Medical Group Management Association®

January 28, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Heath IT and EHRs**

Dear National Coordinator Rucker:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to publication of the "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Heath IT and EHRs." MGMA supports the efforts of the Office of the National Coordinator for Health Information Technology (ONC) to facilitate the deployment and utilization of effective health information technology (IT) across providers and other stakeholders.

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 45,000 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.

As a strong advocate of increased patient safety and improved efficiencies in ambulatory care settings, MGMA has long promoted the adoption of effective, efficient, and affordable health IT. In addition to the clinical benefits associated with health technology, we believe the more efficient availability of clinical data can be leveraged to improve administrative processes resulting in an overall reduction in practice costs.

Passage of the bipartisan 21st Century Cures Act (CURES) creates the opportunity to define and promote the development of improved use of health IT. At the same time, there is an opportunity to leverage health IT to reduce the many clinical and administrative burdens that plague our healthcare system. However, before we can achieve these benefits of health IT, significant modifications to government policy in the areas of quality reporting programs, IT certification protocols, IT standards, and other policy need to occur. ONC's draft report serves as a roadmap for opportunities to reduce clinical and administrative burdens. This roadmap contains four parts: 1. clinical documentation; 2. health IT usability and the user experience; 3. EHR reporting; and 4. public health reporting. With the release of this draft document, ONC has outlined a blueprint that we hope will accelerate adoption of a more effective and efficient health IT environment for physician practices.

Summary of Comments

- **Reduce clinical documentation burden**: While every effort should be made to reduce the burden associated with clinical documentation, the government should not move forward with its current plan to collapse Evaluation and Management (E/M) payment levels.
- **Address prior authorization:** Perhaps the most onerous administrative burden for physician practices, we urge the government to work toward reducing the volume of required authorization requests and increasing automation of prior authorization processes.
- **Publish electronic attachment standards:** Significant burden is associated with manually transmitting clinical information from practices to health plans via fax, mail, or proprietary web portals. We recommend the government release the regulation establishing the X12 275 electronic attachment standard and supporting operating rules.
- **Reduce general MIPS burdens:** We support a reduction in the burdens associated with participation in the Merit-based Incentive Payment System (MIPS). These modifications should include reducing the all-year reporting requirement for the quality component of the program, receiving credit in multiple categories for meeting specific measures, and offering a wide array of qualifying Advanced Alternative Payment Models (APMs).
- **Modify MIPS promoting interoperability (PI):** The PI component of MIPS should be simplified. Deploying 2015 Edition Certified EHR Technology (CEHRT) should qualify for the full 25 points. At a minimum, the current all-or-nothing approach should be replaced with a system that allows clinicians to score partial points from a wider variety of measure options.
- **Extend Stark and Anti-Kickback safe harbors:** The EHR donation exemption should extended past 2021 and the types of technology and services permitted to be donated by group practices, hospitals, and health systems should be expanded to include hardware.
- **Enhance Prescription Drug Monitoring Programs (PDMPs):** We recommend that one of the priorities during implementation of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) is that interoperability between EHRs and PDMPs is required and that clinicians have easy access within their workflow to all state PDMP data.
- **Explore HL7 FHIR:** We support exploring the use of new standards such as Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) for clinical use and administrative transactions. The HL7 Da Vinci and Centers for Medicare & Medicaid Services (CMS) Document Requirement Lookup Service initiatives show great promise in automating a number of onerous administrative requirements. However, physician practices have made great investment in the X12 electronic transactions and should not be mandated to adopt new and unproven standards. Further, clinicians and clinical organizations must be directly involved the FHIR standards development process.
- **Consult with the Physician practice Community**: With the vast majority of all healthcare being delivered in medical practices, the success or failure of health IT initiatives will depend heavily upon the ability of clinicians to efficiently and effectively incorporate technology and standards into their workflow. MGMA encourages the agencies to continue their very positive outreach to this community to ensure that the requirements and concerns of physician practices are addressed.

Comments to Specific Areas of the Draft Document

1. Clinical Documentation

ONC strategy and recommendations:

Reduce regulatory burden around documentation requirements for patient visits

- Continue to reduce overall regulatory burden around documentation of patient encounters.
- Leverage data already present in the EHR to reduce redocumentation in the clinical note.
- Obtain ongoing stakeholder input about updates to documentation requirements.
- Waive documentation requirements as may be necessary for purposes of testing or administering APMs.

MGMA comment:

E/M documentation changes

As Medicare transitions from fee-for-service toward a value-based system and clinicians take on more accountability for their resource use, the cognitive care furnished during E/M services–often the bedrock for the clinician-patient relationship–has increasing importance. MGMA agrees there is significant opportunity to eliminate needless documentation requirements for billing an E/M visit code. We appreciate that ONC is considering the EHR-related burden associated with documentation requirements for patient visits— especially the guidelines for E/M visit codes used by most payers.

In the 2019 Physician Fee Schedule proposed rule (PFS), CMS outlined revisions to E/M documentation requirements intended to reduce clinician burden starting Jan. 1, 2019. Additionally, CMS also proposed coding and payment revisions for new and established patient office visits-applying a single blended payment rate for level 2 through 5 visits. MGMA and other stakeholder groups overwhelmingly supported efforts to reduce documentation burden, but opposed collapsing payment rates, opposed applying the MPPR to same day visits, and expressed concern that add-on code proposals lacked sufficient clarity. In the final PFS rule, CMS aimed to reduce documentation burden beginning Jan. 1, 2019, but delayed change to the coding and payment structure for E/M services (now planning to collapse levels 2 through 4) until CY 2021. CMS finalized the following changes to E/M documentation guidelines that became effective Jan. 1, 2019:

- Practitioners are no longer required to re-record elements of history and physical exam when there is evidence that the information has been reviewed and updated;
- Practitioners must only document that they reviewed and verified information regarding chief complaint and history that is already recorded by ancillary staff or the beneficiary; and
- Practitioners no longer need to document medical necessity of furnishing visits in the home rather than office.

MGMA supports these modifications and endorses the CMS “Patients over Paperwork” initiative’s ongoing efforts to identify opportunities to reduce administrative burden and better align E/M documentation guidelines with the current practice of medicine. However, we again reiterate our opposition to the proposed changes that would collapse E/M payment and RVU amounts.

E/M payment rate and relative value unit (RVU) collapse

ONC references the decision made by CMS in the 2019 PFS final rule to collapse payment and RVU amounts for new and established patients in this draft strategy. We continue to have concern regarding the approach of treating office visits spanning E/M levels 2-4 the same, regardless of a patient's condition or the complexity of the services provided. We recommend CMS work closely with the physician community to analyze E/M coding and payment issues to arrive at workable solutions to reduce documentation burden. MGMA supports the American Medical Association work group of physicians and other healthcare professionals, which is already discussing, in a transparent and open manner, alternatives to the proposal.

As part of this effort, we emphasize our belief that burden reduction will be a product of developing clearer distinctions between levels of the descriptions for office visits. Because the work of creating these distinctions will not be easy, we urge careful consideration of any unintended consequences. We also caution against other policy short-cuts, such as the strategy to merely collapse the distinctions altogether and replace them with ambiguous add-on payments.

MGMA also has reason to doubt the agency's belief that eliminating the distinction between visit levels 2 through 4 would eliminate the need to audit against the visit levels given the absence of any substantive guidance regarding whether the Medicare auditors, including the Office of Inspector General and Recovery Audit Contractors, would follow this instruction. Presumably, there would be some scrutiny of a medical service if billed as a level 4 but documented as a level 2. Prior to moving forward on the unsubstantiated belief that audits would be eliminated, CMS should provide assurance and clarification that auditors would, in fact, recognize this level of medical documentation as sufficient evidence of the medical necessity of an office visit.

Setting the issue of audits aside, we see several gaps in the agency's logic that the proposed payment rate and RVU collapse would "provide immediate relief from the burden of documentation." First, and most importantly, the purpose of the medical record is to promote quality and continuity of patient care. At its core, documentation should reflect clinical findings and knowledge that can facilitate the best possible treatment of a patient. To this end, allowing clinicians to focus on caring for patients and not ticking documentation boxes is a laudable goal. However, we have concerns that relying on nebulous medical necessity guidelines and bare bones medical decision-making documentation will result in an inferior medical record and create problems when patients transition from one provider or care setting to another.

Much of the over-documentation can be attributed to ambiguity in the existing medical documentation guidelines. Although we appreciate the agency's efforts to provide greater flexibility to untether providers from their computers and to provide better care, we have reason to believe the lack of clarity around documentation requirements would do little to address the ambiguity driving much of the over-documentation. Further, CMS itself states in the PFS proposed rule that clinicians and other practitioners would be expected continue to code, and thus document, for medical, legal, and other reasons, according to the CPT level appropriate for the visit, suggesting little change in the real-world documentation of a healthcare encounter. We believe that documenting appropriately for the level of care furnished, as well as for the add-on payment, would likely result in a net increase to documentation requirements compared to the status quo.

In addition, the payment rate and RVU collapse proposal fails to address other factors driving overdocumentation, such as quality measurement requirements, prior authorization requests, risk adjustment considerations, and medical liability concerns. CMS notes "Practitioners could choose to document more information for clinical, legal, operational or other purposes, and we anticipate that for those reasons, they would continue generally to seek to document medical record information that is consistent with the level of care furnished" (83 Fed. Reg. 35836). Without

addressing these broader factors, CMS' proposal will do little to alleviate the "note bloat" associated with over-documentation.

Finally, CMS assumes other payers, including state Medicaid agencies and commercial plans, would follow in their direction, collapsing the payment rates and RVUs for the E/M office visits and thus reducing documentation. Although other payers may be inclined to adopt the lower reimbursement amounts, we think it is unlikely that they would adopt the documentation changes in their entirety. Medicaid and commercial payers currently employ a wide spectrum of policies to interpret medical necessity. Further, we believe the guidelines are not clear and comprehensive enough to be implemented immediately by other payers, suggesting there would be a lengthy window during which physician practices would need to abide by multiple different documentation requirements depending on a patients' insurance coverage. This is simply not sustainable and would add to the current administrative burden faced by practices.

Additional opportunities to reduce documentation and data collection burden
To achieve a reduced level of documentation and data collection burden, MGMA offers the following additional recommendations:

- Exempt clinicians participating in APMs from certain documentation requirements.

- Work collaboratively with provider stakeholders to disseminate best practices for documentation. For instance, limited appropriate use of the "copy and paste" and auto-populate functions within the EHR can ensure records do not become overloaded with extraneous information.

- Support opportunities for single capture of all HIPAA standard electronic transactions enrollment information for all health plans, thus removing the burdensome requirement that clinicians enroll separately with each health plan.

- Streamline the data collection process and improve the accuracy of provider directory information for Medicare Advantage plans by collecting this information centrally (via, for example, a private sector solution) and disseminating it to the plans.

- Ensure better coordination between various government and contractor audit and review programs to reduce duplicative, burdensome documentation requests and disruptions in care.

ONC Strategy and Recommendations:

Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements

- Partner with clinical stakeholders to promote clinical documentation best practices.
- Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models.

MGMA comment:

Modifying clinical documentation requirements is extremely complex, not least of all because it involves clinician behavior as well as health plan business and medical policy. MGMA and other appropriate provider-focused organizations should be convened to discuss how best to tackle the burden associated with clinical documentation. This engagement is critical for the policy outcome to be beneficial to and broadly supported by clinicians**.**

We also encourage ONC, in partnership with CMS, to work directly with Medicare Advantage plans and other commercial payers to seek cross-industry solutions to the burden of clinical documentation. We are concerned that should modifications to clinical documentation requirements be payer-specific (including modifications that only apply to fee-for-service Medicare) the government runs the risk of actually increasing administrative burden.

As part of the effort to revise the documentation guidelines, ONC and CMS should continue to receive wide stakeholder input that includes physician practices and other critical stakeholders to inform future documentation guideline modifications. We concur that a representative task force would be useful, given the widespread uses of medical record information by clinicians of all specialties, public and private payers, EHR vendors, and others. Clinical specialty societies should be requested to provide input to define proper clinical standards for documentation and establish what is required for high quality patient care.

One area of documentation burden that could be addressed is that of clinician credentialing. Medicare and most state Medicaid programs require clinicians to complete a lengthy and complicated proprietary credentialing form. Currently, virtually every commercial health plan received its credentialing data via CAQH ProView, a database that currently includes data on more than 1.4 million providers. Medicare and most state Medicaid programs refuse to participate in this collaborative effort, forcing clinicians to enter the same credentialing information multiple times.

We agree with the ONC call to investigate reducing documentation requirements for purposes of testing or administering APMs. The government should refrain from imposing additional reporting requirements on healthcare providers due to the need for data for model evaluation and other reasons. Finally, we recommend ONC work closely with standards development organizations, industry coalitions, and others to support coordination of multi-stakeholder efforts to advance new approaches to reducing administrative burdens.

ONC strategy and recommendations:

Leverage health IT to standardize data and processes around ordering services and related prior authorization processes

- Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.
- Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers and payers.
- Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.
- Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services.
- Coordinate efforts to advance new standards approaches supporting prior authorization

MGMA comment:

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

Payer utilization-management requirements require and misuse clinician and staff time while interrupting or delaying appropriate care need to be dramatically reshaped to ensure they are

clinically valid and implemented in a way that is transparent, timely, efficient, flexible and standardized. This message is the core of a comprehensive set of 21 principles developed by MGMA and a coalition of 16 other organizations representing clinicians, medical groups, hospitals, pharmacists and patients. We urge ONC to closely review these Principles with the goal of incorporating as many as possible into revised federal policy. The 21 principles are divided into five broad categories:

- Clinical validity: This category includes concepts such as utilization management (UM) criteria being based on up-to-date clinical criteria and never cost alone. This also highlights the need for flexibility to meet patient-specific needs. Principle No. 2, for example, says: "[UM] programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials."

- Continuity of care: This category is designed to ensure that patients' care isn't disrupted by prior-authorization requirements. For example, principle No. 4 says: "Utilization-review entities should offer a minimum of a 60-day grace period for any step-therapy or prior-authorization protocols for patients who are already stabilized on a particular treatment upon enrollment in the plan. During this period, any medical treatment or drug regimen should not be interrupted while the utilization management requirements (e.g., prior authorization, step therapy overrides, formulary exceptions, etc.) are addressed."

- Transparency and fairness: The principles in this category address the need for detailed explanations for denials and full public disclosure of all coverage restrictions in a searchable, electronic format. As an example, principle No. 9 states, "Utilization-review entities should provide, and vendors should display, accurate, patient-specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing."

- Timely access and administrative efficiency: This category includes principles that establish maximum-response times for UM decisions and seek health plans' acceptance of electronic prior authorizations. An example is principle No. 13, which says, "Eligibility and all other medical policy coverage determinations should be performed as part of the prior-authorization process. Patients and clinicians should be able to rely on an authorization as a commitment to coverage and payment of the corresponding claim."

- Alternatives and exemptions: This category includes a call for health plans to offer at least one alternative to prior authorization, such as a "gold card" program. Another option is laid out in principle No. 21: "A provider that contracts with a health plan to participate in a financial risk-sharing payment plan should be exempt from prior authorization and step-therapy requirements for services covered under the plan's benefits."

While the 21 principles were primarily directed to payers and utilization review entities, there are several that could be addressed by better use of EHRs and, as a result, have an impact on EHR and e-prescribing software vendors. For example, principle No. 9 outlines that utilization review entities provide, and vendors display, accurate, patient- specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing.

It is widely believed that the formulary information available to prescribers in the EHR is incomplete, and coverage restrictions aren't always available or displayed. This principle seeks to address the issue from two perspectives. First, to ensure that the payers include complete coverage restriction data in the formulary files provided to the EHRs. Second, to ensure that the

EHR and e-prescribing software vendors have developed their products to accurately display the coverage restrictions.

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

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

Some of the other principles can be enhanced by a new standard that is being developed at NCPDP and companies are piloting that provides patient-specific, real-time formulary and benefit information at the point-of-care (see more information here). As UM entities elect to leverage this emerging technology, EHRs should actively consider incorporating it into their solutions.

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

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

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

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

receive clinician support.

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

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

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

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

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

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

2. Health IT Usability and the User Experience

ONC strategies and recommendations:

Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools and *Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction*

- Better align EHR system design with real-world clinical workflow
- Improve clinical decision support usability
- Improve clinical documentation functionality
- Improve presentation of clinical data within EHRs
- Promote and improve user interface design standards specific to healthcare delivery
- Improve internal consistency within health IT products

- Promote proper integration of the physical environment with EHR use.

MGMA comment:

Clinicians utilize EHRs to perform everyday clinical and administrative tasks, manage their workflows, and participate in federal incentive programs such as MIPS. With EHRs having so many purposes, it is critical that they are navigable, intuitive, and easy-to-use.

Usability is defined by the National Institute of Standards and Technology as the efficiency, effectiveness, and satisfaction with which the intended users can achieve their tasks in the intended context of product use. This definition should assist ONC in establishing a framework for setting usability goals. Efficiency can be measured by the length of time required to complete a task. Efficiency can be measured in absolute terms (e.g., 10 seconds to perform a particular task) or relative to performance with the same task on other systems or on previous versions of the same system.

Efficiency for a task might be compared to a competing application (e.g., ranking applications on efficiency), an absolute standard (e.g., return on investment depends on task times 60 seconds or under), or based on a measured or estimated value for expert performance (e.g., a fully trained expert should be able to perform the task in 90 seconds 90% of the time). Satisfaction consists of a set of subjective measures regarding users' perception of usability and evaluation.

With the definition of EHR usability emphasizing user satisfaction, usability may vary significantly between clinicians, even within the same organization. Personal preferences will determine in some instances how a clinician wants their EHR to perform a certain task, with some finding particular functionalities of an EHR more intuitive and effective than others. Despite this level of variation among clinicians, we believe the industry can identify definitive standards that permit end users to discern usable from non-usable EHR software.

The challenge for ONC will be to incorporate appropriate usability criteria into its software testing protocols. To meet this challenge, it will be important to leverage industry-agreed upon criteria when developing testing protocols. They could include, for example, the criteria developed as part of the EHR User-Centered Design Evaluation Framework from the National Center for Human Factors in Healthcare. These include:

- User-centered design process;
- The number and clinical background of participants;
- Use case rigor;
- Measures of effectiveness, efficiency and satisfaction;
- Effectiveness; and
- Described areas for improvement.

EHR usability is also closely aligned with EHR interoperability. When an EHR system cannot efficiently transmit health data with another system, it becomes less usable because it limits how providers coordinate care. Of particular importance to care coordination and value-based care programs is the flow of data to and from hospital emergency rooms (ERs). ERs have distinct workflow needs due to the time-sensitive nature of the cases they see, and they require an interoperable EHR to efficiently access patient information. Given the many variables that lead patients into an ER, there is possibility emergency providers will need to access health records from a different facility, increasing the challenge and the need for effective data exchange processes. Similarly, to prevent re-hospitalizations, inpatient discharge instructions must be efficiently transmitted to the primary care clinician or other clinician overseeing the patients care for timely follow-up.

In these use cases, the usability of the EHR software is critical if there are to be no logistical barriers to the movement of data. Too often, we hear from clinicians that their software is cumbersome and acts as a deterrent to the exchange of patient data. Systems must be intuitive, operate effectively within the clinician workflow, and be customizable to meet the needs of individual clinicians.

The current EHR certification program, as implemented by ONC, is intended to set the baseline usability standards that EHRs must meet so that physician practices and other healthcare providers can confidently adopt and use the technology to meet requirements in certain federal programs. Under 2015 CEHRT, requirements for EHR usability mandate that EHR developers take two actions. First, developers must document how they consider the needs of clinicians, nurses, and other clinicians in developing the product submitted for certification. Known as user-centered design, this process focuses on understanding the needs of the intended users throughout software development and deployment to improve usability of the product. Second, EHR developers must attest to and describe their user-centered design process in this documentation.

These tests purport to measure efficiency, effectiveness, and satisfaction as clinician's complete representative test cases of certified criteria using the EHR product. Regardless of which test cases are used, ONC's usability criteria require the testing of certain EHR functions, such as the ability to order medications electronically and receive medication alerts. To provide full transparency and be a market differential, these testable criteria should be included in the forthcoming ONC Reporting Program. As ONC develops the Reporting Program, including, these issues should be considered:

- Implementation variation. The usability of EHRs can change significantly once implemented within practices as a result of unique workflows, interactions with other technologies, and individual clinician preferences. The Reporting Program should ensure that data on EHR usability after implementation are also considered given these factors.

- Real-world perspectives. Data on how systems actually perform should be the center of the Reporting Program. While information derived in a qualitative manner from end users can provide important information, comparability across systems would be served best through data on measurable factors. Given variability in how systems can be implemented, some reporting criteria may benefit from providing ranges on which data were received. For example, on quantitative criteria, ONC could list minimums or maximums observed.

- Transparency. It is critical that the factors used to publicly release information on reporting criteria should be made transparent for end users and others. Where applicable, the scoring methodologies and processes used to compile information from multiple sources should be made publicly available.

- Customizability. Rare is the EHR implementation that does not require practice clinical and administrative staff to customize interfaces and templates to meet their unique needs. While all vendors may claim to offer the end user customizing options, it will be the end user themselves who are in the best position to comment on this product feature. As clinicians rarely find the software they purchase meets all their needs immediately, they want the product (i.e., clinical templates) to be easily modified. Even if a product is geared toward a specific medical specialty, there may be sub-specialists within the practice who require custom clinical templates.

ONC should encourage EHR vendors to address key shortcomings that exist in current processes and practices related to the usability of their products. Most critical among these are lack of

adherence to formal user-design processes and a lack of diversity in end users involved in the testing and evaluation process. Again, these issues could be included in the Reporting Program by having the vendor report on their level of adherence to user-centered design and how they engage end users in the testing and evaluation process and collect feedback from a variety of end users.

Usability and Patient Safety

EHRs have transformed the medical profession, providing better data to guide care, supporting enhanced patient safety through new automated tools, and creating more efficient processes by connecting different health systems. At the same time, variations in EHR design, customization, and use can also lead to inefficiencies or workflow challenges and can fail to prevent—or even contribute to—patient harm. Safety hazards can be associated with EHR usability, based on the design and use of the technology and how clinicians interact with it. Usability challenges can frustrate clinicians because they make simple tasks take longer, lead to workarounds, or even contribute to patient safety concerns. These challenges can stem not only from the EHR design, but also from how the technology is implemented and operated in practices; how clinicians are trained to use it; and how the EHR is maintained, updated, and customized. Each stage of EHR development and use—the software life cycle from development through implementation and use in a healthcare environment—can affect the usability and safety of the technology.

Current federal software testing does not address circumstances in which customized changes are made to an EHR as part of the implementation process or after the system goes live. Instead, current testing criteria focus only on the design and development stage of the EHR. While federal regulations mandate the testing of certain safety-related features—such as medication-allergy checks—the requirements do not focus on whether those functions operate in a safe way.

With these factors in mind, ONC should incorporate the following best practices into any new program:

- Consideration of all key tasks in which the use of these systems can affect safety;

- Real-world testing. Usability testing performed for certification is intended to be conducted under reproducible laboratory conditions that do not replicate the actual clinical use of the product, which can limit the tester's ability to discover risks that reflect real-world situations;

- Assessments of the total product life cycle. Certification testing is performed on the EHR product presented to the evaluating lab. Various stages of the product life cycle, including how the product is modified by healthcare facilities and how software upgrades are implemented, can present different usability and safety challenges; and

- The type and level of training clinicians receive. This can determine a clinician's knowledge of the EHR's features, including how to order medications, diagnostic images, and lab tests efficiently and safely.

Focusing on these types of usability issues can create in both the developer world and in the practice a new "culture of safety" by prioritizing usability and safety and working to optimize EHR software to mitigate potential hazards. Optimally, ONC guidelines in this area should serve as a guidepost for all developers, and, in particular, those that do not perform as well on usability/patient safety ratings.

Extending Stark and Anti-Kickback flexibilities

In the draft document, ONC does not discuss the issue of extending the existing Stark and Anti-Kickback flexibilities that have been utilized for a number of years to get standardized health IT in the hands of providers who may not have had the financial capabilities to acquire the technology on their own. Getting this level of assistance can be helpful for providers in not only selecting technology, but also with implementation and optimization. This can significantly decrease the administrative burden associated with adopting EHR technology for those practices that lack technical expertise.

We contend that extending the Stark and Anti-Kickback flexibilities will lead to greater EHR adoption among practices, especially smaller and rural organizations. Not only should these rules be extended beyond 2021, but the scope of permissible donations should be expanded. For example, as the industry moves toward widespread use of a national system of information exchange, many providers will require assistance not only in acquiring the supporting technology, but also the consulting assistance necessary to set up and properly maintain their network in a secure and efficient way. Similarly, as providers seek to adopt APIs, they will need assistance to create and maintain appropriate interfaces. All of these technologies and services should be in the list of permissible donations.

ONC strategy and recommendations:

Promote harmonization surrounding clinical content contained in health IT to reduce burden

- Standardize medication information within health IT
- Standardize order entry content within health IT
- Standardize results display conventions within health IT

MGMA comment:

We concur with ONC that standardizing medication information, order entry content, and result display conventions would improve EHR usability and reduce clinician burden. Prescription drug information in EHRs should be displayed in a standardized format to avoid confusion, increase patient safety, and reduce burden. This standardization is necessary during both the ordering of medications and the display of existing medication information. EHR developers should be encouraged to ensure their products follow best practices including the use of generic drug names, standardized lettering for easily confused medications, and appropriate representation of drug signature information guidance from organizations such as the National Council for Prescription Drug Programs, the Institute for Safe Medication Practices, and the Food and Drug Administration. Once implemented, the EHR Reporting Program will be one lever the ONC has to encourage developers to incorporate standardized formats by allowing potential purchasers access to compare product functionalities.

It is also clear that order entry for laboratory orders, imaging orders, and procedure orders are often burdensome for end users due to the large number of test options. Differences in selectable orders are represented by variances of only several characters, adding additional complexity. EHR developers should be encouraged to collaborate with each other and appropriate provider stakeholders to refine descriptions for unique imaging tests that are clear, concise, and reduce confusion. Similarly, laboratory orders also contain potentially confusing options. Including order entry in the EHR Reporting Program or other ONC policy lever would create transparency and offer the end user additional functionality to compare products.

ONC strategy and recommendations:

Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden

- Increase end user engagement and training.
- Promote understanding of budget requirements for success.
- Optimize system log-on for end users to reduce burden.
- Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.

MGMA comment:

Increasing engagement and training will be critical if clinicians are to see improvements in EHR usability. We agree that clinicians should be involved from the very beginning of the acquisition process to ensure that the product purchased by an organization meets the needs of its end users and their desired workflows. During the implementation process, clinicians should also be involved in the software configuration to ensure that the functionality is both clinically appropriate and usable. This clinician-vendor interaction should continue post implementation to ensure ongoing optimization of the EHR and improvements to clinical and administrative workflow.

ONC can employ various levers to increase clinician engagement in these processes. Augmentation and increased promotion of the *Change Package for Improving EHR Usability* would be helpful for those clinicians seeking information on optimizing their EHR implementations. CMS could also add these types of activities to the list of MIPS Improvement activities and ONC could work with medical organizations to permit clinicians to be given continuing education credits for attending classes, sessions, or webinars on these topics. Further, the forthcoming EHR Reporting Program could include categories focused on what steps the developer takes during the implementation and optimization phases to engage clinicians and their staff.

We also agree that a thorough understanding of budget requirements is a critical factor for a successful EHR deployment. Practices should transition from a model that revolves around a fixed implementation budget to a budget model that incorporates ongoing technical support for end users, ongoing training of clinical staff, and required technical resources to support upgrades, system maintenance, troubleshooting, system backup, and disaster recovery functionality. EHR developers can help institutions plan for this by being transparent with projected costs (and associated benefits) over the anticipated lifespan of EHR implementation. By implementing a budget that provides for these ongoing requirements, clinician burden due to lack of training or support can be minimized.

Further, ONC has conducted many industry “challenges” with monetary awards in the past related to interoperability, patient matching, and others. Improving clinician efficiency and satisfaction, and lowering administrative burden may be excellent candidates for similar types of “challenges.” Technology vendors could be tasked with developing interfaces that improve efficiency and lower administrative burden, with the results widely disseminated to the industry.

3. EHR Reporting

ONC strategy and recommendations:

Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.

- Simplify the scoring model for the Promoting Interoperability performance category.

- Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to clinicians.
- Reduce burden of health IT measurement by continuing to improve current health IT measures and developing new health IT measures that focus on interoperability, relevance of measure to clinical practice and patient improvement, and electronic data collection that aligns with clinical workflow.
- To the extent permitted by law, continue to provide states with federal Medicaid funding for health IT systems and to promote interoperability among Medicaid healthcare providers.
- Revise program feedback reports to better support clinician needs and improve care.

MGMA comment:

MIPS reporting

In the 2019 PFS final rule, CMS established a full calendar year reporting period for the quality and cost performance categories, while the PI and improvement activities categories continue to be any 90 consecutive days. Eligible clinicians (ECs) and groups who report less than 12 months of data would be required to report all performance data available from the applicable performance period. MGMA strongly opposes a full calendar-year reporting period for the quality performance category of MIPS and urges CMS to establish a minimum 90-day reporting period for all MIPS categories that require data collection and reporting by group practices and ECs, including quality and PI.

The agency recognizes the significant benefits of a minimum 90-day reporting period in this rule, which provides: "a 90-day performance period is necessary in order to enable clinicians to have a greater focus on the objectives and measures that promote patient safety, support clinical effectiveness and drive toward advanced use of health IT" (83 Fed. Reg. 35893). CMS also outlines challenges associated with reporting data across a full calendar year due to "clinicians newly employed by a health system or practice during the course of a program year, switching CEHRT, vendor issues, system downtime, cyber-attacks, difficulty getting data from old places of employment, and office relocation" (83 Fed. Reg. 35893).

MGMA agrees these concerns are valid. The enumerated challenges create obstacles outside the control of the group practice, which inhibit their ability to collect and report the full 12 months of MIPS data to CMS-not just for the PI and improvement activities categories but also for the quality performance category of MIPS.

Physician practices must take many steps prior to the start of the performance period to ensure that the proper systems are in place and the necessary data is being accurately collected throughout the performance year so that it can be properly submitted during the subsequent attestation period. For example, clinicians and practices must study amended measure specifications and select the requisite number of clinically-relevant measures, train their staff, and often input the measure information as discreet data into the EHR. Otherwise, a third-party data submission vendor or registry cannot extract the necessary data, nor submit it to CMS, such that a full calendar-year of data is provided. Starting at the outset of the performance period is even more critical for clinicians who report via Part B claims, because quality code information must be included when the claim is processed for payment. Requiring ECs and group practices to accomplish this heavy lift between early November when the final policies and measures are released, and Jan. 1 is unrealistic.

Moreover, if CMS truly intends to influence clinicians and practices to improve care by evaluating quality, cost, EHR use, and practice improvement metrics, desired evidence-based actions must be taken at the point of care, starting on the first day of the performance period. For instance, an

MGMA member practice reported CMS quality measure #376, one of the electronic clinical quality measures. In 2017, the measure specifications evaluated functionality assessments prior to hip surgery and 60-180 days after surgery. In 2018, the measure specifications changed to evaluate whether a functionality assessment was performed prior to hip surgery and 270-365 days after the procedure. As the eligible procedures must have occurred during the year prior to the performance period, this member's group practice had already performed many of the second functionality assessments according to the previous specifications when they were made aware of the measure changes in mid-year 2018. They were then left with the option to conduct a third functionality assessment merely to meet the measure, report data that did not truly reflect their quality of care as it could show them out of compliance or choose to report a different measure entirely more than halfway through the performance period. Scenarios like this one are not uncommon and reinforce the difficulty of complying with ever-changing measure protocols without a shorter reporting period.

We acknowledge that certain reporting options, such as reporting certain outcome-based measures, may require a lengthier reporting period than 90 days to ensure statistical validity, and we encourage CMS to permit groups to report data for longer periods of time in such circumstances. However, we strongly encourage CMS to look for opportunities to shorten the minimum statistically-valid reporting period across all data submission methods. When reporting all-payer data via QCDR, registry, or EHR, any 90 consecutive days should provide a sufficiently reliable data set. Moreover, CMS' case minimums for the cost measures are much lower, at 10, 20, or 35 cases. If those case minimums are valid for cost measures, CMS should consider applying the same logic to quality case minimums.

Moving to a shorter reporting period would also allow for a number of program improvements. A 90-day reporting floor would reduce the administrative burden in MIPS, align the reporting period across MIPS categories, allow the agency to shrink the problematic two-year lag between performance and payment, and increase the timeliness and relevance of feedback, which could be provided on a quarterly basis, as recommended by Congress. Establishing a 90-day reporting floor would also give CMS an opportunity to set benchmarks based on more current data, rather than from four years prior to the payment year.

Furthermore, we urge the government to consider the timing of MIPS feedback reports, which are released halfway through the 365-day reporting period, limiting the effect of any improvements made as a result of feedback to, at best, only one-half of the performance period. For instance, physician practices may need to conduct internal due diligence to identify quality performance variables, explore more clinically relevant reporting metrics and change data capture and input into the EHR, which would require action by third-party vendors who are not subject to the same payment penalties as clinicians. If the reporting period were reduced to a 90-day minimum with the option to submit additional data, clinicians and group practices would have greater flexibility to incorporate the MIPS feedback into their performance and focus more of their attention on improving patient care as opposed to reporting for reporting's sake.

<u>MIPS promoting interoperability</u>

In the 2019 PFS, CMS set the requirements of PI performance category. PI comprises 25 percent of a MIPS ECs final score for the 2019 MIPS performance year and each MIPS payment year thereafter, unless CMS assigns a different scoring weight. CMS also laid out a complex set of requirements that ECs would have to meet in order to the eligible for the 25 points. Changing the PI component of MIPS would not only serve to reduce the administrative burden associated with use of EHRs but might also serve to act as an incentive for clinicians to optimize their software and seek additional interoperability opportunities.

MGMA believes ECs and groups submitting quality measures via end-to-end electronic reporting or using CEHRT in their Improvement activities should also earn full credit towards their PI score. ECs use CEHRT and other tools that leverage interoperable standards for data capture, usage, and exchange to facilitate and enhance patient and family engagement, care coordination among diverse care team members, and to leverage advanced quality measurement and safety initiatives. CMS should recognize that if an EC or group is leveraging CEHRT to report quality measures or improvement activities, they are also demonstrating the use of technology to capture, document, and communicate patient care information and should therefore receive both quality and PI credit.

With MACRA, Congress set out to streamline and harmonize the current siloed quality reporting programs. To satisfy congressional intent, CMS should award credit across multiple MIPS performance categories for certain high-impact behavior. Congress specifically directed CMS to award credit across the quality and PI categories in Section 1848(q)(5)(B)(ii) of the statute:

> "With respect to a performance period for a year, for which a MIPS EC reports applicable measures under the quality performance category through the use of certified EHR technology (CEHRT), treat the MIPS EC as satisfying the clinical quality measures reporting requirement under section 1848(o)(2)(A)(iii) of the Act for such year."

MGMA recommends reconfiguring the MIPS scoring methodology and award PI credit for reporting quality measures via end-to-end electronic reporting.

PI Scoring Methodology

CMS finalized a new scoring methodology, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing PI performance category measures, broken into a smaller set of four objectives and scored based on performance. CMS contended this was a major overhaul of existing program requirements as it eliminated the concept of base and performance scores. While we appreciate the intent to decrease the administrative challenges associated with ECs participating in the PI component of MIPS, implementation of the still challenging finalized approach may actually act as a deterrent to EC participation in the PI component and a roadblock to success in the MIPS program.

For example, we raised the concern in our PFS comment and continue to be concerned about clinician adoption of 2015 Edition CEHRT. Vendors not only developing a 2015 Edition CEHRT product but offering it on time and at a cost practices can afford remain issues MGMA is watching as we move into the 2019 reporting year. Another area of potential PI improvement is in the scoring approach. We were disappointed CMS finalized the "all or nothing" methodology for the 2019 MIPS PI category. Instead of rewarding ECs for using EHR technology to treat their patients, the rule outlined an approach that penalizes an EC for missing even one of the objectives by giving them zero points in the PI category. We urge ONC to work with CMS to discontinue this tactic and permit ECs to score points in any of the PI performance objectives and measures.

Further, meeting the objectives for the PI score (Security Risk Analysis, Eprescribing, Provider to Patient Exchange, and Health Information Exchange) adds unnecessary burden for ECs and groups participating in MIPS. Of note, the Security Risk Analysis has been required by law since the HIPAA Security final rule was implemented in 2005. The remaining three objectives are fundamental functions of 2014 Edition and 2015 Edition CEHRT and practices have been using these features for years.

ECs attesting to successfully participating in one or more of the improvement activities options requiring the use of CEHRT or successfully reporting quality measures using CEHRT should be deemed to have met the PI requirements and be awarded the full 25 PI points. Should this cross-category approach to meeting program requirements not be adopted, we recommend a methodology employed in the 2018 Advancing Care Information component of MIPS. The 2018 program established two measures with a numerator of just one patient–e-prescribingand patient access. By doing so, the agency required the EC to attest not only to having 2014 or 2015 Edition CEHRT, but also having the capability of using the features of the EHR being measured. We believe that this same approach could be adopted for future reporting periods and applied to other objectives. Removing the requirement for the EC to collect denominators and numerators will significantly decrease the administrative burden associated with this component of MIPS.

Regardless of what specific objectives and measures are adopted, for the 2019 reporting period CMS should apply the same 50-point scoring standard finalized for the 2019 Stage 3 Meaningful Use Program to the MIPS PI. Thus, ECs who earn 50 points or higher in MIPS PI should be deemed to have satisfied the PI category's requirements. These ECs should receive 100 points in the PI category, translating to 25 points towards an EC's final composite score. ECs scoring 49.9 or fewer points should be scored according to their finalized PI score (i.e., an EC scoring 30 PI points would receive 7.5 MIPS composite score points).

This approach would address several critical issues. First, the PI component of MIPS would no longer be an "all or nothing" approach with ECs able to select among the measures within an objective to meet their clinical needs. This would permit them to score points in any of the categories--selecting measures that are most relevant to their patient population and within their control. Second, ECs would be incentivized to adopt 2015 Edition CEHRT with 20 points automatically added to their PI score. ECs continuing to use 2014 Edition CEHRT would have those points moved to the health information exchange categories. Finally, we also believe that removing the administrative requirements associated with meeting superfluous objectives would be a further incentive for physician practices to adopt and optimize CEHRT.

Rather than have CMS and ONC dictate how ECs should leverage their technology to treat their patients, we urge these agencies to permit ECs to work directly with their EHR vendor and provider community to develop and implement the infrastructure and workflow necessary to effectively and efficiently exchange patient data.

Alternatively, CMS could only require clinicians to attest in 2020 to simply meeting the program's measures—i.e., ECs would only be required to report "yes" or "no" on whether they had at least one patient in the numerator of each measure. Each "yes" would be worth whatever that measure's potential points are (e.g., under the current proposal, a "yes" attestation to e-prescribing would be worth 10 points). In addition to reducing reporting burden, a yes/no attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and clinician needs, rather than designed simply to measure, track, and report. This will help close the gap in health IT functionality and usability.

CMS should also require that health IT vendors, not ECs, report CEHRT functionality utilization levels. EHR software typically captures what functionalities are used to perform specific clinical tasks, permitting EHR vendors to aggregate the data and provide it to CMS and ONC. Requiring EHR vendors to provide information directly to CMS and ONC on the real-world use of technology will provide insight into an EHR's usability and conformance to certification.

PI performance scoring

To receive PI points, ECs and group practices must strive for significant numerator thresholds for a number of required objectives. There are four such measures, e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. Three of these measures (Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange), rely on the actions of a third party (e.g., patient, outside clinical setting, public health or exchange entity) for the EC to be successful. Recording a high score in a category that is within the EC's control (i.e., e-prescribing patient medications) is far more achievable than recording a high score in a category such as exchanging data with an outside clinical setting. ECs should only be required to report their capability to meet an objective that requires third-party action.

In addition, many smaller, rural, or specialty practices are inherently disadvantaged when it comes to achieving high scores for many of the PI measures. For instance, medical specialties that traditionally do not have ongoing patient communication (i.e., a specialist who might see a patient only one time for a consult) struggle to achieve high scores.

ONC strategy and recommendations:

Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.

- Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting.
- Adopt additional data standards that makes access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for clinicians and hospitals.
- Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products.

MGMA comment:

It is critical to recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting. We concur that mistakes in data mapping, and poor data integrity overall, not only necessitate added costs for practices but may result in adverse payment adjustments through a variety of reporting programs. We urge that the agency coordinate stakeholders focused on best practices for data mapping and data integrity and include industry-approved mappings as part of the Interoperability Standards Advisory. Certified health IT developers should then be required to adhere to these mapping standards.

We are pleased to see ONC recommend the adoption of additional data standards to make access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for practices. Practice access to data, both within their own systems and across health IT and other electronic platforms, is a significant challenge not only for participating in and reporting to quality programs, but also in repurposing the data.

We agree with the ONC recommendation regarding the use of FHIR-based standards for the development of electronic resources to facilitate requests for data without requiring a clinician or healthcare provider to individually address potential variations in each individual request. We also concur that FHIR could support data segmentation for privacy in health information exchange and recently released mobile solutions, which can integrate clinical data with a patient's personal health tracking applications on their mobile device.

Open APIs

MGMA supports timely and efficient patient access to health information and believes that use of open APIs should be explored as a vehicle to provide that access. APIs have the potential of enhancing access to patient data in the EHR while at the same time permitting clinicians and patients to leverage medical information for innovative purposes. For this to occur, we believe a number of security issues must be addressed.

While APIs have a lot of potential to facilitate a new interface providing access to sensitive or protected health information, there is the concern that there will be an increased potential for unauthorized access to that information. Many practices are still working through the complications and security requirements necessary to limit the data exposure of their EHRs. APIs will add to these security concerns by creating another opportunity for hacking or other cybersecurity attacks. The API is also a new EHR function which has largely gone untested in real-world use. As EHR vendors continue to update, patch, or make changes to EHR software, there will be instances where APIs will need to be brought offline for maintenance. Additionally, as with any complex technology, APIs may be interdependent with other health IT products. If those products fail, access to the API may be impacted and data security compromised.

ONC strategy and recommendations:

Improve the value and usability of electronic clinical quality measures while decreasing healthcare provider burden.

- Consider the feasibility of adopting a first-year test reporting approach for the newly developed electronic clinical quality measures.
- Continue to evaluate the current landscape and future directions of electronic quality measurement and provide a roadmap toward increased electronic reporting through the eCQM Strategy Project.
- Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.

MGMA comment:

MGMA appreciates that ONC is examining the issue of improving the value and usability of eQMs while decreasing healthcare provider burden. We encourage ONC to work with CMS to better promote clarity and stability of this component of the MIPS program. Requiring practice administrators and clinicians to re-educate themselves year-over-year about substantive policy changes to the reporting requirements, coupled with seemingly arbitrary changes in terminology is unreasonable. We also support the approach of adopting a first-year test reporting for newly developed eCQMs.

We assert that the best way to improve the clinician community's understanding of the program requirements, measure specifications, and scoring rules remains the same: release information about the program prior to the start of the performance period. As in the case of 2017, medical group practice leaders did not have basic eligibility information until the second quarter of 2018.

Even more inexcusably, CMS published the following essential measure information after the program year had begun on Jan. 1, 2018:

- *Quality Measure Specifications,* published Feb. 9, 2018
- *Qualified Clinical Data Registry (QCDR) Measure Specifications,* published May 29, 2018
- *Promoting Interoperability Measure Specifications,* published June 6, 2018
- *Cost Measures*, published July 27, 2018
- *Quality Measure Specifications supporting documents*, published July 31, 2018

- *Web Interface Measures & supporting documents*, published Aug. 7, 2018
- *MIPS data validation criteria*, published Aug. 16, 2018

Lack of information not only disadvantages practices in complying with MIPS but also hampers their ability to capture information at the point of care, track data, and make any necessary adjustments throughout the performance period. If CMS is serious about MIPS as a quality improvement program, the agency needs to release all measure and eligibility information well prior to the start of the performance period.

MGMA continues to advocate for CMS to reduce the reporting burden in this category by decreasing the data submission requirements and allowing ECs and group practices to report additional quality measures at their discretion. MGMA regularly hears from practices that it is challenging to identify six clinically-relevant measures, even within the specialty measure sets. Rather than requiring practices to split their focus among measures that may not be relevant to their patient population and clinical specialty, the number of reporting requirements could be reduced. This approach would allow practices to prioritize their energy and resources on a few meaningful measures that, if performed well, could move the dial on improving care and reducing costs.

MGMA also has concerns regarding the feasibility of a 60 percent data tracking and reporting threshold, as it reduces any flexibility a practice may need to make technological infrastructure changes or address any system interruptions or other administrative factors that often fall outside the control of the clinician or practice. Moreover, expanding most reporting mechanisms to all-payer data inherently increases the amount of data the agency receives, calling into question any need to increase the threshold.

We encourage CMS to reexamine the utility of a 60 percent data completeness threshold and seek stakeholder feedback regarding any increase in the threshold only when program data show a large majority of group practices are meeting existing data completeness requirements. For cost measures, the agency requires only 10, 20, or 35 patient encounters to meet a reliability score of 0.4. For quality measures, MGMA recommends CMS consider an alternative data completeness threshold that meets a minimum reliability score of 0.8, which would increase the confidence that ECs and groups would have on their performance scores and comparisons. Moving to a minimum number of patients or some other predictable methodology also facilitates planning of resources and staffing required for this effort.

To achieve the goal of reduced administrative burden, any refinements to this category must continue to allow ECs and groups flexibility to report across multiple mechanisms. There must also be an openness to accept and implement emerging measures that would demonstrate quality based on new evidence and data.

4. Public Health Reporting

ONC strategy and recommendations:
Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into healthcare provider workflow.

- Federal agencies, in partnership with states, should improve interoperability between EHRs and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules.**

- HHS should increase adoption of electronic prescribing of controlled substances with access to medication history to better inform appropriate prescribing of controlled substances.

MGMA comment:

One of the tools most critically underutilized in the fight against the opioid epidemic is e-Prescribing. E-prescribing of opioids would allow providers to flag potential overuse or misuse for patients more easily when prescribed by multiple practices or providers through real-time notifications. It would also facilitate the collection of data that could be studied and used to inform ongoing efforts to curb opioid overuse and misuse.

E-Prescribing of non-controlled substances was a required component of the Medicare and Medicaid Meaningful Use EHR Incentive Program and is currently required as part of the 2019 PI component of MIPS. As a result, a high percentage of clinicians use this approach to prescribe medications for their patients. Unfortunately, e-prescribing of controlled substances is obfuscated by a myriad of complex federal and state regulations and requirements that impose administrative burden on practices and prohibit more widespread adoption. With many clinicians forced to write paper prescriptions for controlled substances, the ability to identify patient overuse or misuse is significantly decreased and hinders automated data collection.

For maximum effectiveness, efforts to incentivize e-prescribing should be coupled with efforts to promote a nationally-accessible Prescription Drug Monitoring Program (PDMP). Currently, 45 states participate in the National Association of Boards of Pharmacy's (NABP's) prescription monitoring program (PMP) and data sharing systeBP PMP InterConnect. This type of federated model allows states to retain control over their own databases while granting access to appropriately authorized clinicians in other regions. This enables more effective treatment decisions and closes the loophole that exists when addicted patients seek new prescriptions across state lines. All remaining states should be encouraged to join this broad effort to communicate prescription information.

In addition, integration of this data into electronic health record systems should ensure that the clinician has access to the data during the time of the patient encounter. Currently, some EHR PDMP interfaces permit the clinician to access various state PDMPs, but each state must be clicked individually—meaning it is incredibly burdensome for the clinician to search a patient's prescribing history in multiple states before or during the encounter. A more effective approach would be to have the patient's PDMP records automatically combined from each state and presented to the clinician in an easy-to-read format and available in real-time. This would allow the clinician to engage with the patient during the encounter and take appropriate actions.

Congress recently passed opioid legislation that should help in addressing issues related to e-prescribing of controlled substances and PDMPs. We urge CMS to be as flexible as possible with the e-prescribing and PDMP PI measures and incorporate any applicable legislative changes into the PI component. Further, in recognition of the importance of the query of PDMP measures, we urge the agency to increase the MIPS bonus points available to 10 points. Having the clinician query a PDMP, especially if the system reports data from all or nearly all states and verifying the patient's treatment agreement can have a dramatic impact on the nation's opioid epidemic. The points could be drawn from the Verify Opioid Treatment Agreement bonus as this clinical approach is controversial, with many behavioral providers opposed to employing this type of agreement during treatment.

We agree that federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules. This would improve timely access for clinicians to medication histories in PDMPs. States should also leverage funding

sources, including but not limited to 100 percent federal Medicaid financing under the 2018 SUPPORT for Patients and Communities Act (SUPPORT Act), to facilitate EHR integration with PDMPs using existing standards.

We concur with ONC that accessing prescription histories from PDMP is typically not well integrated into the routine workflow of patient care or even the e-prescribing workflow. If we are to effectively combat the opioid crisis facing this nation, clinicians require efficient and rapid access to data from all state PDMPs. The SUPPORT Act now allows states to receive 100 percent Federal Medicaid matching funds in 2019-2020 for qualified PDMPs that integrate into a provider's workflow and their health IT application for e-prescribing of controlled substances. We urge that, in implementing the SUPPORT Act, ONC coordinates the federal funding agencies to develop a shared strategy to ensure that all PDMPs adopt common standards over time to support PDMP and health IT integration.

HHS should look at various policy levers to promote the e-prescribing of controlled substances with access to medication history. One would be to include e-prescribing of controlled substances as one of the scoreable MIPS Improvement activities. A second option would be to require future CEHRT to include these functionalities. We agree that, when appropriately implemented, e-prescribing of controlled substances will permit all prescribing to remain in a single workflow, reduce the time clinicians spend on medication reconciliation, automate clinical decision support such as drug-drug interactions, and facilitate the tracking of prescription fulfillment. As the SUPPORT Act also requires the Drug Enforcement Agency (DEA) to update clinician multifactor authentication requirements to leverage biometrics and modern approaches to authentication, we recommend ONC work with DEA to ensure that the solutions developed are clinician-friendly and seamlessly integrated into provider workflows.

Conclusion

In conclusion, MGMA supports the overall objective of deploying HIT in physician practices and expanding opportunities to improve the sharing of clinical data between physician practices and other care settings while decreasing administrative burdens. Considerable work must be accomplished due to numerous technical, legal, and logistical barriers to the widespread and effective use of health IT. Through implementation of appropriate policies, processes, and incentives, as well as outreach to physician practices and other key stakeholders, we believe that the nation's health IT infrastructure can achieve the goals and vision laid out in this document.

We thank you for taking on the formidable task of reshaping public policy to create a healthcare environment that will lead to improved patient care and more efficient delivery of care. We look forward to continuing to work with ONC and other federal agencies to facilitate physician practice transition to effective and efficient health IT and ensure that the promise of improving the nation's healthcare system through technology becomes a reality. Should you have any questions regarding these comments, please contact Robert Tennant, Director, Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs