

August 9, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services' (CMS) Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork. The AMA supports this initiative and the agency's goal of alleviating the administrative burden federal programs place on physician practices. The increasing amount of administrative responsibility forced upon physicians adds unnecessary costs not only to practices and the Medicare program but also negatively impacts patient care. Unnecessary administrative tasks undercut the patient-physician relationship. For example, studies have documented lower patient satisfaction when physicians spend more time looking at the computer and performing clerical tasks.¹ Moreover, for every hour of face-to-face time with patients, physicians spend nearly two additional hours on administrative tasks throughout the day. The increase in administrative tasks is unsustainable, diverts time and focus away from patient care, and leads to additional stress and burnout among physicians.²

By reducing administrative burden, CMS can support the patient-physician relationship and let physicians focus on an individual patient's welfare and, more broadly, on protecting public health. In addition, CMS should review subregulatory guidelines, which create additional burdens on physicians, and reduce the number of subregulatory guidance documents that are issued.

Accordingly, the AMA believes CMS should address the following concerns to reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care.

¹ Street RL et al., *Provider Interaction with the Electronic Health Record: The Effects on Patient-Centered Communication in Medical Encounters*. Patient Educ. Couns., 2014; Kazmi Z, *Effects of Exam Room EHR Use on Doctor-Patient Communication: A Systematic Literature Review*. Inform Prim Care, 2013; Farber NJ et al., *EHR Use and Patient Satisfaction: What We Learned*. J Fam Pract 2015.

² Sinsky C et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*, Annals of Internal Medicine 2016.

Prior Authorization (PA) and Utilization Management (UM)

According to a recent AMA survey of 1,000 practicing physicians, 65 percent of surveyed physicians reported waiting at least one business day for PA decisions from health plans, while 26 percent reported waiting at least three business days.³ Not surprisingly, 91 percent of physicians said that PA can delay a patient's access to necessary care. These delays may have serious implications for patients and their health, as 75 percent of physicians reported that PA can lead to treatment abandonment, and 91 percent indicated that PA can have a negative impact on patient clinical outcomes. Most alarmingly, over one-quarter (28 percent) of physicians reported that PA has led to a serious adverse event (e.g., hospitalization, disability, death) for a patient in their care. These physician burdens and patient care barriers are routinely experienced by Medicare Advantage (MA) beneficiaries. According to a U.S. Department of Health and Human Services (HHS) Office of Inspector General review of MA service denials in 2014-2016, more than 116,800 PA requests were denied and eventually overturned on appeal for drugs/services to which the patient was entitled, a total that is particularly concerning because beneficiaries and providers appealed only one percent of denials.⁴

In 2017, the AMA, working with organizations representing physicians, hospitals, patients, and other health care stakeholders, released reform principles identifying problems with and recommending improvements to PA, step therapy, and other UM programs.³ Additionally, the AMA recently partnered with the American Hospital Association, America's Health Insurance Plans, the American Pharmacists Association, the Blue Cross Blue Shield Association, and the Medical Group Management Association on a consensus statement for reducing PA burdens.⁴ While many insurers have focused their PA improvement efforts on technology development, it is critical to note that only one out of the five reform areas identified in the Consensus Statement address process automation. The AMA and our partners in this agreement support adoption of standardized electronic PA technology, but we strongly believe that other key reforms, such as overall PA volume reduction, improved transparency, and continuity of care protections, are needed to meaningfully improve the PA process.

Because Medicare beneficiaries represent a particularly vulnerable patient population, PA requirements must be carefully and thoughtfully applied to prevent care delays that can lead to negative clinical outcomes. The AMA is eager to partner and continue the conversation with CMS on PA, as this is a critical issue to our members and, most importantly, to patients. **We urge CMS to take a leadership role on this issue and develop a comprehensive strategy to address PA concerns that includes all areas of the Consensus Statement:**

- Selective application of PA (CMS should continue the successful Targeted Probe and Educate program; the AMA supports identification of outliers and education as needed);
- Review/adjustment of services/drugs that require PA to eliminate low-value PA—applying PA to services with high approval rates is costly for plans and providers;
- Improved communication of PA requirements to patients and health care professionals (including CMS encouraging plans to disclose the clinical basis for their PA requirements);

³ AMA, *Prior Authorization and Utilization Management Reform Principles* (2017), available at <https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf>.

⁴ AMA, *Consensus Statement on Improving the Prior Authorization Process* (2018), available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

- Protections of patient continuity of care, particularly when patients enroll in new plans or plans change PA requirements; and
- Automation to improve PA transparency and process efficiency while maintaining physician oversight of payer access to EHR data.

Additionally, we have serious concerns about CMS' final rule that allows MA plans to utilize step therapy protocols for physician-administered drugs covered under Medicare Part B. We find the growing trend towards the use of restrictive and burdensome UM tactics by payers concerning and urge CMS to reconsider its stance on this critical patient care issue. To that end, we appreciate Secretary Azar's recent comments before the AMA's National Advocacy Conference stating that it is "disturbing" that patients switching from one insurance plan to the next can be required to start over for a step therapy or "fail-first" regimen, and that such a policy is "not just injurious to [the patient's] health, it is also penny wise and pound foolish."

Recommendations:

- **When evaluating any PA requirements in the Medicare program (including Part D and Medicare Advantage [MA]), CMS should carefully consider the care delays associated with PA and the resulting impact on beneficiaries and their health and well-being;**
- CMS should ensure that all UM requirements are based on accurate and up-to-date, publicly available clinical criteria and never cost alone;
- CMS should require all MA and Part D plans to publicly disclose to both patients and physicians in a searchable electronic format all drugs and medical services that are subject to coverage restrictions (PA, step therapy, formulary restrictions, quantity limits) and provide this information to vendors to be displayed in electronic health record systems;
- CMS should require a 60-day grace period for UM requirements when a patient changes MA and Part D plans, align PA approvals with the duration of the prescribed/ordered treatment, and prohibit plans from requiring patients to retry therapies that failed under previous plans;
- MA and Part D plans should abide by PA decisions and pay for any services approved in a PA request by performing eligibility and all other medical policy coverage determinations as part of the PA process and not revoking or restricting coverage for authorized care provided within 45 business days from the date the authorization was received;
- CMS should prohibit MA plans from denying claims for services or procedures when a PA for a similar procedure was previously approved (i.e., increase flexibility of PA approvals to cover a range or bundle of codes);
- Except where there is evidence of widespread misuse, PA should not be required for drugs that are standard treatment for the patient's condition and/or have been previously approved for treatment of an ongoing/chronic condition;
- CMS should ensure that any "peer-to-peer" reviews utilize physicians from the same specialty/subspecialty as the ordering or prescribing physician; and
- CMS should restrict PA requirements to "outlier" providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix by using a process similar to the successful Targeted Probe and Educate program.

Quality Payment Program

The AMA is encouraged by results showing 95 percent of eligible clinicians successfully participated in the Merit-based Incentive Payment System (MIPS) in 2017, increasing to 98 percent in 2018 based on preliminary results. We were also pleased to see the number of small practices participating increased by 9 percent in 2018. CMS' efforts to assist small practices are working, and we urge the agency to maintain the low-volume threshold, the small practice bonus, as well as targeted outreach and education to these groups. However, the AMA continues to hear from physicians and specialty societies that the MIPS program should be more intuitive, less administratively burdensome, and more clinically relevant. The current program is too costly, requires reporting for the sake of reporting and diverts time away from patient care.

The AMA has worked closely with the physician community and CMS staff to develop a solution that would allow physicians to target a certain condition, procedure, or public health priority and earn points across all four MIPS categories. This proposal would help CMS achieve its "Patients Over Paperwork" goals including reducing physician burden, providing more opportunities for small practices, and creating a stepping stone to alternative payment models (APMs).

In addition, we believe the recommendations in our [Quality Payment Program comment letter](#) would help encourage physicians to focus on more clinically relevant measures that lead to quality improvement and better care for patients.

Recommendations:

- Simplifying the MIPS scoring methodology;
- Reducing the overall performance threshold;
- Returning the small-practice bonus to overall score rather than the quality category;
- Allowing physicians and groups the option to submit a minimum of 90 days' worth of quality data;
- If CMS reduces the number of quality measures in MIPS, the agency should also reduce the number of required measures for satisfactory reporting under the quality category;
- Providing timely notification to practices that qualify for special treatment and exceptions;
- Ensuring methodology and data are sound before scoring physician improvement;
- Providing maximum flexibility for virtual groups;
- Maintaining the quality data completeness criteria and not increasing the reporting threshold;
- Modifying the quality provisions on topped-out measures and benchmarks;
- Eliminating requirements related to outcomes measures, all-payer data and administrative claims measures;
- Keeping weight in the cost category low during next three years while better measures are developed;
- Eliminating the cost measures carried over from the value-based modifier, including the total cost of care measure which holds physicians accountable for costs outside their control;
- Simplifying and reducing burden through yes/no measure attestation;
- Reducing reporting requirements on physicians by leveraging health information technology vendor reporting on utilization of certified electronic health record technology (CEHRT) functionality; and
- Providing a more robust APM pathway under the Quality Payment Program (QPP).

MIPS Qualified Clinical Data Registry (QCDR) Reporting

CMS must do more to promote the use of qualified clinical data registry (QCDR) reporting in MIPS. A major ongoing issue for specialists is the ability to report on measures that are meaningful to them and a major reason why many specialty societies have invested millions in developing registries. Specialty-led QCDRs are a private sector funded effort and the literature specifically shows QCDR participation and reporting reduces burden for physicians and makes MIPS reporting a more meaningful experience. It also allows physicians to better integrate quality reporting and MIPS into their workflow and report on more outcomes and patient reported outcome (PRO) measures—a goal of CMS’ Meaningful Measures initiative. Therefore, based on the direct user feedback specialties receive from participants, registry stewards utilize the information to update the registry, improve the user experience, and develop new measures. As a result, physicians are receiving regular feedback and constantly improving, but CMS makes continued participation a major challenge.

CMS routinely changes the requirements and physicians are disincentivized to report through a QCDR when no stability exists with the reporting mechanism. Moreover, it is extremely difficult for physicians to know what they are being measured on when CMS changes or removes measures on an annual basis. The AMA believes that the only way to truly measure improvement and track data over time is to have a process in place that allows for longitudinal data collection and tracking. Additionally, QCDR measure owners develop these measures for use beyond MIPS reporting (e.g., research, guideline development, quality improvement, etc.) and use for MIPS is secondary. Section 1848(q)(5)(B)(ii)(I) of the Social Security Act, as added by Section 101 of MACRA, requires HHS to encourage the use of QCDRs to report quality measures under MIPS. We continue to strongly support this statutory requirement; however, CMS must refine the QCDR option under MIPS and reimagine physician QCDR participation. Specifically, we urge CMS to streamline the self-nomination process, and provide better incentives for organizations, including specialty societies, to continue to invest in their QCDRs and develop new, meaningful measures for specialists to use for MIPS reporting and other clinical and research purposes. Otherwise, we will continue to see specialty-run QCDRs drop out of the MIPS program. Furthermore, we recommend that physicians who participate in the QCDR reporting option should receive full credit for at least the quality, IA and EHR portions of MIPS by virtue of their reporting to a QCDR.

Timeline to Propose New Quality Measure in MIPS

The AMA remains concerned that the time to develop, propose for use, and implement a measure into MIPS is too long. Multiple stages in the measure development timeline and CMS’ own requirements on measure developers to propose a measure for MIPS significantly delay acceptance of a new measure. We remind CMS that Section 1848(q)(2)(D)(viii) of MACRA does not require CMS to utilize the Measure Application Partnership (MAP) to provide guidance into the pre-rulemaking process on the selection of MIPS quality measures, but requires the Secretary to consult with relevant eligible clinician (EC) organizations, including state and national medical societies. Eliminating review of MIPS measures by the MAP would significantly accelerate the timeline for measure implementation and help achieve CMS’ goal of moving to “Meaningful Measures.” For example, to propose a measure for the 2020 MIPS program, a measure developer must have submitted their application to CMS by June 1, 2018. Prior to the MAP requirement, measure developers would put forward a measure about one year prior to finalization in a program (Winter 2019 for use in 2020 program). Furthermore, CMS now requires measures to be fully tested upon proposing the measure to CMS and make it onto the measure under consideration (MUC) list. This additional testing requirement may add an additional two years to the developer timeline

given the difficulty in finding testing sites and the length of time it takes to test a measure. For instance, the AMA initiated development of pre-diabetes measures (a MIPS measure gap area and public health priority) roughly two years ago and submitted them for the 2019 MUC list for implementation in 2021 MIPS. However, due to CMS' testing requirements they were rejected and the earliest they may make into MIPS is 2022 (5 years after initial development).

The lack of reliable processes leads to inadequate review of the measures—especially in the context of considering appropriateness based on program requirements—and unpredictable MAP proceedings and reports issued with limited time to comment.

Recommendations:

If CMS continues to insist that measures must undergo MAP review and requires testing at the time of submission for the MUC list, we recommend the following issues be addressed to improve the MAP process:

- The MAP treats measures undergoing maintenance/updates as if they are under development despite the fact that CMS has data about and experience with the measure, which, if shared, could lead to a more focused and meaningful discussion.
- Stakeholders often only have one week to 30 days to comment on MAP recommendations—depriving stakeholders and the programs of a thorough review and constructive feedback.
- Opportunity to re-review and consider measures after MAP flagged issues have been addressed by the measure steward.
- Consider new measures in the context of the entire program, specifically the existing measures and whether new measures are warranted.
- The deliberations of the MAP coordinating committee and workgroups are highly dependent upon who has a seat at the table. If a measure within a particular specialty area is being reviewed, and that specialty is not represented on the committee or workgroup, legitimate issues may be overlooked and measure review may be inadequate.
- Notices of opportunities for measure developers or stakeholders to publicly comment are sometimes inadequate. Agendas are all too often unavailable until on or close to the day of a MAP meeting. The order of review of items on the agenda frequently deviates from the published schedule, making it difficult for those not present, including clinicians and the public, to participate or provide comments.

Small and Rural Practices in QPP

The AMA strongly supports the free technical assistance available for clinicians in small practices and has heard that the assistance has been helpful, but more must be done to continue to support small and rural practices. In 2017, the national mean and median scores for all MIPS eligible clinicians were 74.01 and 88.97 points. However, the mean and median scores for small practices were 43.46 and 37.67. The lower scores achieved by small practices illustrate the need for CMS to work with Congress and the physician community to continue to support and make changes that will help small practices and solo practitioners succeed in the program. Costs for reporting must be kept low, so that the value of a high score is more than the cost to achieve it.

The simplest way to ensure small and rural practices remain viable is to maintain the low volume threshold. To eliminate or reduce the threshold and force physicians to participate in MIPS would harm

the viability of small practices. Financially, it does not make sense for these practices with limited resources to invest in MACRA compliance when they have such a small Medicare patient population—less than four Medicare patients a week.

In addition, for those small practices that treat larger Medicare patient populations and participate in the MIPS program, the most helpful assistance comes in shaping the MIPS program to allow practices of all sizes to be successful. For example, the reduced reporting requirements for small practices in several of the MIPS reporting categories, hardship exemptions from the Promoting Interoperability performance category for qualifying small practices, or bonus points for small practices greatly help small practices succeed in MIPS.

MIPS Audits

On June 20, 2019, CMS announced it had begun auditing MIPS data for performance years 2017 and 2018. The AMA has shared several concerns about the audits with CMS staff and urges the agency to carefully evaluate the burden of complying with these audits, particularly considering the onerous cost to participate in MIPS overall. Requests for medical records and other documentation will add to the administrative burden of participating in MIPS. Additionally, this will be a significant burden on small practices who do not have staff to pull chart requests or other documentation, and we think they should be given additional assistance and time to respond to the audit request. Finally, we have concerns about the notice of the MIPS audits. The announcement was made on June 20 when audit requests were already being sent to practices and before there was a guide for physicians and practices to reference to be successful in responding to the audit requests.

Recommendations:

- The AMA urges CMS to audit the vendors rather than increasing the burden of MIPS on physicians and practices.
- We urge CMS to support small and rural practices by providing them with additional assistance if selected for an audit.
- Finally, it would be helpful if CMS publicly posted a copy of the audit request letter so practices, state and national specialty medical societies have more clarification of what is expected of them in order to be successful in responding to the audit.

Promoting Interoperability (PI)

Reporting by Attestation

CMS should utilize the authority granted to the Secretary through HITECH to permit reporting in PI through yes/no attestation. Each “yes” would be worth a certain amount of points. In addition to relieving the reporting burden, an attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report, and could help prioritize both existing and future gaps in health IT functionality. This can be accomplished by adding the following to 1848(q)(2)(B)(iv): “For the performance category described in (A)(iv), the requirements shall be met via attestation or other less burdensome means.”

Reduce Reporting Burden by Leveraging Stronger Interoperability and Patient Access Incentives

We strongly encourage CMS to reevaluate the need for prescriptive PI measures and objectives given the multitude of patient access and interoperability incentives for physicians. We appreciate CMS' emphasis on patient access and interoperability measures in the current PI programs. These two priorities will continue to receive a large emphasis from physicians as there will be multiple levers—with significant penalties—to accelerate patient access and health information exchange: MIPS information blocking requirements, Office of National Coordinator for Health Information Technology's (ONC's) information blocking regulation and Trusted Exchange Framework and Common Agreement (TEFCA), and the Health Insurance Portability and Accountability Act's (HIPAA) patient right of access (The Office of Civil Rights' Director Severino has already noted publicly that patient access enforcement will increase this year). These levers provide significant motivation for physicians to use health IT, greatly empower patients to access their records, and advance interoperability. **Removing the burden of PI compliance and reporting will also help alleviate physician burnout related to EHR use.** Continuing to require prescriptive PI measurement will detract from clinical relevance, add burden, and focus PI participation on documentation, reporting and compliance rather than patient access and interoperability. Furthermore, technology continues to evolve, and current PI measures are likely to become quickly outdated or fail to promote innovative uses digital health tools. Said another way, even the proposed 2020 MIPS PI measures are tied to the legacy of Meaningful Use. **Given the Administration's focus on Patients over Paperwork and emphasis on reducing physician burden, measures that track and monitor physicians' use of EHRs should be abandoned.**

CMS should create broad categories of PI objectives allowing physicians to attest “yes/no” to the use of CEHRT to achieve those categories. This will provide flexibility for patients and physicians to efficiently test new uses of technology—identifying what does and does not work while encouraging the use of EHRs. Compliance with MIPS information blocking requirements, ONC's information blocking regulation, TEFCA, and HIPAA's patient right of access are themselves far better mechanisms to drive interoperability and promote patient access while reducing federal regulatory burden.

Leverage EHR Vendor-Generated Information to Reduce Physician Burden

CMS and ONC should leverage EHR data generated as a byproduct of PI participation. EHR vendors already track and record many data points used for PI reporting, so there is no need to continue to use physicians as reporting intermediaries. For instance, CMS' “Support Electronic Referral Loops by Receiving and Incorporating Health Information,” PI measure groups summary of care records received and the reconciliation of clinical information into one process. Physicians are required to manage and report both the acceptance of summary documents and the reconciliation process. This tasks physicians with juggling the technical aspect of interoperability, i.e., digital document capture and incorporation, and the laborious process of reconciliation. In fact, our members view information reconciliation in an EHR as “overwhelming” and adding “a lot of non-meaningful noise” to their patients' charts.

Instead of focusing on EHRs as a tool for measuring physician actions, more clarity is needed on whether the EHR was able to use the summary of care document without burdening the physician, whether the EHR was able to provide the physician with usable and actionable clinical information in a format that supports clinical decision making, and if the EHR enabled a closed-loop referral. Essentially, more needs to be done to understand how EHRs actually function and should function in the real world. This type and level of information is far more meaningful and valuable to physicians, CMS, and ONC, and should be what federal EHR reporting programs promote. Analyzing this information would expose the usefulness of the EHR, if the EHR could accommodate the needs of the physician, whether the EHR contributed to

or detracted from patient care, and whether the EHR supported the goal of health information exchange. Knowing this will also help EHR vendors build better products. Opportunely, because EHRs already track what functionalities are used to perform tasks, EHR vendors should directly provide such information to CMS and ONC. This data capture mechanism also conveniently provides an audit trail for CMS.

ONC and CMS should work together to implement a “record once, reuse multiple times” approach, leveraging EHR-captured data for multiple needs—including CMS’ Promoting Interoperability programs and to inform EHR development going forward. To be clear, the intent is to reduce the reporting requirements on physicians by using EHR-captured data—provided by the EHR vendor—as an alternative, supplement, or direct replacement for physician reporting in programs like Promoting Interoperability. Ideally, EHR vendors would report on how a measure was achieved and physicians would attest (as discussed in the previous section) to their experience in meeting that measure. This not only reduces physician reporting burden, but also creates a feedback loop to EHR vendors—allowing them to improve EHR use based on physician need. The AMA strongly suggests ONC and CMS identify a plan to operationalize this concept. We offer our assistance in further reducing physician burden through this and other novel approaches.

Encourage Coordination when Developing Quality Measures

CMS and ONC should also coordinate with health IT developers and measure stewards, including national medical specialty societies, to ensure optimal development of electronic quality measures. EHR development continues to be shaped by federal reporting requirements—not the needs of patients and physicians—which severely limits their ability to support actual patient care and improvement. While FHIR is a step in the right direction it is still a premature standard for quality measurement. As a result, in order to achieve meaningful use of the right health care data, used at the right time, for the right patient, practices continue to have to utilize multiple modalities of data collection and dissemination, which increases burden and cost. Disconnecting the linkage between EHR development and federal reporting requirements is also a crucial step in improving physician satisfaction.

Recommendations:

- Permit reporting in PI through yes/no attestation.
- Allow more powerful incentives to drive interoperability and patient access while reducing regulatory burden on physicians.
- Leverage EHR vendor-generated information to reduce physician burden.
- Encourage coordination when developing quality measures.

Medicare Access and CHIP Reauthorization (MACRA) Legislative Refinements

Since the enactment of MACRA, the AMA has worked closely with both Congress and CMS to promote a smooth implementation of MIPS and APMs under the QPP. We continue to believe that MACRA represents an improvement over the flawed sustainable growth rate payment methodology and the previous quality reporting programs. However, the implementation of a new Medicare quality and payment program for CMS and physicians has been a significant undertaking, and further refinements are still needed to improve the program and reduce administrative burden for physicians. While this is not a

comprehensive list, the AMA is seeking the following legislative refinements to continue to improve the QPP:

- Allowing CMS flexibility to set the performance threshold beyond 2022, and the possibility of separate performance thresholds for small and large practices;
- Including clear legislative language allowing for multi-category credit;
- Allowing doctors to use CEHRT or technology that builds on CEHRT to be considered a meaningful user within the promoting interoperability category;
- Allowing the use of episode-based cost measures in lieu of the less reliable total cost of care measure; and
- Extending the Advanced APM bonus payments to fulfill Congress' original intent and provide support to physicians as they transition to new payment models.

We urge CMS to support these statutory refinements as we believe they are complementary to the agency's goals of alleviating administrative burden on physicians who are participating in the QPP. The QPP is a complex program that remains complicated for CMS to implement and difficult for physicians to understand; however, the AMA is confident that if Congress, CMS, and the medical community continue to work together to improve the program, we can ensure physicians have the opportunity to be successful and provide high value care to patients.

Virtual Credit Card Payments

Because of virtual credit cards (VCC), physicians are faced with up to a five percent payment cut and increased administrative burdens. Health plans and their vendors are increasingly issuing claims payments to physicians and other health care professionals using VCCs, a nonstandard form of electronic payment.

CMS issued guidance via Frequently Asked Questions (FAQs) in 2017 that provided critical protections to health care providers by pushing back on coercive and unfair practices by health plans regarding virtual credit cards. Unfortunately, CMS' FAQs were removed from its website, leaving physicians with uncertainty, potential administrative hassles, and the challenge of fighting coercive payer business tactics. Physicians need appropriate industry safeguards to successfully run their businesses as they see fit. The CMS FAQs endorsed honest, fair business in the health care industry by enabling physicians to make informed, independent choices regarding the appropriate payment method for their practice. Moreover, the ambiguity left in the wake of the FAQs' removal undermines widespread industry efforts to increase voluntary adoption of the EFT standard, reduce manual burdens, and achieve significant cost savings. **Accordingly, CMS should reaffirm physicians' right to refuse virtual credit card payments and receive basic standard electronic funds transfer without fees imposed by health plans or their vendors.**

Certification and Documentation

Eliminating and streamlining reporting, monitoring, and documentation requirements will improve the health care delivery system by reducing unnecessary burdens for physicians and making the health care system more effective, simple, and accessible. Medicare documentation requirements are a major imposition that delay care with redundant requirements for verifying physician orders and voluminous medical records, where the salient patient information is buried in reams of purposeless, formulaic language. In particular, CMS should review subregulatory guidance documents and the burden they can

have on physicians. Moreover, individuals need to first understand the intricacies of CMS policies to even know where to find information or to combine statements from multiple CMS manuals to attempt to find a potential answer for questions regarding payment and coverage. Unfortunately, no one set of rules exists that physicians can go to for clarity. Instead, physicians must navigate a patchwork of state and federal regulations and carrier-specific requirements that govern what information is necessary to support a service, who can perform elements of the service, and who can enter the information into the medical record.

Recommendations:

- CMS should reduce certification requirements and standardize forms.
- CMS should provide a single source of information for physicians or administrators looking for clarification of a CMS policy.

Unique Device Identifier (UDI) and Claims

The UDI for medical devices aims to improve post-market surveillance and patient safety. While the AMA strongly supports the incorporation of the UDI on medical devices, there is some debate about the most appropriate place to capture this information. CMS and the Food and Drug Administration (FDA) have called for including part of the UDI in the next claims form template update, which has yet to be published by the responsible standards development organization (X12) and is years away from being federally mandated for industry use. However, new certification requirements that allow EHRs to capture and transmit the full UDI will be implemented throughout 2019. The AMA views EHRs and registries as the most appropriate method to capture and manage the UDI. Capturing UDI information in administrative claims represents a significant cost to providers, as well as the industry, and claims information does not follow a patient as they switch insurers. The claims form changes would also not require the capture of the full UDI, instead capturing only the device identifier (“DI”) portion and excluding the product identifier portion. Both the Production Identifier and DI are key in providing the complete picture about a medical device when safety issues arise. Capturing this information in a patient’s EHR allows the full medical device information to follow patients, and their longitudinal medical history, regardless of changes in insurance.

Recommendation:

- CMS should not require the capture of the DI portion of the UDI on administrative claims forms. The full UDI should be captured instead within a patient’s electronic medical record and managed by EHRs and appropriate registries. Registries that collect data from EHRs could gather UDI data in the aggregate to support comparative studies and post-market surveillance.

Medicare Advantage Star Ratings

As the Star Ratings program has expanded and plays a larger financial role on health plans’ bottom lines, the administrative demand has simultaneously increased on physicians and is impeding clinical care and thus does not provide a beneficiary benefit. A large percentage of the measures within the MA Star Ratings program are based completely on physician action, compliance and communication. In order for health plans to increase their Healthcare Effectiveness Data and Information Set (HEDIS) scores and earn greater incentives from CMS, plans are requiring practices as part of their clinical data submission

requirements to submit data on all patient lab results and tests and the plans state it is due to the Star Ratings HEDIS requirements. Many of the measures, particularly the HEDIS Effectiveness of Care measures, have more to do with physician quality than assessment of a health plan. The Effectiveness of Care measures are really targeting clinical quality, which is a physician or facility issue—and therefore physicians and facilities have the data. In addition, the patient experience ratings are heavily based on Health-Plan, Consumer Assessment of Healthcare Providers & Systems (CAHPS) that focus on physician communication and behavior. While communication between a physician and patient is important, asking the questions in a de-identified survey does not lead to quality improvement or address potential challenges patients experience when seeking care. Similar questions are also in the hospital and clinician-group CAHPS survey and the more appropriate avenues for addressing provider communication in the context of patient experience. Without a better focus the MA ratings program is just one more burden on physicians and does not provide beneficiaries with the information they need to determine the most appropriate and high-quality MA or drug plan.

Recommendations:

- CMS should refine Star Ratings to better measure the quality of plans and things over which the plan has control and the supporting data (e.g., access);
- CMS should require health plans to allow practices to respond at-will at a time of their choosing, at a minimum allow for at least 90 days to respond, support use of electronic methods of data submission, and adequately compensate physicians for the time and burden;
- CMS should allow for more general exclusions for patients with specific conditions, comorbidities or allergies from measures to ensure patient and clinical differences are accounted for and do not interfere with clinical decision making;
- Denominators of quality measures should be appropriately defined to ensure patients for whom the treatment may not be appropriate are excluded from measurement; and
- CMS should work with AHRQ to update the Health-Plan CAHPS survey to better consider barriers to access, such as the intentional design of narrow networks. The current survey focuses heavily on physician communication and behavior and is duplicative of Hospital and Clinician-Group CAHPS.

Data Requests to Support MA Risk Adjustment Scores

MA plans routinely demand medical records from physician practices as a means of identifying information plans use to support increases in payments from CMS that are tied to the health status of plan enrollees. Only a small fraction of these requests is linked to CMS audits of MA risk adjustment data. Plans generally provide no compensation for staff time required to pull records and make copies. Physicians frequently complain that charts are demanded for large numbers of patients and that the same practices are repeatedly subject to these demands, often for the same patients. MA plans frequently subcontract the chart audits to third parties so the medical practice has no idea which plan is making these demands, and misleading statements are made that the audits are required by CMS when they are not. Although having more complex patients involves more physician work, physicians do not receive any additional compensation from MA plans that have higher risk adjustment scores. Instead, those practices that are able to help plans increase their scores are likely to face repeated demands for risk information in the future, adding to their regulatory burdens.

Recommendations:

- CMS should accept physician attestations to support MA beneficiaries' diagnoses instead of requiring documentation from medical records;
- Once beneficiaries have been diagnosed with a permanent condition (e.g., multiple sclerosis, quadriplegia, arthritis), this diagnosis should follow them from year-to-year and not have to be re-designated each year; and
- To eliminate ambiguity as to the authority, regulation, policy, and MA plan contract that is the basis for medical record requests, CMS should require all MA plans to use a standard letter.

2-Midnight/Observation Care

Medicare considers observation care to be an outpatient status, even though it is provided within the hospital walls, and in many cases, is virtually indistinguishable from care provided to inpatients. Since observation care and inpatient admissions are billed under different payment systems (Medicare Part B and Part A, respectively), physicians must prospectively predict how long patients will need to stay in the hospital to bill for observation services. This feature of payment policy is unnecessary, illogical, and unrelated to caring for patients.

Navigating the rules around inpatient admissions and outpatient observation care requires a significant shift of health care resources away from direct patient care. Hospitalists report that, in addition to themselves as the direct health care provider, status determinations between inpatient admissions and outpatient observation care require the input of a myriad of staff including nursing, coding/compliance teams, utilization review, case managers and external review organizations.⁵ A recent study in the *Journal of Hospital Medicine* indicated that an average of 5.1 full time employees, not including case managers, are required to navigate the audit and appeals process associated with hospital stay status determinations.⁶ Another recent study in *Professional Case Management* indicated “hospital case managers’ time is inordinately leveraged by issues related to observation status/leveling of patients and CMS compliance. The data also suggest that hospital case management has taken a conceptual trajectory that has deviated significantly from what was initially conceived (quality, advocacy, and care coordination) and what is publicly purported.”⁷ The result for providers is staff, time, and money being directly pulled away from patient care and quality improvement efforts (such as novel transitions programs, communication, and coordination of care) to comply with existing Medicare policies. Medicare rules developed 54 years ago do not work well in today’s health care environment.

The “2-Midnight” rule has had significant unintended negative consequences that burden Medicare beneficiaries. It remains an artificial construct reflecting a flawed approach that gets in the way of the patient-physician relationship and unnecessarily increases the administrative burden of admitting

⁵ Society of Hospital Medicine. *The Hospital Observation Care Problem: Perspectives and Solutions from the Society of Hospital Medicine*. September 2017. Accessed July 23, 2018 via <https://www.hospitalmedicine.org/globalassets/policy-and-advocacy/advocacy-pdf/shms-observation-white-paper-2017>.

⁶ Sheehy AM, et al. Recovery audit contractor audits and appeals at three academic medical centers. *J Hosp. Med.* 2015 Apr;10(4):212-219.

⁷ Reynolds JJ. Another Look at Roles and Functions. Has Hospital Case Management Lost Its Way? *Prof. Case Mgmt.* 2013 Sept./Oct.; 18(5):246-254.

physicians. The Medicare Payment Advisory Commission voted unanimously on a recommendation to withdraw the “2-Midnight” rule as it detracts from admission criteria that depend upon clinical judgment.

Recommendation:

- CMS should rescind the “2-Midnight” rule by terminating observation status in total and instead rely on physicians’ clinical judgment to determine a patient’s inpatient/outpatient status.

Ordering Therapeutic Shoes for Persons with Diabetes

There is a collage of statutory and regulatory requirements that must be met in order to certify, order, and supply therapeutic shoes to Medicare patients with diabetes. The statute requires a physician who is managing the patient’s diabetic condition to certify the need for therapeutic shoes. In sub-regulatory guidance, CMS has interpreted this to mean that the certifying physician (MD or DO only) must either: (1) personally document that the patient meets the criteria and had an in-person visit within 6 months prior to delivery of the shoes, or (2) obtain, initial, date and indicate agreement with information about a patient’s in-person visit with a podiatrist, other physician, PA, NP, or CNS that is within 6 months prior to delivery of the shoes. Then, the certifying physician (MD or DO only) must have an in-person visit with the beneficiary during which diabetes management is addressed within 6 months prior to delivery of the shoes and sign a certification statement on or after the date of the in-person visit and within 3 months prior to delivery of the shoes.

As a result of this complex web of hurdles to ordering therapeutic shoes for diabetic patients, a certification of a patient’s medical need for therapeutic shoes and inserts for diabetes is required on an annual basis, even when there is no change to the patient’s condition and treatment plan. The AMA urges CMS to amend its sub-regulatory guidance to deem the physician’s initial certification of the patient’s medical need and qualifications for therapeutic shoes as meeting the statutory requirements for this benefit. Re-certification should only be required when there is a change to the patient’s underlying condition or treatment plan, such as when a patient’s diabetic condition improves and, thus, therapeutic shoes are no longer medically necessary. Patients, including patients with a chronic condition such as diabetes, deserve the full and undivided attention of their physicians in managing their condition. One way to do this is to eliminate the need for redundant paperwork.

In addition, we urge CMS to clarify that Doctors of Podiatric Medicine, or podiatrists, who are considered physicians under Section 1861(s)(12) of the Social Security Act, are able to prescribe, fit, and also certify the medical necessity for therapeutic shoes without a physician’s co-signature. We have heard that physicians receive requests to co-sign prescriptions and accompanying forms for therapeutic shoes from podiatrists who are qualified to prescribe, fit, and certify the medical need for the shoes simply to meet CMS’ sub-regulatory guidance. We believe this duplication of signatures is a result of confusion around the sub-regulatory requirements for ordering therapeutic shoes for individuals with diabetes and should be clarified to reduce burden.

Recommendations:

- CMS should modify its sub-regulatory guidance to require that a physician re-certify the medical need for therapeutic shoes and inserts for persons with diabetes as necessary when there is a change to the patient’s condition or treatment plan, rather than on an annual basis.

- CMS should clarify its sub-regulatory guidance to permit a podiatrist who is prescribing therapeutic shoes and inserts for individuals with diabetes may independently meet the requirement to certify the patient's need for such shoes without a co-signature from a physician.

Positive Incentives for Cybersecurity

Cybersecurity is a national priority and physicians, other health care providers, and patients need tools to secure sensitive patient information in the digital sphere. Cybersecurity is also a patient safety issue, as recognized by the FDA, the Healthcare and Public Health Sector Coordinating Council (HPHSCC), and HHS' own Cybersecurity Task Force's report to Congress. As clinical adoption of digital medicine tools accelerates with new innovations, and in light of increased public and commercial insurer coverage of digital medicine tools and services, there is increased urgency to advance policies that remedy vulnerabilities in cybersecurity. To protect practice continuity and patient information, this conversation should be seen as an opportunity to encourage cybersecurity activities rather than punitive requirements.

Recommendations:

- Create a cybersecurity anti-kickback safe harbor/Stark exception; and
- Create improvement activities for the Medicare Quality Payment Program that promote good cyber hygiene.

Modernizing the Stark Law

Significant changes in health care payment and delivery have occurred since the enactment of Stark. Numerous initiatives are attempting to align payment and coordinate care to improve the quality and value of care delivered. The delivery of care is going through a digital transformation. However, Stark—in its almost 30 years of existence—has not commensurably changed. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all may run afoul of these laws. For example, the Stark law impedes care coordination. Specifically, in certain circumstances, it prohibits physicians from coordinating care on behalf of their patients.

Recommendations:

- Create a Stark exception to facilitate coordinated care and promote well-designed Alternative Payment Models (APMs). This exception should be broad, covering both the development and operation of a model to allow physicians to transition to an APM model, and provide adequate protection for the entire care delivery process to include downstream care partners;
- Revise the definition of group practice or create a new type of value-based care bonus that allows physicians to receive shared savings or incentive payments that directly take into account the volume or value of referrals and still qualify as a group practice; and
- Repeal the ban on physician-owned hospitals that reduces and restricts competition and choice in health care markets.

Quality Improvement Organization Alignment

AMA staff met with CMS officials regarding concerns with how the Quality Improvement Organizations (QIO) appeals process is currently structured. Physicians who have experienced a QIO appeal have voiced concern that the process, and particularly redeterminations, lacks fairness. The Medicare QIO Manual explicitly states that the QIO must inform the beneficiary that, if the QIO receives a request for reconsideration from any of the parties, the results of the Final Initial Determination could change.⁸ CMS officials indicated that providers are also informed in these situations. However, the QIO Manual does not include this parallel requirement that the provider must be informed. Therefore, we ask that the QIO Manual be updated to align with the actual practice.

Perhaps more troubling, when one party initiates a redetermination request, the QIO Manual does not discuss offering the other party the opportunity to provide any information.⁹ While we recognize that the QIO process is administrative in nature, we have heard specific concerns from our members on this issue. We understand that situations exist, particularly in rural areas, where the beneficiary may not want to jeopardize their relationship with a provider. Thus, while allowing for certain exceptions to cover specific situations, we urge the Agency to adopt a policy that notifies parties when a redetermination review is initiated. The burden should fall on the party initiating the redetermination to explain why the other party should not be informed of a reconsideration. The AMA believes that giving both parties appropriate notification during redeterminations would help rectify the current inequities built into the QIO appeals process.

Recommendations:

- Align the QIO Manual guidance on redeterminations to be consistent with current Agency instructions to the QIOs; and
- Adopt a policy that notifies parties when a redetermination review is initiated.

Medicare Contractor Transparency and Oversight

CMS should demonstrate operational flexibility by eliminating or streamlining the audits and reviews by pre- and post-payment contractors. The AMA appreciates the efforts of CMS in implementing the Targeted Probe and Educate program for Medicare Administrative Contractors (MACs) and encourages expansion of similar efforts. However, the amount of reviews and types of reviewers is confusing, adds unwarranted physician burden and unnecessary costs, and disrupts and distracts from delivering patient-centered care. CMS should also recognize clinical factors unique to each patient prior to imposing financial penalties on patients. Furthermore, some contractors are performing audits or recoupments beyond those required by Medicare or are not adhering to CMS requirements surrounding the approval of Local Coverage Determinations (LCD). **Physicians need a single transparent, consistent, and fair review process to reduce administrative burden.**

CMS can simplify rules and policies for physicians surrounding these reviews.

⁸ CMS, *Quality Improvement Organization Manual*, Chap. 5, § 5055.6 (“[A] QIO must also inform the beneficiary if the QIO receives a request for reconsideration from any of the parties, the results of the QIO’s Final Initial Determination could change.”).

⁹ *See id.* § 5060.

Recommendations:

- Develop a uniform approach for reviewers in notifying physicians of a review, requesting records, informing physicians of the specific reason why a claim is denied, and conspicuously stating a physician's appeal rights and avenues;
- Apply consistent and clear Medicare and Medicaid payment and coverage policies including having contractors follow the proper notice and comment process regarding LCDs;
- Issue guidance to contractors that minor wording or clinically insignificant documentation inconsistencies should not result in nonpayment or extrapolation of overpayments;
- Work with HHS to eliminate duplicate review of claims among different Federal government reviewers;
- Clarify the function and scope of authority of the contractors;
- Establish an internet portal for consolidating information on program integrity efforts including contractor sampling and extrapolation methodologies;
- Publish data on an annual basis about contractor activities including the number of denials and appeals, net denials (defined as total denials minus denials overturned on appeal), each contractor's appeal rate, and common coding and billing errors and omissions (e.g., error type, omission type, physician specialty, contractor, and region);
- Increase its physician education efforts on how to avoid common coding and billing mistakes and work with physician practices to address internal deficiencies that may have led to a high volume of coding and billing errors;
- Refine reviews using predictive analytics to focus on claims that are at high risk for improper payments and providers that are identified as outliers;
- Capture and consider specialty, patient mix, and site of service;
- Ensure that audits are reviewed by a practicing physician of the same specialty;
- Apply a financial penalty on contractors when denials are overturned on appeal; and
- Replace financial penalties with corrective action plans.

Recovery Audit Contractors

While CMS needs to streamline the amount and type of all reviewers, focusing on Recovery Audit Contractors (RACs) will reduce burden for physicians, decrease costs, and ensure physicians are focused on providing patient-centered care and improving outcomes. RAC auditors retain a percentage of the amount they recover for the government with little regard for the burden and accuracy of the audits. These audits are a great source of frustration for the physician community.

RACs are tremendously inaccurate. In FY 2016, 65 percent of Medicare RAC Part B determinations appealed were decided in the provider's favor.¹⁰ This is an unacceptable rate and cannot continue.

¹⁰ CMS, *Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2016*, p.16, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY-2016-Medicare-FFS-Report-Congress.pdf>.

Recommendations:

With RACs, the AMA recommends that CMS:

- Allow for settlements for Part B claims to ease appeal backlog;
- Require RACs to reimburse the costs (including interest) to physicians who win on appeal of a RAC audit;
- Implement meaningful financial penalties and fines for RACs who make errors;
- Repeal the contingency fee structure of the RAC audits;
- Retain the current RAC medical record request limits to ensure audits are not overly burdensome; and
- Ensure that RAC audits are reviewed by a practicing physician of the same specialty or subspecialty and in the same jurisdiction.

Sunshine Act/Open Payments

The AMA supports significant modifications to the Sunshine Act including substantially increasing the monetary threshold for reporting, protecting physician rights to challenge false and misleading reports, changing the dispute process so that successfully disputed charges are not included publicly on the Open Payments database, and providing a meaningful, accurate picture of the physician-industry relationship.

Challenging Reports and Changing Disputes

As currently structured, the Open Payments Review and Dispute process is not fair for physicians because no reporting option exists when there is not a mutually agreed upon resolution to a disputed payment with an applicable manufacturer or Group Purchasing Organization (GPO). The reporting options—Resolved, Resolved No Change, and Withdrawn—and the definition of “Resolved” appear to heavily favor industry by assuming that all disputes will be resolved to the satisfaction of both parties when that is not always the case. This appears related to CMS’ decision, at the inception of the Open Payments Program, to leave the dispute resolution process up to the parties—applicable manufacturers and GPOs and physicians—to resolve. Unfortunately, this approach was not designed to guarantee physicians an equitable, transparent, or fair process but rather to process disputes as quickly as possible, allowing applicable manufacturers and GPOs to unilaterally dismiss disputes lodged by applicable physicians and teaching hospitals. The AMA has heard from members that some manufacturers and GPOs are not, in fact, acting in good faith to resolve disputes. This is contrary to what one would expect in terms of fair notice and transparency.

The final rule implementing Open Payments does not authorize applicable manufacturers or GPOs to dismiss disputes without both parties agreeing that the dispute is resolved. In fact, it requires both parties to reach a mutually agreeable resolution and, when that is not possible, to mark the payment as disputed.¹¹ Given the intent of the final rule, CMS should, at a minimum, amend its reporting options to reflect the reality that payment disputes are not always resolved. Accordingly, CMS must change the dispute process so that successfully disputed charges are not included publicly on the Open Payments data base.

¹¹78 Fed. Reg. 9458, 9502 (Feb. 8, 2013) (“If a dispute cannot be resolved [by the end of the 15-day resolution period], the parties may and should continue to work to reach resolution and update the data. However, [CMS] will continue to move forward with publishing the original and attested data, but will mark it as disputed.”).

Eliminate Disincentives for Clinicians to Accept Educational Materials

To provide a more meaningful and accurate picture of the physician-industry relationship, CMS should place textbooks and scientific peer-reviewed medical journals, reprints, supplements, and abstracts among items excluded from reporting requirements.

The Sunshine Act was designed to promote transparency about payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined 12 specific exclusions from the reporting requirement, including educational materials that directly benefit patients or are intended for patient use. In its interpretation of the statute, CMS concluded that medical textbooks, reprints of peer-reviewed scientific clinical journal articles and abstracts of these articles are not directly beneficial to patients, nor are they intended for patient use.

We believe that patients benefit directly from improved physician medical knowledge. The importance of up-to-date, peer-reviewed scientific medical information as the foundation for good medical care is well documented. Scientific peer-reviewed journal reprints, supplements, and medical text books have long been considered essential tools for clinicians to remain informed about the latest in medical practice and patient care. Independent, peer-reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients.

Moreover, Congress included a specific exclusion of items that directly benefit patients, such as reference materials that are often used side-by-side with a patient as a first resource when a patient brings an unfamiliar medical issue to a clinician. Many medical textbooks and scientific medical journal supplements and reprints are used in this way by physicians. The design of the reporting requirement presents a clear disincentive for clinicians to accept high-quality, independent educational materials; an outcome that was unintended when the provision was passed into law.

Recommendations:

- CMS should amend its reporting options to reflect the reality that payment disputes are not always resolved.
- CMS must change the dispute process so that disputed charges are not included publicly on the Open Payments data base.
- CMS should place textbooks and scientific peer reviewed medical journal reprints, supplements, and abstracts among the items excluded from the Sunshine Act's reporting requirements.

Medicare Opt-Out

In 2015, Section 1802 of the Social Security Act was modified by the Medicare Access and CHIP Reauthorization Act (MACRA) to remove the previous requirement for physicians who have opted out of Medicare to renew the opt-out affidavits filed with their Medicare Administrative Contractor every two years. The AMA strongly supported this MACRA regulatory relief provision.

In addition to filing an affidavit, physicians who opt-out are required to privately contract with each of their patients who is insured by Medicare. Medicare regulations no longer require physicians to renew their opt-out affidavits every two years, but they still require physicians' private contracts with each

patient to be renewed every two years. Our members indicate that their patients view this requirement as excessive bureaucratic red tape.

There is no statutory requirement for the private contracts to be renewed every two years. As patient encounters with physicians may occur at any time, the every-two-years renewal date is likely to vary from patient to patient, making it burdensome to keep track of when each patient's private contract is due to be renewed. This regulatory requirement serves no purpose and should be eliminated.

Recommendation:

- Effective as soon as possible, CMS should remove the requirement for physicians who have opted out of Medicare to renew their private contracts with patients every two years.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

On July 26, 2019, CMS released a transmittal to the Medicare Administrative Contractors (MACs) about accepting G-codes and modifiers for Appropriate Use Criteria (AUC) on Medicare claims for advanced diagnostic imaging beginning Jan. 1, 2020. We were pleased CMS will continue to pay claims that do not include the consultation information or that contain errors related to the AUC information as there remain many outstanding technical and operational questions and challenges that will limit physician voluntary participation. For instance, CMS' MLN Matters fact sheet acknowledges that "[I]nstitutional claim providers do not have the capability to report line level ordering physician information on the institutional claim at this point. CMS is working with industry partners and will provide additional instructions on reporting line level ordering physician information for institutional claims at a future date."

We strongly believe that continuation of the voluntary education and testing period is necessary until CMS has adequately addressed technical and workflow challenges with its implementation and interaction between the QPP and the use of advanced diagnostic imaging AUC. We remain concerned about the scale and complexity of the AUC mandate along with the implementation of other complex programs like the QPP and believe more time is necessary for proper education and preparation.

With AUC, both CMS and physician practices will have to work out significant technical and workflow challenges prior to full-scale implementation including the use of G-codes with modifiers. Additional time may also allow CMS to determine whether incentives in the QPP offer a less burdensome means of achieving the AUC objectives. CMS should also consider exempting physicians from the AUC requirements when the physician is participating in the QPP. This means that additional delay may be necessary. Then, having gained additional information, CMS can evaluate the program via analysis of claims data and determine whether the AUC program is ready for full implementation.

Significant Hardship Exceptions

CMS finalized three significant hardship exceptions from the AUC requirements that are specific to the AUC program and independent of other Medicare programs. The AMA supports the three significant hardship exceptions relating to insufficient internet access, EHR or qualified clinical decision support mechanism (CDSM) vendor issues, and extreme and uncontrollable circumstances.

In order to promote administrative simplification, CMS also needs to align the hardship exceptions in the QPP with the AUC program including the exemptions for new physicians for one year and for low volume of Medicare patients. The AMA does not understand why CMS established different exemptions for closely related and similarly burdensome programs. Allowing for new physicians or low volume physicians to be exempted from participating in MIPS but not from the AUC program with its highly complex and potentially expensive requirements is inconsistent, confusing, and burdensome. Moreover, to reduce burden, CMS should also consider allowing for physicians to attest once as to the existence of certain hardship exemption rather than having a physician attesting with every individual order and on every claim, especially in extreme and uncontrollable circumstances like a natural disaster.

Coding Methods

CMS established the coding methods to include G-codes and modifiers to report the required AUC information on Medicare claims. While the AMA believes that any new reporting information introduces significant burden to physicians in multiple respects, the new G-code and modifier approach likely represents the best option that is available at this time. The claim fields already exist to report the data and individuals generally know how to report G-codes and modifiers. Furthermore, CMS should intend that the G-code/modifier be a long-term solution. Implementing a temporary solution and then a different permanent solution will be burdensome to providers from both a technology and education standpoint.

The AMA realizes the law requires that each claim identify the specific G-code representing the consulted CDSM for a particular imaging service; however, given the burden, CMS may need to consider discussing potential legislative fixes with Congress or limiting the required data reporting to only the priority areas. We also have concerns regarding the burdens of tracking when G-codes are available for newly approved CDSMs. CMS should tie the time when a specific G-code becomes available to the availability of newly-approved CDSMs. This approach provides more certainty than when the specific G-code “becomes available.”

In using the G-code and modifiers, CMS needs to address the issue of reporting multiple services in the same claim and how to address situations in which the service lines are unintentionally re-ordered during processing. Reporting additional data in the claim to link the procedure and AUC service lines should not be required, as this adds more burden on the physician to report the data. Instead, CMS should develop a process to identify these claims and a solution for how to maintain the original pairing of the procedure and AUC service lines.

More broadly, we have significant concerns about numerous workflow challenges and questions that will result from the AUC program requirements. It was our initial understanding that AUC reporting requirements would be limited to only the priority clinical areas identified by CMS. Based on the language of the July 26, 2019 transmittal to the MACs, the AUC reporting requirement appears to be for all advanced diagnostic imaging services. While it will be burdensome for ordering physicians to easily identify the diagnoses and specific advanced diagnostic imaging services to which the AUC requirements apply so that they can consult the CDSM at the time of ordering, it will be more problematic to query a CDSM with the ordering of every advanced diagnostic service. Not all physicians will have the CDSM incorporated into their EHR or workflow and it will be time consuming and disruptive to complete a query for every advanced diagnostic imaging order, especially since CMS has identified that it will only be analyzing the AUC data for the priority clinical areas.

The other workflow challenge will be communicating the information regarding the CDSM consultation from the ordering to the furnishing providers, as the physician ordering the imaging service in most cases will be different than the physician performing the imaging. Thus, not only must the claim change but also all methods used to send an order (electronically or otherwise).

While a standard and technological solution for transferring this information from ordering to furnishing providers (Integrating the Healthcare Enterprise Radiology Technical Framework Supplement Clinical Decision Support Order Appropriateness Tracking) is in development, it is in an immature, pilot stage, meaning that providers will most likely need to rely on manual workflows to exchange these data during the implementation of the AUC program. Additionally, providers will need to determine optimal procedures for these communications. For example, will ordering providers send the applicable G-codes and modifiers to the furnishing physician, or will they simply send the information in text format that the furnishing provider will need to translate into the code and modifier? These communications and reporting burdens will be further compounded when different providers are responsible for the technical and professional components of the imaging service, as the ordering physician will need to send the CDSM consultation information to two separate providers to be reported on the technical and professional claims.

Outliers and PA

The AMA has numerous concerns regarding outlier identification and PA. Since the AUC program is in the early stages of development, we strongly urge CMS to take what will be learned from voluntary and testing periods and allow for proper evaluation of that experience prior to implementing any type of outlier approach. We also strongly urge CMS to be cautious and judicious in identifying outliers subject to PA, due to the patient care delays and potential for negative impact on clinical outcomes associated with PA. These concerns reinforce the need for restraint in implementing new PA requirements via the AUC program to avoid harm to Medicare patients.

Outliers can occur for a variety of reasons. While some may reflect a pattern of inappropriate ordering, outliers may also arise because a physician is aware of new information or changes in clinical practice, the AUC is outdated, or a patient's specific clinical condition warrants a particular service. CMS should not mislabel physicians as outliers for being innovators and delivering cutting edge care. Therefore, CMS needs to use pattern analysis to determine whether the issue is with the criteria or the physician. It is also not clear that physicians will have enough cases in all of the priority areas to accurately judge their performance when outlier identification starts.

CMS should focus its outlier identification on areas where there is consistent underutilization of appropriate services and consistent overutilization of services that are not recommended by up-to-date clinical guidelines. It will also be important to select only those conditions where there is significant variation in utilization among physicians and where there are generally agreed upon treatment guidelines. Physicians should only be compared against the criteria in the particular CDSM that they chose and not to all physicians who also ordered the service but used a different CDSM. The AMA recommends that CMS focus outlier identification on a few of the clinical priority areas. Finally, as with any program that profiles clinician performance, CMS should furnish any physician deemed as an outlier, well in advance of the implementation of any PA requirements, with a patient-level data report detailing the information used to make this determination and allow the physician the opportunity to request reconsideration based

on unique clinical circumstances and/or changes in evidence-based guidelines not yet reflected in the CDSM.

With the delay of the AUC program, the AMA believes there should be at least a similar delay as to when PA implementation begins. For example, the statute has the AUC program starting in 2017 with PA starting in 2020. Thus, if AUC is fully operational in 2021, PA should not start until at least 2024. Furthermore, any calculation used in determining PA must be based on at least two full years of data to match the statutory requirement that two years of data must be used to identify any outliers. Finally, data collected during the educational and operational testing period should not be used to determine a physician's outlier status.

Quality Payment Program

CMS should exempt physicians from AUC requirements when the physician is participating in the QPP. Physicians participating in Alternative Payment Models (APM) and MIPS APMs should be exempted because those physicians are already being held accountable for costs and outcomes, and are assuming risk. It is inherently in the practice's best interest to avoid inappropriate over- or under-utilization if they are participating in an APM. Furthermore, physicians participating in MIPS should also be exempt from AUC requirements because physicians are held accountable for cost and quality measures in the MIPS program. Additionally, there are at least 12 MIPS clinical quality measures that address imaging appropriate use, and there are likely more when considering Qualified Clinical Data Registry measures are not part of traditional rulemaking. We realize that this recommendation may require amending existing statute and thus recommend that CMS seek legislative authority to exempt physicians participating in the QPP from the AUC requirements.

The AMA appreciates CMS' belief that the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for advance notice of all involved parties. As a part of this stepwise approach, CMS needs to adequately address technical and workflow challenges with its implementation. Adding an additional year to the voluntary testing period may provide CMS adequate data to demonstrate whether the AUC program should be fully implemented or require further delay.

Recommendations:

- The AMA urges CMS to delay implementation of the AUC program and extend the voluntary education and testing period until CMS can adequately address the interaction between the QPP and MIPS by exempting physicians from AUC requirements when the physician is participating in the QPP.
- To reduce administrative burden and complexity, CMS also should align the hardship exceptions in the QPP with the AUC program including the exemptions for new physicians for one year and for low volume of Medicare patients.
- Finally, CMS should address and mitigate workflow and technical challenges with implementation, such as the burden of tracking when G-codes are available for newly approved CDSMs.

Improve Utilization of Medicare Care Management Services

To improve utilization of chronic care management (CCM), transitional care management (TCM), and other care management services by Medicare patients, the AMA recommends that CMS eliminate the cost-sharing requirements for these services. Physicians report several positive outcomes for beneficiaries who receive care management services, including improved patient satisfaction and adherence to recommended therapies, improved clinician efficiency, and decreased hospitalizations and emergency department visits. Although utilization of these services has been increasing in recent years, patient cost-sharing remains a barrier. Trying to promote participation in a care management program to patients, and then having to talk about patients' cost-sharing obligations, puts physicians in an uncomfortable position. With TCM in particular, physicians often begin the care coordination work prior to a face-to-face visit with the patient and there is some concern that patients will not understand the co-pay change.

To make matters worse, for those enrolled in Medicare Advantage, the costs to the patient can be prohibitive. Because these patients often have high deductibles, they can end up paying the full cost of the program. As a result, patients are reluctant to consent to participate in a care management service or program, and if they do, they frequently complain about the cost. These concerns often lead to them withdrawing from the program.

Recommendation:

- CMS should eliminate the cost-sharing requirements of CCM, TCM, and other care management services to improve the health of Medicare patients.

Clarify TCM Billing Guidelines for Medication Reconciliation

There is confusion regarding the Medicare billing requirements for TCM services, and in particular, whether clinical staff may complete and document medication reconciliation prior to or during the face-to-face visit. Medicare requirements indicate clinical staff, under the direction of a physician and subject to relevant state laws, may assess and support treatment adherence and medication management. The same sub-regulatory guidance goes on to say that a physician must furnish medication reconciliation and management on or before the date of the face-to-face visit. While we understand the significance of the timing of medication reconciliation for purposes of furnishing TCM, the AMA urges CMS to clarify that clinical staff, under the direction and supervision of a physician and subject to relevant state law, may complete and document medication reconciliation.

Recommendation:

- For purposes of Medicare billing requirements for the TCM, CMS should clarify that clinical staff, including registered nurses, subject to state supervision and scope of practice laws, may perform medication reconciliation under the direction of the physician or non-physician practitioner.

Teaching Physician Supervision During Minor Procedures

The AMA urges CMS to change its policy to allow reimbursement for minor procedures performed by residents as long as the supervising physician is present for the key portions of the minor procedure. Under current CMS regulations, for major surgical procedures a teaching physician must be physically

present during the key portions of the service and must be immediately available to provide the service during the entire procedure. During minor procedures, which are defined by CMS as lasting five minutes or less, the teaching physician must be physically present during the entire service in order to be reimbursed for the service by Medicare. The teaching physician is required to document his or her level of participation during the service.

The AMA does not believe that it is logical to treat major and minor procedures differently based solely on the length of the procedure. Many major procedures that are high-risk, intense procedures only require the physician to be present for the key portion of the procedure, whereas the physician is required to be present for the entire procedure for many less intense minor procedures. For example, in a dermatology practice, a physician may only be required to be present for certain key portions of a nasal soft tissue reconstruction procedure being performed by a resident, which is a major, high-intensity procedure. However, the teaching physician would be required to be present for the entire wart removal procedure performed by residents, which is defined as a minor procedure. Other minor procedures that would require a physician to be present throughout the entire procedure include 11719, trimming of nondystrophic nails, or 11055, pairing or cutting of benign hyperkeratotic lesion (corn or callus).

Also, the definition of the critical or key portions of a procedure is defined as the part or parts of a service that the teaching physician determines are critical or key portions. Currently, many specialty societies define the key portions of relevant major procedures. The determination of which portions of a major procedure a physician must be present for are left up to the specialty society, physician, or facility. Therefore, we believe that physicians should determine which portions of both a major and minor procedure they should be present for, as opposed to relying on the time the procedure takes to complete

Recommendation:

- CMS should change its policy to allow reimbursement for minor procedures performed by residents as long as the supervising physician is present for the key portions of the minor procedure.

Use of Third Parties to Design and Administer CMS Programs

Over the years we have seen an expansion and reliance on third party contractors to design and administer programs. For example, with the QPP program, we are aware of at least 6 different third parties that are involved with program design and drafting regulatory text. Increasingly, this reliance becomes more of a challenge because CMS staff must coordinate with numerous third parties to address problems, understand concerns and come up with proactive solutions. It is also leading to bad policy because the right hand is often not talking to the left hand. CMS should consolidate the work that is contracted out so that fewer outside organizations are involved and the overall effort is better coordinated.

Recommendation:

- CMS should consolidate the work that is contracted out so that fewer outside organizations are involved and the overall effort is better coordinated.

Real-Time Benefit Tools (RTBTs)

Physicians currently lack accurate, granular, patient-specific formulary data at the point-of-care, which limits their availability to have informed discussions about drug selection and costs during office visits. Formulary and benefit data must be seamlessly integrated within electronic health record (EHR) systems, as well as reliable and sufficiently detailed (unlike currently available Formulary and Benefit batch files), to be widely adopted by physicians. Provision of accurate, current information about a patient's prescription benefit will enable physicians and patients to evaluate drug costs and consider possible alternative therapies when selecting a medication regimen. Drug price transparency at the point-of-care has the potential to reduce drug costs for patients. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of prior authorization and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. Transparency of coverage restrictions in EHRs can thus prevent medication nonadherence and treatment abandonment.

We support the CMS' efforts to expedite industry implementation of RTBTs to support drug pricing transparency. However, the AMA disagrees with the specific approach detailed in the Medicare Advantage and Part D Drug Pricing Final Rule, which merely requires Part D plans to support a single RTBT that integrates with only one physician EHR/e-prescribing system. As such, physicians and their EHR vendors could presumably need to support a different RTBT for every Part D plan to have access to prescription benefit information for every patient treated by the practice. As projected by CMS in the proposed rule, this will be an overwhelming, expensive, and burdensome proposition for vendors and physicians and will discourage adoption of this technology. Expenditures in these proprietary tools will be particularly wasteful if CMS mandates a standard RTBT within the next few years, since vendors, physicians, and Part D plans will have to rebuild technology to support the mandated RTBT.

The AMA recommends that CMS require plans to support a single RTBT standard that will integrate with all EHR systems, when made available. The National Council for Prescription Drug Programs (NCPDP) has been developing an electronic standard for the communication of real-time prescription drug coverage and pricing information, including therapeutic alternatives, between payers and prescribers over the past few years. The AMA participates in the NCPDP group involved in this effort and expects that a standard RTBT will be published by NCPDP within the next year.

We believe that this approach will ensure that physicians have access to accurate, real-time formulary data across payers, without which this technology will not realize its full potential. We also note that in its current format, the draft NCPDP RTBT standard supports use of two different syntaxes (SCRIPT and Telecommunication standards). We have concerns that this will create interoperability challenges between EHR vendors and payers who are not using the same syntax. We therefore support a testing period after the initial publication of the NCPDP RTBT standard to ensure seamless translation between the two different syntaxes and that any RTBT can provide physicians with accurate and complete prescription drug formulary and pricing data across all payers and patients.

Recommendations:

- CMS should require plans to support a single RTBT standards that will integrate with all EHR systems, when available.
- CMS should support a testing after the initial publication of the NCPDP RTBT standard.

Electronic Prescribing of Controlled Substances (EPCS)

Section 2003 of the SUPPORT for Patients and Communities Act (SUPPORT) requires, with certain exceptions, that covered drugs in Schedules II, III, IV and V prescribed to patients with Medicare Part D prescription drug coverage must be transmitted electronically in accordance with the United States Drug Enforcement Administration (DEA) regulations for EPCS effective January 1, 2021. Section 2003 of the SUPPORT Act also requires that, not later than one year from the act's enactment (which would be October 24, 2019), the DEA must update the requirements for the biometric component of multifactor authentication with respect to EPCS.

The rules governing the biometric component of multifactor authentication for EPCS are a serious problem. In 2010, the DEA issued an interim final rule setting forth the requirements that EPCS systems must meet in order to be utilized by DEA registrants. Even though the final rule was "interim," no subsequent rulemaking has ever been issued. The AMA agrees that requiring multifactor authentication increases EPCS security, but the rigid and burdensome requirements for biometrics included in the 2010 regulations preclude physicians from deploying user-friendly devices already found in their practices to satisfy these requirements. Instead of using laptop computers and smartphones with fingerprint scanners, they must utilize separate biometric technology that has been reviewed by the DEA or a DEA-approved certifying organization for specific compliance with EPCS requirements. These requirements state, for example, that the "biometric subsystem must operate at a false match rate of 0.001 or lower." Yet even though Apple products, for example, have a biometric error rate of less than one in 50,000 and are validated for compliance with Federal Information Processing Standards (FIPS) [140-2 Level 1](#), Apple products have not been certified to meet DEA requirements and cannot be used for EPCS.

The biometric fingerprint scanners found on consumer devices commonly found in medical practices are used for secure access to other sensitive information, like banking and medical records, but typically do not comport with rigid rules for EPCS. The regulations further require that the biometric device either be co-located with or built into the computer that is being used for EPCS. This rule has led to development of a niche market for EPCS products, such as Imprivata's Confirm ID, which have been certified to comply with DEA regulations for EPCS. The fingerprint reader on a smartphone could not be used by a physician for EPCS because, even if it had been reviewed by the DEA, the smartphone would be separate from and work independently of the e-prescribing software and hardware being used in the practice. The existence of this niche market allows health information technology vendors to charge high prices to physician practices to add the technology they need for EPCS, and even after assuming these costs, EPCS technology is still likely to disrupt workflows because it is not integrated with physicians' other systems. The AMA stresses that it is the cost and impact to physicians' workflows that has led to the low uptake of EPCS, not physicians' lack of desire to adopt these tools.

The volume of controlled substance prescriptions for a subset of physician practices makes compliance with the biometric component of two-factor authentication, particularly as a distinct process from

The Honorable Seema Verma

August 9, 2019

Page 28

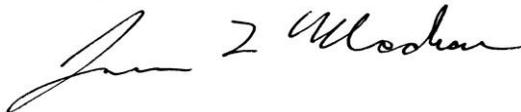
e-prescribing of non-controlled substances, onerous and a significant strain on practice workflows. On top of the fact that few health information technology vendors support EPCS, and the cost of add-on modules and separate monthly service fees, the methods and processes that vendors utilize for EPCS are often not well-aligned with normal e-prescribing workflows. These problems with EPCS systems and DEA requirements were also noted in the strategy for reducing administrative and regulatory burden issued by the National Coordinator for Health Information Technology.

Recommendation:

- The AMA has provided specific recommendations to the DEA for modifying its EPCS regulations under §1311.116 *Additional requirements for biometrics*. Until the DEA complies with the mandate from SUPPORT that the EPCS requirements for the biometric component of multifactor authentication be updated, the AMA strongly urges CMS not to issue any regulations requiring EPCS for Medicare Part D prescriptions.

The AMA appreciates the opportunity to provide comments and thanks CMS for considering our views. If you should have any questions regarding this letter, please feel free to contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org, or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD