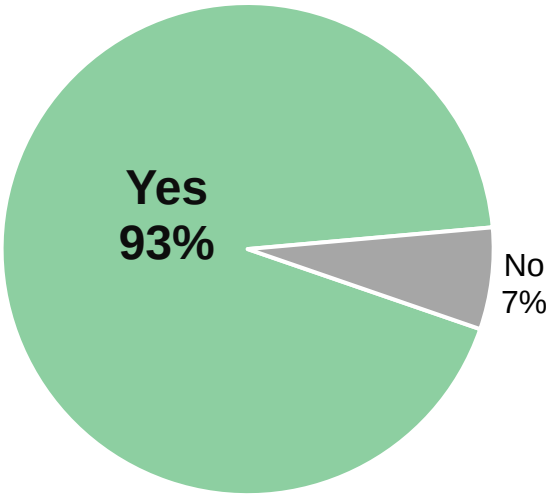
9. How do you view the Medicare MIPS program as implemented to date?

As a government program that supports our practice's clinical quality priorities	9%
As a government program that does not support our practice's clinical quality priorities	**73%**
No opinion	13%
N/A	5%

10. Do you support a single credentialing source for Medicare, Medicaid, and commercial payers in the United States?



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11. Please rate your degree of concern with federally-mandated EHR certification requirements.

Not concerned	Slightly concerned	**Moderately concerned**	Very Concerned	Extremely Concerned
7%	10%	**29%**	27%	27%

Survey Demographics

How many full-time-equivalent (FTE) physicians are in your organization?	
1-5	30%
6-20	**37%**
21-50	15%
51-100	7%
100+	10%
N/A	1%
Which of the following best describes your organization?	
Independent medical practice	**79%**
Hospital or integrated delivery system (IDS), or medical practice owned by hospital or IDS	10%
Medical school faculty practice plan or academic clinical science department	4%
Managed services organization (MSO)	1%
Physician practice management company (PPMC)	1%
Independent practice association (IPA)	1%
Other	5%
Which of the following best describes your organization's specialty focus of care?	
Multispecialty with primary and specialty care	19%
Multispecialty with specialty care only	7%
Family practice	12%
OB/GYN	6%
Orthopedic surgery	7%
Internal medicine	5%
Cardiology	4%
Radiology	2%
Ophthalmology	2%
Other	**37%**

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