AMA
AMERICAN MEDICAL ASSOCIATION

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September 11, 2017

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

Re: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

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) on the proposed rule for calendar year (CY) 2018 to revise the Medicare Physician Fee Schedule (PFS) and Part B, published in the *Federal Register* on July 21, 2017 (82 Fed. Reg. 33950).

The AMA supports many of CMS' proposals, including the addition of new covered telehealth services, the delay of the implementation of the Appropriate Use Criteria (AUC) program, the reduction of penalties under the Value Modifier program in 2018, and the reduction of documentation submission requirements for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs). We also support the expansion of the Medicare Diabetes Prevention Program (MDPP), and urge CMS to include online/virtual diabetes prevention programs in the MDPP model.

In addition, we have significant concerns about many of CMS' proposals including setting payment for nonexcepted items and services at provider-based off campus hospital outpatient departments at 25 percent of the hospital outpatient prospective payment system (OPPS) payment rate. We also have significant concerns with proposals to report 2016 Physician Quality Reporting System (PQRS) data on Physician Compare.

We have provided detailed comments below about many of the issues on which CMS requests feedback, including the expansion of coverage of telehealth and remote patient monitoring services in the Medicare program, methods to reform evaluation and management (E&M) guidelines, the 2018 implementation of the clinical laboratory fee schedule (CLFS), and the current policy for payment of biosimilars under the Part B drug benefit. Finally, we include a detailed description of issues CMS should address to reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care.

The following outlines our principal recommendations on the 2018 Medicare PFS proposed rule:

- The AMA appreciates the Agency's adoption of the AMA/Specialty Society RVS Update Committee's (RUC) recommendations for the 2018 Medicare Physician Payment Schedule. The RUC has most recently worked closely with CMS to provide greater standardization in the direct practice expense recommendations. We strongly encourage further collaboration to improve the relativity within the payment system. The AMA encourages CMS to carefully review the detailed RUC comment letter for information related to a number of technical questions raised by CMS in the Proposed Rule.

- The AMA recommends a measured approach to expand coverage of telehealth and remote patient monitoring services in the Medicare program. The AMA strongly supports CMS' proposal to provide telehealth coverage to seven new codes and urges CMS to expand coverage to unbundled remote monitoring services. In addition, the AMA outlines areas where increased coverage will allow physician practices, health systems, and other health care providers to diagnose and treat earlier manifestations of disease in less costly care settings.

- The AMA urges CMS to maintain its existing payment methodology for nonexcepted items and services at provider-based off-campus hospital outpatient departments instead of reducing payment to 25 percent of the Hospital OPPS payment rate. While we appreciate CMS' efforts to create site neutral payment policies, we cannot support payment changes based on insufficient data.

- The AMA urges CMS to focus revisions to the evaluation and management (E&M) codes on the current E&M guidelines rather than the underlying code set to reduce unnecessary administrative burden. In addition, if CMS determines that it must reform E&M codes we strongly urge the Agency to work with the Current Procedural Terminology® (CPT®) Editorial Panel which includes advisors from every national medical specialty society, insurers, hospitals, and a broad cross section of other impacted health care providers and practitioners.

- The AMA has significant concerns with CMS' proposals to implement the new CLFS. CMS has not outlined how it will ensure the final rates accurately reflect the submitted data without corruption once processed by CMS and there have been extensive challenges associated with data collection that call into question the accuracy of payment rates that CMS plans to issue on January 1, 2018.

- The AMA urges CMS to revise its current policy for payment of biosimilars under the Part B drug benefit and instead of blending prices for multiple biosimilars into a single code with one payment rate, assign each biosimilar a unique Healthcare Common Procedure Coding System (HCPCS) code for billing and payment effective January 1, 2018. This will ensure continuity of a patient's course of treatment.

- The AMA supports CMS' delay of implementation of the AUC program. However, we are concerned that, given the scale and complexity of this program, the January 1, 2019 start date will not provide sufficient time for education and preparation. Therefore, the AMA recommends that the proposed educational and operational testing period last an additional year.

- The AMA supports CMS' efforts to align the 2016 PQRS reporting requirements with the Merit-Based Incentive Payment System (MIPS) quality reporting requirements and to reduce the penalties physicians will receive under the Value Modifier in 2018.

- The AMA supports CMS' proposals to reduce physicians' regulatory burden by reducing documentation submission requirements for MSSP ACOs.

- The AMA has concerns with CMS' proposals for publicly reporting 2016 PQRS data on Physician Compare. We believe Physician Compare should align with PQRS calculations and only information that is used in the final PQRS determination should be publicly released and utilized for Star Ratings.

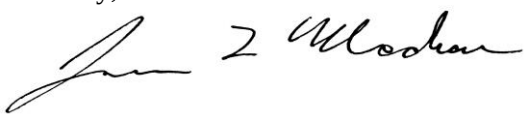
- The AMA supports CMS' decision to have physicians identify their roles using patient relationship modifiers rather than codes, and to adopt official CPT modifiers once they are available. We encourage CMS to consider additional AMA suggestions as the Agency moves forward with implementing patient relationship codes.

- The AMA continues to strongly support the MDPP expanded model. We urge CMS to also include online/virtual diabetes prevention programs in the expanded model.

- The AMA provides a detailed list of issues CMS should address to reduce the regulatory burden for physicians and simplify the health care system. We believe reducing the administrative burden for physicians will reduce cost, improve quality, and create a more accessible health care system for patients.

We thank you for the opportunity to provide input on this proposed rule and look forward to continuing to work with CMS to improve the physician payment system and reduce the administrative burdens physicians face. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD

Attachments

I. PROVISIONS OF THE PROPOSED RULE FOR THE 2018 PHYSICIAN FEE SCHEDULE

A. Physician Payment Update and Misvalued Codes Target

The Protecting Access to Medicare Act (PAMA) and the Achieving a Better Life Experience Act required CMS to identify misvaluation in the relative values and implemented a targeted reduction. 2018 is the final year of this target reduction and CMS was instructed to identify at least 0.5 percent in expenditure decreases. CMS has stated that incorporating the RUC recommendations and other changes will result in a 0.31 percent reduction, leaving 0.19 percent of the target unmet. **Therefore, CMS proposes to offset the 2018 Medicare Conversion Factor by 0.19 percent. The AMA strongly opposes this proposal.**

The RUC Practice Expense (PE) Subcommittee and Health Care Professional Advisory Committee (HCPAC) Review Board conducted a comprehensive review of the direct practice expense inputs and submitted significant decreases in clinical staff time for physical medicine and rehabilitation codes (97010-97762) to CMS. Our understanding is that these codes had substantial duplication in the time spent by the physical therapists, physical therapy assistants and physical therapy aides. The PE Subcommittee and HCPAC utilized standards that are applied to all procedure codes and applied their understanding about the number of services reported and the resulting multi-procedure payment reduction. Even though this was clearly articulated in the recommendations to CMS, CMS has proposed to leave the overvalued direct practice expense inputs in place for 2018, suggesting that the committees did not fully understand the impact. It is inherently unfair for all health care professionals to be subjected to a 0.19 percent decrease to the Conversion Factor when the misvalued target was not met due to this CMS decision. CMS should either implement direct practice expense inputs that reflect the true resource costs of providing physical medicine and rehabilitation services or hold all other health care professionals harmless from their decision to leave over-valuations in place for 2018.

The AMA fully supports and endorses the recommendations and comments of the RUC regarding physician work, practice expense, and malpractice relative value units for particular services, the process and methodology for valuing services, and potentially misvalued services. The AMA also supports the RUC's additional comments on other relevant issues.

B. Determination of Professional Liability Insurance Relative Value Units (PLI RVUs)

The AMA applauds CMS' proposal to override claims data for low volume services with an expected specialty for both the practice expense and professional liability insurance valuation process. This proposal is consistent with a long-standing RUC recommendation to use the expected specialty for services performed less than 100 times per year. Even a few claims made in error by one physician could result in substantial year-to-year payment swings to these codes. This has been particularly problematic when the low volume services in Medicare are actually high volume codes in the Medicaid or private payer population. The AMA understands that CMS relied on the RUC's list from 2016 to initiate this proposal, and supports the RUC's modified list that they have submitted with their comment letter. We recommend that CMS utilize the RUC's list for rate setting for the CY 2018 Medicare Physician Payment Schedule.

The AMA is also concerned specifically about existing codes with no Medicare volume reported for any given year. According to the contractor report, CPT codes lacking utilization received a crosswalk created by CMS that assigns the same risk factor as codes with similar specialty mix. In contrast, when a

service is reported with no Medicare volume, it receives the average risk factor for all physician specialties. The crosswalks are clear when related to new CPT codes reviewed by the RUC, as the RUC provides, and CMS uses, specified crosswalks for each code selected to ensure the providing specialties are analogous. However, it is inappropriate for a service to have fluctuating PLI risk factors simply due to whether or not it is reported in Medicare claims data for a given year. Therefore, the AMA supports the RUC's recommendation that the RUC's proposed list of expected specialty overrides be utilized for both low volume and no volume codes.

C. Digital Health

At this critical time of health care delivery redesign and payment reform, it is essential to provide patients, physicians, and other health care system stakeholders the flexibility to utilize proven telehealth and remote patient monitoring modalities that technological advances in the past decade have made a reality. While other federal health programs like the Veterans Health Administration, state Medicaid programs, as well as private health plans have increasingly embraced telehealth and remote patient monitoring services, the current Medicare restrictions have impeded the uptake of now well-validated technologically enabled modalities for delivering services. Furthermore, increased access to telehealth and remote patient monitoring services is urgently needed to effectively address the looming demographic health demands driven by the Baby Boom that will be placed on the Medicare program, health care providers, caregivers and the nation in the near future.

The U.S. Census Bureau has projected that by 2030—in a mere 13 years—more than 20 percent of U.S. residents will be 65 and over.[1] During this same timeframe, the unofficial safety net of family providers and caregivers will continue to shrink markedly. From 2010 to 2030, the caregiver ratio (defined as the number of potential caregivers aged 45–64 for each person aged 80 and older) declines sharply from 7.2 to 4.1, and the caregiver ratio is expected to continue to decrease from 4.1 to 2.9 from 2030 to 2050.[2] In addition, as the Baby Boomers moves into retirement and global aging trends accelerate, the labor force in the U.S. (and around the globe) will shrink and strain funding for safety net programs like Medicare.[3] In light of the foregoing, national strategic planning is needed across society right now to develop and scale a sustainable infrastructure to center care where the patient is located to the greatest extent it is clinically efficacious and cost-effective, and to ensure physicians and other health care providers have the tools to optimize care delivery. Telehealth and remote patient monitoring will become an essential cost effective and reliable means to expand capacity in a health care system marked with significant and persistent specialty shortages and geographic disparities.

We have outlined below a measured approach to expanding coverage of telehealth and remote patient monitoring services in the Medicare program. The AMA has provided comments on specific services for which CMS is seeking input, and offered recommendations for increased coverage for services CMS has already deemed clinically efficacious when delivered via telehealth. The AMA strongly supports CMS' proposal to provide telehealth coverage to seven new codes and urges CMS to expand coverage to unbundled remote patient care management services (called remote patient

[1] Given current aging and fertility trends, by 2050 developed economies will have twice as many older persons as children. No Ordinary Disruption: the Four Global Forces Breaking All the Trends, Richard Dobbs, James Manyika, Jonathan Woetzel (2015)

[2] *The Aging of the Baby Boom and the Growing Care Gap: A Look at Future Declines in the Availability of Family Caregivers*, AARP Public Policy Institute, In BriefIB213, August 2013.

[3] No Ordinary Disruption: the Four Global Forces Breaking All the Trends, Id.

monitoring services by CMS). In addition, we have outlined key areas where increased coverage will allow physician practices, health systems, and other health care providers to diagnose and treat earlier manifestations of disease in less costly care settings and help patients improve compliance and adherence with their care plans. The AMA is also actively promoting efforts to use validated tools and modalities to scale and expand prevention methods in order to markedly reduce the disease burden that will be unsustainable to the Medicare Trust Fund if left unaddressed. As a result, as discussed in the MDPP section, the AMA strongly urges CMS to include virtual MDPP in the expansion of this critical prevention intervention in order to ensure adequate access and to begin reaping the clinical and financial benefits.

Background

There has been a well-documented rapid rate of technological innovation and broad adoption by consumers and patients as well as health care providers of new technologies that can be leveraged and modified to power health care services. Utilizing these new modalities to provide care that is the same as in-person care or to offer new clinical services altogether promises to accelerate transformations in medical care. However, digital medicine also has significant implications for altering established patterns and methods of patient care and associated policies that require informed and thoughtful engagement and leadership from the physician community and other health care stakeholders. The range of ethical and health policy considerations have been far-ranging and will continue to evolve. The AMA has an established process designed to accommodate advancements in medical practice. In 2010, AMA physician leaders, comprised of representatives from every national medical specialty society and state medical association, adopted the first AMA policy statement concerning telemedicine and remote patient management. In quick succession since that time, a range of AMA policies have been developed, debated, and adopted by these same physician representatives addressing a range of topics including research and clinical validation resources, regulatory oversight and accountability, coverage and payment, ethical practice, virtual supervision, medical education, and integration of mobile health applications and devices into practice.[4]

In 2016, the AMA commissioned a survey of physicians in order to investigate their motivations, current usage, and expectations for integrating digital health tools into their practice (Digital Health Study).[5] The Digital Health Study includes specific questions concerning telemedicine as well as others related to mobile health, remote patient monitoring (management), and mobile health applications. The Digital Health Study findings provided additional data to guide AMA digital strategic programming, partnerships, and advocacy. The overarching findings: physicians are optimistic that digital medicine tools will improve medical practice and patient care. Surveyed physicians in large and complex practices tended to use digital health tools more. Notably, age was less of a factor than practice size and setting for physician adoption which suggests economies of scale and the ability of relatively larger practices to scale infrastructure may play a role in adoption. Interestingly, more surveyed physicians reported adoption of

[4] *Telemedicine and Medical Licensure* (Council on Medical Education (CME) Report 06-A-10); *Professionalism in Telemedicine & Telehealth* (Board of Trustees (BOT) Report 22-A-13); *Coverage and Payment for Telemedicine* (Council on Medical Service (CMS) Report 7-A-14); *Facilitating State Licensure for Telemedicine Services* (BOT Report 3-I-14); *Ethical Practice in Telemedicine* (Council on Ethical and Judicial Affairs (CEJA) Report 1-A-16); *Virtual Supervision of "Incident to" Services* (CMS Report 5-A-16); *Telemedicine in Medical Education* (CME 06-A-16); and, *Integration of Mobile Health Applications and Devices into Practice* (CMS Report 06-I-16)

[5] Kantar: The Digital Health Study: Physicians' motivations and requirements for adopting digital clinical tools, 2016.

telehealth visit than those reporting adoption of remote patient monitoring (for efficiency and management for improved care), but physicians have greater enthusiasm for the clinical benefit and work efficiencies of remote patient monitoring than telehealth. In addition to ensuring that the tools and delivery models were clinically effective, surveyed physicians ranked in order of importance the key issues that must be addressed to support their adoption of digital health tools including:

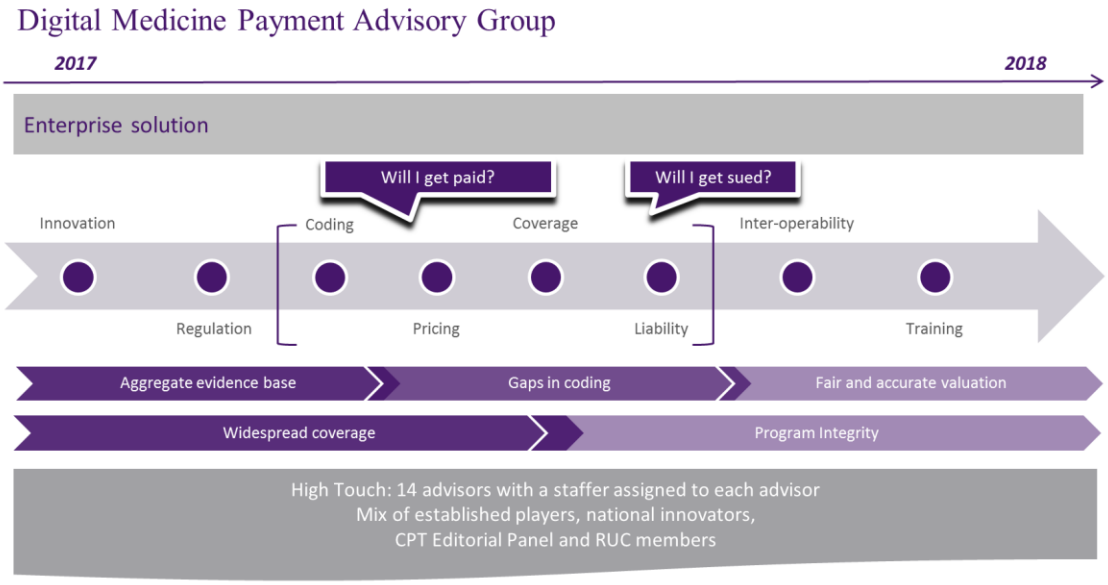
- standard liability insurance coverage;
- data privacy/security is assured by experts;
- workflow integration with electronic health record (EHR) systems; and
- coverage and payment.

The Digital Health Study continues to inform how the AMA prioritizes initiatives and strategies to support physician adoption of telemedicine and remote patient monitoring. The AMA is developing solutions in the areas identified through this survey in order to support widespread clinical integration. To that end, the following figure depicts the innovation to clinical integration path that the AMA fashioned to organize initiatives, policy development, advocacy, and partnerships in order to advance clinically validated 21st Century medicine adoption. In parallel, AMA is pursuing several initiatives that blend traditional partnerships and advocacy to address barriers to adoption of which payment (coding, valuation, coverage) represents a significant obstacle.

The AMA's Digital Medicine Payment Advisory Group

In late 2016, the AMA determined that, while telehealth and remote patient monitoring offer the promise to improve patient care and increase efficiencies in care delivery, these services do not represent an iterative change, but present transformative changes that disrupt established care delivery models and established payment frameworks. In order to ensure physicians are not deterred from integrating these important modalities into care delivery because clinical services utilizing new modalities do not have a clear path to payment, a comprehensive strategy was deployed to address the sometimes complex interplay between coding, valuation, and coverage guided by expert opinion, literature, and health care system data on digital medicine deployment.

As a result, in January 2017 the AMA established the Digital Medicine Payment Advisory Group (DMPAG), comprised primarily of nationally recognized telehealth physicians and other practitioners at leading health systems around the country, subject matter expert physicians in coding and valuation, as well as industry experts with knowledge of expected technology advancements. The AMA also staffed the DMPAG with cross-enterprise internal staff experts to provide support along a broad continuum of activities such as environmental surveys and research, coding, valuation, state and federal laws and regulations, and advocacy.



Consistent with the AMA's goals and policy, the DMPAG has provided regular advice and counsel on a clear pathway to clinical integration of digital medicine in order to ensure access to high quality and safe clinical care for patients and their physicians that achieve improved health outcomes.[6] (Though the DMPAG's focus is on addressing payment barriers, the advisors are briefed regularly on related AMA initiatives and advocacy to address other factors impacting adoption such as interoperability, reliable broadband and wireless connectivity, and quality assurance for the digital products used to deliver services, for example.) The DMPAG is specifically charged with providing expert opinion on and information to address:

- creation and dissemination of data supporting the use of digital medicine technologies and services in clinical practice;
- existing code sets (with an emphasis on CPT and HCPCS) and the level to which they appropriately capture these services and technologies;
- factors that impact the fair and accurate valuation for services delivered via telehealth and remote patient monitoring;
- widespread coverage of digital medicine (including telemedicine and remote patient monitoring), including greater transparency of services covered by payers and advocacy for enforcement of parity coverage laws; and

[6] The DMPAG advisors have been scheduled to meet once a month, typically for two hours. Except, however, two of the monthly meetings have been all day in-person meetings and a third such day-long in-person meeting is scheduled for October. In addition, nearly every advisor has served on sub-workgroup(s) and/or participated in the in-depth interview series involving additional hours every month to confer with other advisors, AMA staff, and their institutions to obtain additional data and literature. A number of the advisors are practicing physicians in addition to spearheading digital health adoption in their systems.

- program integrity concerns of payers including, but not limited to, appropriate code use, and other perceived risks unique to digital medicine.

The DMPAG has played a critical role in providing substantive input on the:

- rate and scope of telehealth and remote patient monitoring adoption and projected future clinical integration (including utilization data);
- clinical considerations when utilizing digital modalities to deliver medical services, published literature, and health system information on clinical efficacy of remote patient care management, telehealth, and physician-to-physician e-consults;
- data on the overall value (including savings) to the health system of telehealth and remote patient monitoring services; and
- detailed coding information and recommendations for remote patient monitoring and physician-to-physician e-consults (that will be considered by the CPT Editorial Panel later in September 2017).

National Expert Advisors	**Used for Identification Only** Title, Institution/Organization/Company
Michael Adcock, FACHE	Administrator, Telehealth Services, University of Mississippi Medical Center
Peter Antall, MD	Chief Medical Officer, American Well
David Flannery, MD	Medical Director, American College of Genomics and Genetics
Peter A. Hollmann, MD **DMPAG Co-Chair**	Chief Medical Officer, University Medicine at Brown University, Alpert Medical School, Department of Internal Medicine Faculty Practice; Former Chair of CPT Editorial Panel; AMA Alternate Member of RUC
Robert Jarrin, JD	Senior Director, Wireless Health Public Policy Qualcomm Incorporated; Adjunct Assistant Professor, Emergency Medicine The George Washington University School of Medicine and Health Sciences
Joseph C. Kvedar, MD, FAAD **DMPAG Co-Chair**	Vice President, Connected Health, Harvard Partners HealthCare
Katharine L. Krol, MD, FSIR, FACR	CPT Editorial Panel Executive Committee Member; RUC Member (CPT liaison) ; Co-Chair of the Emerging Issues CPT/RUC Workgroup
John Mattison, MD	Chief Medical Information Officer and Assistant Medical Director, Kaiser Permanente
Peter A. Rasmussen, MD, FAHA, FAANS	Medical Director for Distance Health and Associate Professor of Neurosurgery in the Cerebrovascular Center at the Cleveland Clinic in Cleveland, Ohio
Morgan Reed	Executive Director, ACT | The App Association
Jordan Pritzker, MD, MBA, FACOG	Senior Medical Director, Medical Policy and Operations, Aetna, Inc.; CPT Editorial Panel Member
Karen S. Rheuban, MD	Professor of Pediatrics (Cardiology), Senior Associate Dean for Continuing Medical Education, & Director of the Center for Telehealth, University of Virginia
Ezequiel "Zeke" Silva, III, MD, FACR, RCC	Director of Interventional Radiology, South Texas Radiology Imaging Centers and Diagnostic and Interventional Radiologist, South Texas Radiology Group, San Antonio, Texas; RUC Member
Lawrence Wechsler, MD	Professor of Neurology & Neurological Surgery, University of Pittsburgh School of Medicine, Vice President of Telemedicine

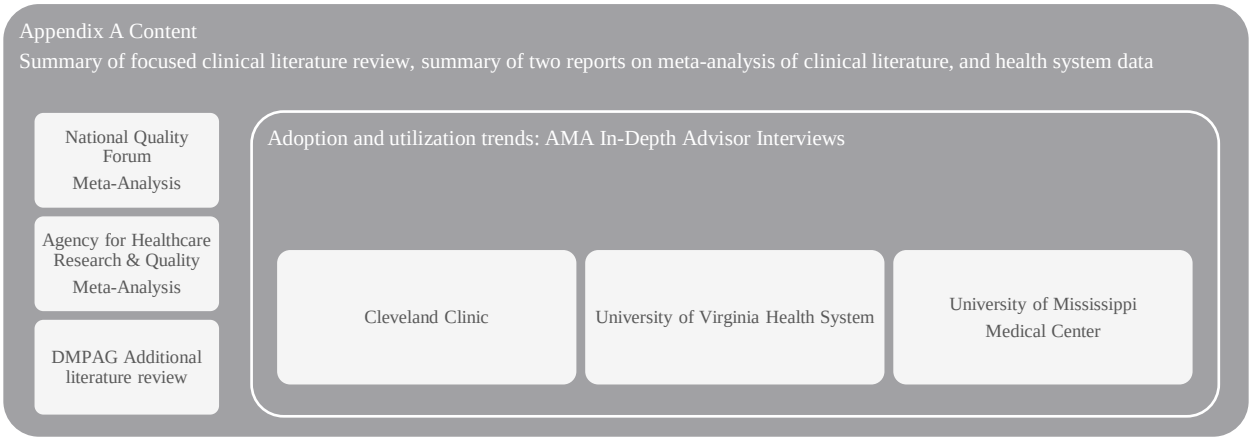
The DMPAG's recommendations and feedback have informed the AMA's advocacy efforts to address the statutory restrictions that have limited Medicare's coverage of telehealth services, identified applicable factors to consider concerning perceived and actual program integrity risks, provided utilization data and projections for expansion in the near term from advisor systems, and general coding recommendations as well as detailed recommendations and feedback that have resulted in two code change applications that will be considered by the CPT Editorial Panel at its September 2017 meeting.

The following comments reflect AMA policy as well as DMPAG advisor input including data, expertise, and literature.

Medicare Telehealth Services

The AMA supports CMS' proposal to add seven new codes as covered telehealth services, as discussed below. However, the AMA strongly urges CMS to initiate a call for a far broader range and scope of demonstration projects that waive geographic and originating site restrictions based on existing CMS waiver authorities in order to establish the cost savings or cost neutrality of providing currently covered Medicare telehealth. The AMA has made the latter recommendation previously, but the Congressional Budget Office (CBO), Medicare Payment Advisory Commission (MedPAC), and CMS have stated repeatedly that there is a paucity of evidence and data that include a patient population comparable to those served by Medicare. To be clear, though, CMS has already considered the clinical evidence and determined that there is clinical efficacy for telehealth services Medicare currently covers. Instead, the question policymakers have is whether or not expanded coverage will drive utilization without a commensurate benefit in clinical outcomes that would offset inevitable coverage and cost of in-person care for more advanced or acute disease in higher cost centers. (Any such analysis would have to account for the expected growth in Medicare utilization due to the Baby Boomers.)

Through the work of the DMPAG advisors, the AMA has collected data demonstrating that leading health systems are scaling up access to telehealth and remote patient monitoring services because of the improved patient health outcomes (due to enhanced compliance and improved continuity of care, for example) and efficiencies (care delivered in lower cost sites of care including reduction in readmissions, for example). A general survey of the DMPAG expert advisors from health systems was followed-up with in-depth interviews of three health system advisors from Cleveland Clinic, University of Virginia Health System, and University of Mississippi Medical Center. The purpose of the in-depth interviews was to identify clinical adoption of telehealth and remote patient care monitoring in established health care systems and other community providers and identify payment (or lack thereof) for telehealth services. The method involved structured interviews of DMPAG advisors identifying: (1) growth/rate of adoption over time; (2) payment models; (3) revenue and cost savings/value proposition; and (4) unique attributes that warrant focus. The results of the in-depth interview strongly indicate that instead of supplementing overall patient utilization, digital medicine modalities substitute for otherwise more costly health care services including readmissions or emergency department visits for unmanaged chronic conditions. The results of the in-depth interviews are included in Appendix A.



The evidence and expert opinion provided by the DMPAG advisors substantiates the clinical efficacy of services delivered via telehealth. In addition, the in-depth interviews of DMPAG advisors from Cleveland Clinic, University of Virginia Health System (UVA), and the University of Mississippi Medical Center, establish that health systems are deriving value as well as improved clinical outcomes by deploying these modalities. These health systems are proxies for the larger Medicare program given the distribution of patient acuity and complexity, diversity, economic status, geographic distributions, and access challenges.[7] Furthermore, unlike telehealth-only providers that focus primarily on relatively simple, acute, non-chronic conditions without ongoing responsibility for patient care, the health systems provide a valuable look at how wider integration of telehealth and remote patient services in health systems and community-based, out-patient settings could enhance quality and value. And, like Medicare (which bears risk along the continuum of care) the systems that are utilizing telehealth and remote patient monitoring to reduce readmissions have found that these interventions improve clinical outcomes, but in lower cost sites of care, which reduces exposure. The AMA's three in-depth interviews with DMPAG advisors from these health systems have been augmented with additional data provided by advisors from the University of Pittsburgh Medical Center and Harvard Partners. These surveys also make clear that even though utilization of the services will increase and there are costs associated with delivering care through these modalities, remote patient monitoring and telehealth are allowing for more efficient targeting of care and moving sites of care to lower cost centers. In brief, it allows the systems to serve more patients in lower cost sites of care which reduces the need for care in higher cost sites like the emergency department or in-patient hospitalization.

Given the looming demographic challenge, the decision to expand telehealth offerings is a rational response—namely leveraging technology to provide care more efficiently without compromising quality (and, in some cases, increasing quality). UVA has the goal to scale telehealth encounters to 60,000 per year within the next two years and Cleveland Clinic has set a goal of 35,000 telehealth encounters by the end of 2017. These reports are bolstered by an annual survey conducted by the American Hospital Association (AHA) on technology adoption. In AHA's 2017 report Telehealth: Delivering the Right Care, at the Right Place, at the Right Time, it was noted that 65 percent of hospitals have implemented

[7] In addition to the demographics and volume health systems have, the AMA looked to health care systems to gather data because most physician practices are not able to offer a telehealth service or remote patient monitoring without reimbursement. Physician practices do not have the same economies of scale or safety network payment adjustments that mitigate the losses associated with uncompensated care.

telehealth in at least one care unit while an additional 13 percent plan to implement telehealth within the next year.

The demonstration projects proposed by the AMA should have accelerated windows for data submission and analysis of relative costs. CMS has already determined that there is clinical efficacy for currently covered Medicare telehealth services (but which are subject to statutorily imposed geographic and originating site restrictions). Thus, the purpose of the demonstrations would be to enable health systems and other providers that have developed telehealth capabilities to provide these services to a critical mass of Medicare beneficiaries without geographic and originating site restrictions to enable CMS (including the CMS Chief Actuary) to assess impact on utilization overall. The availability of such claims data will ensure CBO and MedPAC are better positioned to determine whether telehealth results in cost savings or cost neutrality utilizing Medicare claims data and based on the Medicare population.[8] We also urge CMS to increase flexibilities to offer telehealth services without restrictions physicians and patients participating in alternate payment models (including one-sided risk models), such as ACOs and bundled payment models. In these delivery models the payment and delivery structures are fundamentally designed to ensure utilization reflects clinical need and efficient targeting of clinical care.

Specific Codes CMS Proposes to Add

CMS proposes to add HCPCS Level II code G0296 [counseling visit to discuss need for lung cancer screening using low dose CT scan (LDCT) (service is for eligibility determination and shared decision making]. The AMA agrees that this code is sufficiently similar to office visits currently on the telehealth list. In addition, the AMA agrees that all of the components of this service, which include assessment of the patient's risk for lung cancer, shared decision making, and counseling on the risks and benefits of LDCT, can be furnished via interactive telecommunications technology.

CMS proposes to add CPT codes 90839 and 90840 (psychotherapy for crisis; first 60 minutes) and [psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service)]. The AMA agrees that these services are sufficiently similar to the psychotherapy services currently on the telehealth list, even though these codes describe patients requiring more urgent care and psychotherapeutic interventions to minimize the potential for psychological trauma. The AMA strongly agrees that CMS should add the codes to the telehealth list with the explicit condition of payment that the distant site practitioner be able to mobilize resources at the originating site to defuse the crisis and restore safety, when applicable, when the codes are furnished via telehealth. "Mobilization of resources" is a description used in the CPT prefatory language. CMS believes the critical element of "mobilizing resources" is the ability to communicate with and inform staff at the originating site to the extent necessary to restore safety. The AMA concurs with CMS that a remote practitioner is able to mobilize resources at the originating site to defuse the crisis and restore safety as long as CMS makes clear that this is a prerequisite for payment.

CMS is proposing to add four additional services to the telehealth list. All four of these codes are add-on codes that describe additional elements of services currently on the telehealth list and would only be

[8] Both the CBO in a July 2015 blog post, *Telemedicine*, and Government Accountability Office in its April 2017 *Report to Congressional Committees: Telehealth and Remote Patient Monitoring Use in Medicare and Selected Federal Programs* have noted that the limited claims data shows low proportions of Medicare beneficiaries are accessing remote patient monitoring and even fewer beneficiaries are accessing telehealth. This is in sharp and marked contrast to the broad adoption of both telehealth and remote patient monitoring by the VA.

considered telehealth services when billed as an add-on to codes already on the telehealth list. The four codes are:

- CPT code 90785 [Interactive complexity (List separately in addition to the code for primary procedure)].
- CPT codes 96160 and 96161 [Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument) and (Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument].
- HCPCS code G0506 [Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service].

The AMA supports the addition of these codes as covered telehealth services when added on to telehealth services already covered.

Remote Patient Monitoring Services

CMS seeks comment generally on whether unbundled payment is warranted for remote patient monitoring services. As a threshold matter, the AMA concurs with CMS that remote patient monitoring services are not subject to statutory restrictions that apply to telehealth services in the section 1834(m) of the Social Security Act and associated regulations including, but not limited to, originating site and geographic restrictions. Also, although the AMA presents information to frame the discussion around utilization, it is limited, and the AMA welcomes the opportunity to work closely with CMS to more fully address valuation and utilization questions through the RUC.

In brief, the AMA strongly supports coverage and payment of unbundled remote patient management services (which more accurately describes the services provided). The DMPAG advisors have discussed extensively for the past six months whether remote patient monitoring services should be unbundled and related questions posed by CMS. In addition to recommending coverage and payment of unbundled remote patient monitoring services based on their expertise and experience, the DMPAG advisors considered the meta-analyses conducted by the Agency for Healthcare Research & Quality, Technical Brief Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews (2016), and the summary of the meta-analysis conducted by the National Quality Forum summarized in NQF's draft report Creating a Framework to Support Measure Development for Telehealth (July 2017).[9] The DMPAG advisors also offered and considered peer reviewed literature in support of unbundling remote patient monitoring services for a number of conditions. As summarized in Appendix A, there is extensive evidence that validates clinical efficacy of remote patient monitoring/management for chronic conditions (asthma, COPD, obesity, hypertension, diabetes, and congestive heart failure) and other follow-up care (post-surgical, cancer).

Drawing heavily on DMPAG deliberations, the AMA offers the additional following comments:

[9] In addition, two DMPAG advisors, Dr. David Flannery and Dr. Peter Rasmussen serve on the NQF Telehealth Framework Advisory Committee and were able to evaluate the underlying meta-analysis and literature review.

- services such as remote patient management have been widely performed including in the VHA system and increasingly in a rapidly growing number of health systems;
- remote patient medical care is an accepted part of patient medical care;
- as noted in the proposed rule, CPT has very general codes for remote monitoring (CPT 99090, 99091);
- the existing CPT remote monitoring codes do not include the technical component of these services;
- CPT also contains very specific codes for cardiac device, sleep studies and other remote monitoring services that are valued and paid by Medicare (and other payers);
- new codes may be needed to describe remote monitoring of chronic care diseases; and
- these types of services can allow for patient-centered care and more frequent appropriate duration interactions as an alternative to in-person services.

CMS is specifically seeking comments regarding CPT code 99091 [collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time)] and whether it should be unbundled for payment. Furthermore, CMS is seeking comment on CPT code 99090 ([analysis of clinical data stored in computers (e.g., ECGs, blood pressures, hematologic data] and whether it should be unbundled. There are no RUC recommended values for this service, and therefore, CMS currently does not assign RVUs.

While the AMA supports unbundling CPT codes 99090 and 99091, based on the information provided by the DMPAG advisors, it does not appear that these codes would be frequently used for what have emerged as the typical deployments of remote patient management services. The DMPAG advisors from health systems with remote patient monitoring programs have reported that they do not utilize these codes. As a result, the DMPAG has submitted code change applications requesting the addition of new codes for physiologic monitoring to the CPT Editorial Panel, an independent panel charged with maintenance of the CPT code set, for consideration during the latter's upcoming September 2017 meeting.

The DMPAG crafted a two-part solution establishing a technical component for the set-up and technician monitoring, and a professional component for the physician services. Below is a brief summary of the proposed codes. Although there is substantially more detail included in the code change applications submitted by the DMPAG to the CPT Editorial Panel, confidentiality rules limit disclosures outside of the established CPT Editorial Panel process. However, these proceedings are open to public attendance and participation and CMS representatives have access to all code change applications. If the applications are approved, these will be released to the public by the CPT Editorial Panel with any relevant modifications approved by the Panel.

Physiologic Monitoring Management —Service Component

The DMPAG recommended the addition of a code to report the physician/provider services of chronic care monitoring/management of a patient using remote monitoring technology. It is for physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified

health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.

Physiologic Monitoring and Management —Technical Component and Set-Up

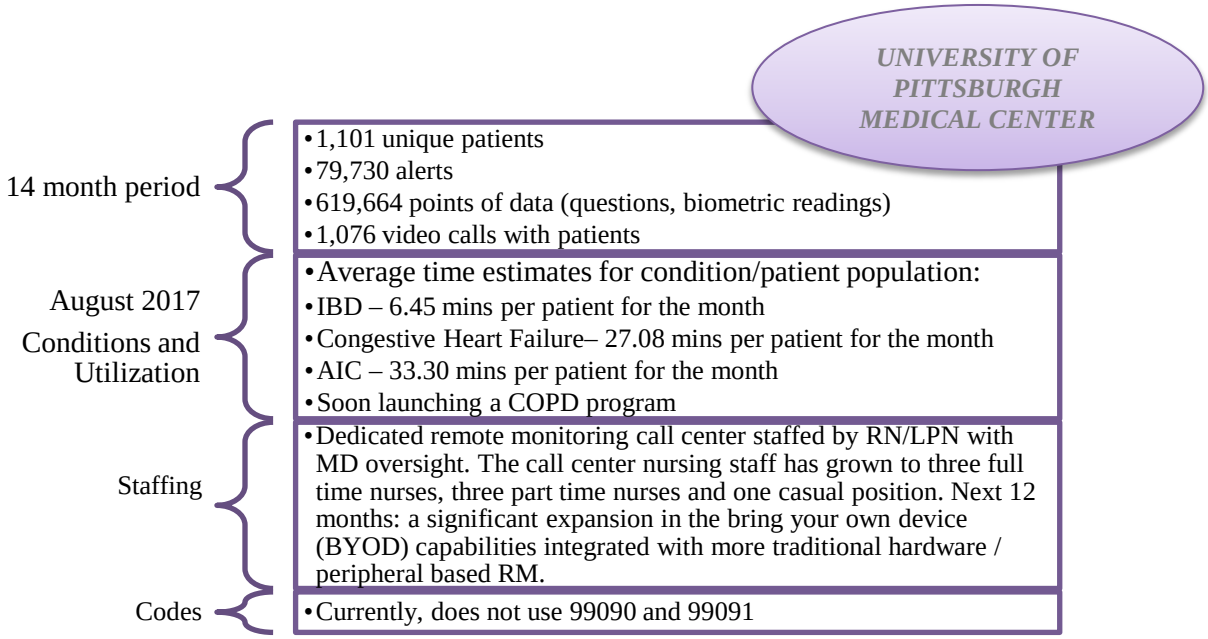
The DMPAG also recommended the addition of codes to report the technical component of monitoring/management for chronic care patients with remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate); set-up and patient education on use device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.

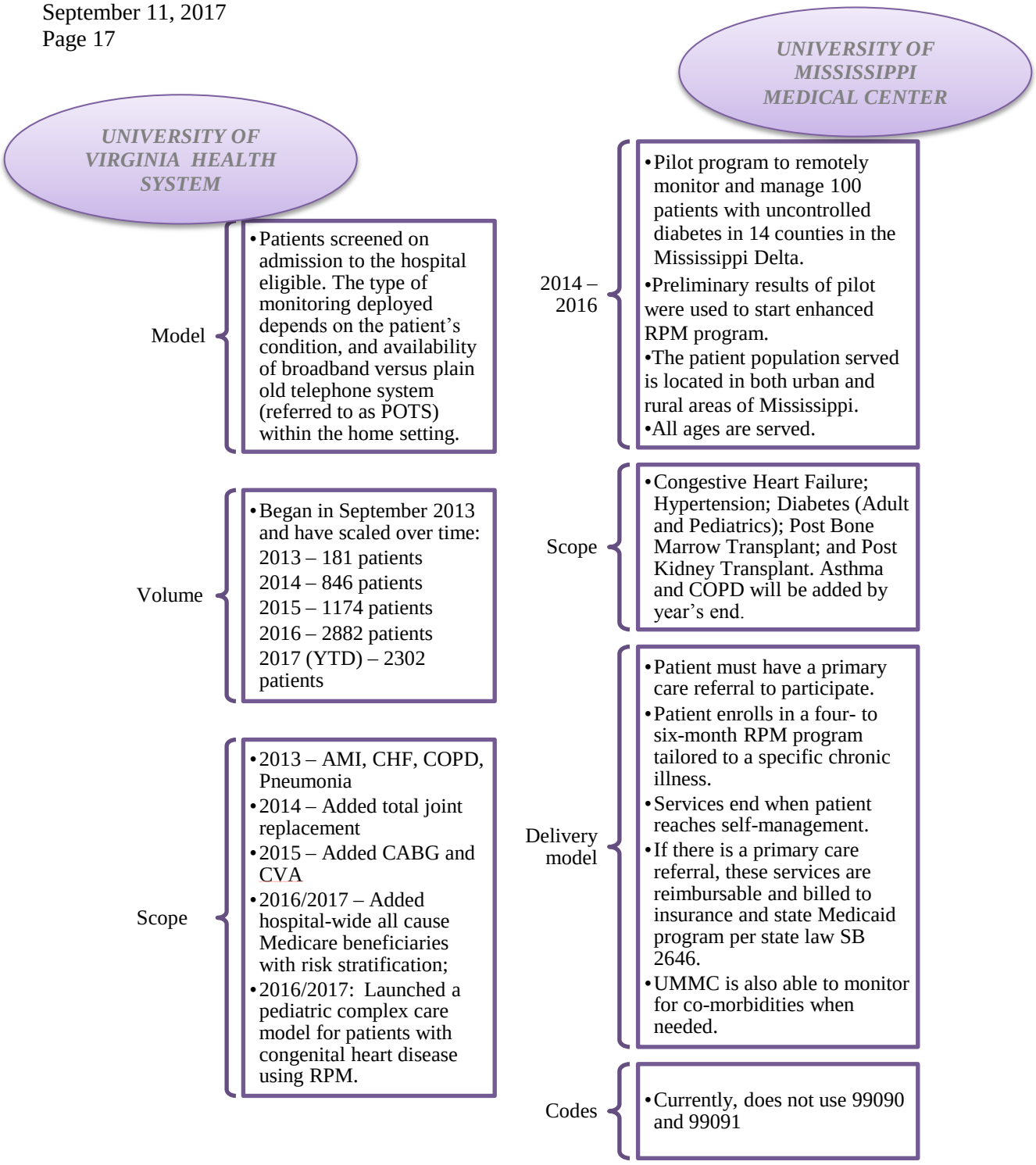
Professional	Technical

• Interpretation and report
• Using the data to manage care
  • E&M
  • Care management
	• Supply of devices
	• Set up and instruction
	• Data Collection
	  • Attended
	  • Unattended w/ algorithmic alerts
	  • Unattended
	• Transmittal
	• Report preparation and quantitative results (score)

The DMPAG advisors grappled with the appropriateness of creating relatively general codes of broader application for remote patient monitoring as opposed to remote patient management codes for specific conditions (e.g., remote patient monitoring codes specifically for diabetes or congestive heart failure). The DMPAG advisors also discussed whether greater specificity was needed vis-à-vis technologies used. The DMPAG advisors deliberated over these questions and, then, ultimately recommended broader codes in order to accommodate the rapid advances and technological improvements that will enable the application of the general codes to new conditions consistent with the proposed code descriptions. The DMPAG advisors also reached consensus that such an approach would avoid triggering a cascade of codes. Increased specificity would also create undue complexity when a patient presents with multiple co-morbidities that warrant such services (and for which multiple codes would then be implicated creating coding ambiguities and potential program integrity challenges).

To address concerns that, payers, including Medicare, may have that the general codes would be used to deliver services that are not part of the plan benefit or do not meet the payer's evidentiary requirements for particular conditions or technologies, the DMPAG advisors noted that payers are able to issue limiting coverage instructions for the conditions/technologies for which such services would be covered and paid by each payer. (This is no different than coverage policies that apply to other general codes such as the evaluation and management codes.) The DMPAG advisors also discussed how to differentiate the time related to these services from other services, including care management services that involve analysis of patient-generated health data that are included in chronic care management (CCM) services (CPT codes 99487, 99489, and 99490). The DMPAG advisors specified that the proposed new code involving professional interpretation and analysis could not be coded/billed together. The following provides a snapshot of information provided by three DMPAG advisors concerning remote patient management services modalities, staffing, adoption rates, and conditions covered in their health systems.


UNIVERSITY OF PITTSBURGH MEDICAL CENTER
14 month period
•1,101 unique patients
•79,730 alerts
•619,664 points of data (questions, biometric readings)
•1,076 video calls with patients
August 2017
Conditions and Utilization
•Average time estimates for condition/patient population:
•IBD – 6.45 mins per patient for the month
•Congestive Heart Failure– 27.08 mins per patient for the month
•AIC – 33.30 mins per patient for the month
•Soon launching a COPD program
Staffing
•Dedicated remote monitoring call center staffed by RN/LPN with MD oversight. The call center nursing staff has grown to three full time nurses, three part time nurses and one casual position. Next 12 months: a significant expansion in the bring your own device (BYOD) capabilities integrated with more traditional hardware / peripheral based RM.
Codes
•Currently, does not use 99090 and 99091



While DMPAG advisor health systems have remote patient monitoring program(s) that share similarities, the snapshot of the three underscore that highly prescriptive codes based on conditions and/or technologies could create unnecessary limitations. As a result, the DMPAG advisors deliberated carefully over the appropriate description of the services and the relevant limiting language to guide consistent and accurate coding. In addition, the DMPAG advisors proposed recommendations, and descriptors and guidelines that would minimize inappropriate billing. However, the CPT Editorial Panel, which includes representatives from private payers and Medicare, as well as experienced coding experts, may identify

additional important considerations that may result in modifications and an alternative method for developing such descriptors. Regardless of the ultimate decision of the CPT Editorial Panel with regard to the level of specificity and parameters needed for remote patient monitoring coding nomenclature, the information provided by the DMPAG advisors unequivocally establishes that unbundled remote patient monitoring services are efficacious for an array of conditions utilizing a number of different technologies. In addition, it is also clear from the information provided by the DMPAG advisors that remote patient monitoring services result in care delivery in lower cost centers and improved health outcomes.

In light of the foregoing, the AMA is prepared to support efforts by CMS to address coding and relative valuation questions including expanded efforts to identify utilization and adoption rates.

Interprofessional Internet Consultation

CMS is also seeking comment on other existing codes that describe extensive use of communications technology for consideration for future rulemaking.[10] **We urge, in the alternative, that as part of this rulemaking CMS cover services as outlined in the DMPAG's request for new codes in the context of interprofessional internet consultation**. The DMPAG has proposed the addition of two codes to the CPT code set. The first code proposed by the DMPAG would be used to report the work of the referring physician in compiling the patient materials. The second code would be for the service in which a consultation report is provided asynchronously without a verbal requirement. The proposal also asks for revision of current codes 99446-99449 to include "electronic medical record." Finally, the request proposes revision of the current Interprofessional Telephone/Internet Consultations guidelines by adding "electronic medical record" as a method of consultation.

The DMPAG advisors compiled literature in support of these proposed codes that comply with the CPT Editorial Panel level of evidence requirements and include:

- Telemedicine REsuscitation and Arrest Trial (TREAT): A feasibility study of real-time provider-to-provider telemedicine for the care of critically ill patients, *Heliyon* 2 (2016);
- Los Angeles Safety-Net Program eConsult System Was Rapidly Adopted And Decreased Wait Times to See Specialists, *Health Affairs*, March 2017, 36:3;
- A Safety-Net System Gains Efficiencies Through 'eReferrals' to Specialists, *Health Affairs*, May 2010, 29:5;
- Implementation of an Electronic Referral System for Outpatient Specialty Care, *AMIA* Annual Symposium Proceedings 2011,1337-1346; and
- Electronic Consultations to Improve the Primary Care-Specialty Care Interface for Cardiology in the Medically Underserved: A Cluster-Randomized Controlled Trial, *Annals of Family Medicine*, Volume 14, Issue 2, March/April 2016.

[10] As CMS has narrowly defined the technologies that fit within the definition of telehealth, it is important to note that all other technologies that enable virtual care are not subject to the telehealth statutory geographic and originating site restrictions. As with remote patient monitoring, CMS has significant discretion to expand coverage of covered services utilizing a full array of technologies that enable the delivery of virtual care. We urge CMS to consider these flexibilities and employ an evidence-based manner to optimize the delivery of coordinated, high quality medical care.

In addition to the clinical literature, the DMPAG advisor from the University of Virginia Health System, which has facilitated more than 2,500 e-consults between providers, facilitated discussions with the Association of American Medical Colleges (AAMC) to fact find concerning the Coordinating Optimal Referral Experiences (CORE) Project. The Center for Medicare and Medicaid Innovation (CMMI) named the AAMC as one of 39 recipients in the second round of their Health Care Innovation Awards. This grant funded CORE to improve quality and efficiency in the ambulatory setting by focusing on the referral process between primary care providers and specialists. The initiative uses EMR-based tools — eConsults and Enhanced Referrals, and a shift in physician workflow and incentives, to reduce marginal referrals, improve access to specialists, and enhance the patient experience. We urge CMS to consider coverage of these services based on the ability to better target services, particularly in underserved communities where accessing specialty care is particularly challenging.

Coding Modifiers

CMS proposes to eliminate the required use of the Medicare GT modifier on professional claims when services are delivered via telehealth. **The AMA strongly urges CMS to utilize the telehealth modifier that the CPT Editorial Panel adopted after this was recommended by the Telehealth Services Workgroup (TSW) recommendation, CPT modifier 95**. The CPT Editorial Panel TSW had approximately 50 participants and reflected a broad set of stakeholders including private payers, health systems, physicians, allied health professionals, and industry representation. The use of the 95 modifier consistently among payers will enable uniform coding to facilitate payment, but to also ensure that CMS and other payers and researchers are more easily able to track and evaluate telehealth services. Because institutional claims do not use a POS code, CMS proposes for distant site practitioners billing under CAH Method II to continue to use the GT modifier on institutional claims. We urge at a minimum, that CMS adopt a uniform method for identification of telehealth and substitute the 95 modifier with the GT modifier for institutional claims.

D. Proposed Payment Rates under Medicare PFS for Nonexcepted Items and Services

The AMA urges CMS not to adopt its proposal to pay for nonexcepted items and services at off campus provider-based departments (PBDs) at 25 percent of the hospital OPPS payment rate. CMS arrived at this proposed fee schedule relativity adjustment by making a code-level comparison for the service most commonly billed in the off-campus provider-based department (PBD) setting: a clinic visit using HCPCS code G0463. CMS compared the CY 2017 OPPS national payment rate for G0463 to the difference between nonfacility and facility physician fee schedule amounts for the weighted average of outpatient visits (including CPT codes 99201-99205 and CPT codes 99211-99215) billed by physicians in an outpatient hospital place of service. **We do not believe it is appropriate to change an entire payment system based on a single code comparison.**

As CMS notes in the proposed rule, the comparison between the OPPS and PFS payment systems for services other than the most commonly billed code varies greatly. There are other factors, including the specific mix of services furnished by nonexcepted PBDs, the packaging of codes under OPPS, and various payment adjustments that contribute to the differences in payment amounts for a broader range of services. In addition, CMS notes that in considering the appropriate fee schedule relativity adjuster for 2018, it believes claims from 2017, which are not yet available, are needed to guide its approach. The AMA agrees that CMS must analyze claims from 2017 prior to making any additional significant changes in payment methodology for services furnished at nonexcepted off-campus PBDs. **While we appreciate**

CMS' efforts to create site neutral payment policies, we cannot support payment changes based on insufficient data.

Instead, we encourage CMS to continue its transitional payment methodology of establishing payment rates for items and services furnished by nonexcepted off-campus PBDs by scaling OPPS payment rates downward by 50 percent until CMS is able to obtain better data. In establishing the methodology to reduce OPPS rates by 50 percent for 2017, CMS used 25 high-volume codes to estimate a percentage to use in scaling OPPS rates to MPFS payment rates. CMS' analysis resulted in an average reduction of OPPS rates by 45 percent. In addition, CMS considered that broader Ambulatory Surgery Center (ASC) rates are reduced by approximately 55 percent. While we believe a comparison of 25 codes is too few to create an entire payment system, we believe CMS should continue with the transition policy until such time when it has more precise data to better identify and value services at nonexempt off-campus PBDs.

E. E&M Guidelines

CMS is seeking comment on methods to reform the E&M guidelines, reduce the associated burden, and better align E&M coding and documentation with the current practice of medicine.

The AMA appreciates the opportunity to provide input on ways to reduce physicians' administrative burden. We strongly agree with CMS that burdensome documentation requirements and the associated onerous features of EHRs degrade communication among health care professionals and detract from patient care. We are committed to working with CMS and ONC, as well as other stakeholders, to identify strategies to ease these pain points. **We strongly concur with CMS' decision to focus at this time on revisions of the current E&M guidelines because we believe that it is the guidelines, rather than the underlying code set, that create an unnecessary administrative burden.**

It is our view that with a collaborative effort, it should be possible to reduce complexity and ambiguity of the guidelines while bolstering guidelines that help distinguish meaningful differences among code levels. The current guidelines are one of the major obstacles to the development of electronic medical records that actually help, rather than hinder, patient care. Medical records are intended to capture physicians' medical decision making for future reference or for relaying informing to other providers during transfers of care. Current documentation guidelines require physicians to include a variety of additional information simply to justify code selection as opposed to prioritizing documentation relevant to the patient's current and future treatment. Consequently, EHR vendors use very prescriptive methods to capture "structured" information to align physician services with coding levels, adding unnecessary and extraneous work that blurs the focus of clinical care and detracts from the physician/patient narrative. The rules for which health care professional can record various parts of the record add to the burden by failing to recognize the team-based approach to care that has been widely promoted as a solution to growing fragmentation in care.

We urge CMS to consider methods to balance the goals of ensuring program integrity with those of clinical need and burden reduction. As an initial step, **CMS should evaluate and juxtapose the actual utility of guideline compliance and the associated downstream audit considerations with CMS' goals of transitioning to value-based reimbursement models and the shifting focus of patient outcomes over services.** In general, the AMA agrees that the guidelines should focus on medical decision-making rather than detailed descriptions of the history and physical exam. While time is also a relevant factor, we would fervently object to any system that relied primarily on time to determine and

document the appropriate E&M code level. CMS should also clarify that because the physician is required to sign off on the medical record and therefore verify its accuracy, all data entry in the record—staff can be delegated to ancillary staff. It will also be necessary for CMS to ensure that any new set of guidelines does not make physicians vulnerable to additional oversight and penalties from Medicare audit contractors.

Although it is "immediately focused" on revisions in the E&M guidelines, CMS also intends to "continue to explore changes in the underlying code set in order to address concerns from many stakeholders that the E&M code set itself is outdated." The AMA believes that it would premature to undertake such an effort before the new guidelines have been implemented and evaluated. We also wish to caution that any proposal to "simplify" the E&M codes would be extremely complex.

We would be particularly concerned if such efforts led to reductions in the number of visit levels. The AMA did not support CMS' decision to collapse five visit levels to one in the Hospital Outpatient Department and believes that this or any similar approach would be an even less appropriate way to measure physician work. In fact, some physicians who provide intense care to complex patients have argued that there are actually too few levels of E&M codes. E&M code levels, and their associated attributes, are carefully crafted to appropriately reflect the varying degree of complexity in evaluating and managing patient care. No changes in the codes should be undertaken without significant clinical input and without a review of the important redistributive questions and potential unintended consequences they raise.

Proposals to reduce or modify the E&M codes without a careful consideration of a number of likely, negative externalities would be imprudent absent an established process to engage front line practicing physicians. For example, hastily-made code modifications such as collapsing the codes could result in overpaying physicians for moderately complex services while underpaying physicians for the most complex cases; as a result, specialists treating high-risk patients may be unable to offset losses resulting from consistent underpayment, which could jeopardize such patients' access to care. Also, CMS must recognize the potential for perverse incentives, such as whether patients with greater complexity would find it more difficult to obtain medical care because they represent financial risk. Furthermore, code modification could discourage care coordination since Medicare no longer pays for consultations.

Past concerns with the E&M codes centered on the belief that they failed to adequately recognize certain work such as care coordination, which is necessary in the growing population of patients with multiple chronic diseases. New codes that better recognize care coordination have alleviated these concerns and could be expanded in the future. However, the new codes apply only to specific types of patients and circumstances and would in no way make up for payment reductions if, for instance, high-level codes were consolidated. A comprehensive reform of the E&M codes would require a multi-year, collaborative effort among stakeholders. **If CMS determines that it must reform E&M codes, we strongly urge the Agency to work with the CPT Editorial Panel, which includes advisors from every national specialty society, insurers, hospitals, and a broad cross section of other impacted health care providers and practitioners.**

We reiterate, however, that physicians' major complaint with E&M services lies not with the codes themselves but rather with the burden resulting from associated documentation guidelines. The AMA urges CMS to prioritize its work in this area.

F. Publication of RUC Recommendations for Non-Covered/Bundled Medicare Services in the Medicare Physician Payment Schedule Proposed Rule for CY 2018

The AMA requests that CMS publish the values for non-covered/bundled Medicare services in which the RUC has made a recommendation. The AMA reviewed the need to for CMS to publish relative value units (RVUs) for non-covered and bundled Medicare services at the 2017 AMA House of Delegates Annual Meeting and determined that it is important for the Agency to publish relative values for all services, including non-covered and bundled services. There is a long-standing precedent established by the preventive medicine service codes (99381-99397) and other codes, which are Medicare status indicator "N," yet have had RUC recommended values published on the Medicare Physician Payment Schedule Appendix B since their inception.

We identified 27 services reviewed by the RUC in which CMS has determined a Medicare status of "bundled," "not valid for Medicare purposes," "non-covered," or "contractor priced" but did not publish the RUC recommended value.

It is imperative that CMS publish the work, practice expensive and professional liability insurance relative values for these 27 services (see Attachment B) in the Medicare Physician Payment Schedule because the resource-based relative value scale (RBRVS) is used by Medicaid and many private payers. CMS established this precedent and the AMA requests that CMS continue to follow it. Physicians have reported problems seeking payment for these services by other payers because CMS simply has not published RVUs for these services.

II. OTHER PROVISIONS OF THE PROPOSED RULE

A. Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

CMS has requested feedback on the experience of applicable laboratories collecting and reporting data (each private payer payment for each test) that will be used by the Agency to calculate the rate for each test on the CLFS.[11] CMS is required by PAMA to implement this new payment methodology. **In brief, there were extensive challenges associated with the data collection and data reporting that call into question the accuracy of the payment rates that CMS intends to issue on January 1, 2018.** We emphasize that the lack of data accuracy has been driven by the Agency decision to impose a retrospective data collection period. This was further exacerbated by the sheer detail and volume of data requested for a period covering six months when a shorter period would have reduced the administrative burden and possibly increased accuracy.

We are also very concerned that CMS has not outlined how it will ensure that the final rates accurately reflect the submitted data without corruption once processed by CMS. Our concern is driven by the data errors found in the Open Payment Program in the first year of that program where both CMS and manufacturers alleged that the other party was responsible for the errors. (The situation is even more concerning here because unlike with the Open Payments Program where physicians are able to look at a

[11] The AMA's comments in response to the CMS question and implementation of the PAMA CLFS provisions focus nearly exclusively on clinical diagnostic laboratory tests (CDLT) as the same issues and problems with accurate reporting and transparent calculation by CMS of the final payment rate do not apply to advance diagnostic laboratory tests (ADLTs) or sole source tests that are CDLTs.

report and challenge the accuracy, there is no similar process for clinical laboratories to assess whether data that is substantially different from their payment for each test reflects legitimate market variance from other clinical laboratories performing the tests or errors in CMS data processing.)

During PAMA CLFS rulemaking, the AMA urged CMS to provide applicable laboratories adequate time to prepare for and then comply with the reporting obligations. The AMA noted that the reporting requirements are detailed, resource intensive, ambiguous in some areas, and confusing. We underscored that this would be difficult for all clinical laboratories subject to reporting, but to the extent physician office based laboratories (POLs) would be reporting the complexity of the statute, the proposed rule, and the interplay of the various provisions would be overwhelming.

This new law and then proposed rule was the most significant change to occur on the CLFS since 1984 when Medicare began paying for clinical testing services. It was further exacerbated by the fact that there is a general lack of awareness among POLs and the vast majority of national medical specialty societies that POLs receive payment for their clinical test based on the CLFS. The AMA specifically noted that we did not support the start of the initial data collection period until six months after the Agency issued the final rule. Though several stakeholders that were not experienced in implementing large scale changes in payment recommended the initiation of the reporting period potentially before the final rule was issued, the AMA stated in our comments that applicable laboratories may have to hire/train staff and resolve software issues in advance to ensure the data is being captured contemporaneous with the data collection period.

The AMA noted that to the extent POLs must report, they are not as likely to have the resources, including the data analytics, to assess whether they will be subject to the reporting requirement the first year of reporting and every third year thereafter. The AMA noted that CMS has claims datasets and the analytics to assess whether a POL meets the reporting requirements based on prior year claims. We strongly urged CMS to provide POLs with advance notice that the POL will be subject to the data collection and reporting requirements. The AMA observed that this was one strategy to enhance the accuracy and reliability of the data that CMS would rely upon to calculate the weighted median of private payer payments and mitigate the risk of civil monetary penalties. CMS rejected both recommendations and effectively created a perfect storm where it has been impossible for many clinical laboratories to accurately report, particularly POLs.

The above was further exacerbated by CMS' decision to require six months of data collection. The AMA strongly urged CMS to reduce the data collection period from a full calendar year every three years to three months of data collection every three years for clinical laboratory developed tests (CDLTS). The AMA stated that the data collection burden of reporting every private payer payment for all tests for a full year would divert already scarce health care resources to administrative tasks instead of to providing clinical care and services. The AMA was aware that other major clinical laboratory stakeholders were recommending six months, but it was very evident that they did not understand the sheer volume of data involved and the strong possibility of errors introduced into the data collection due to the lengthy reporting period. And, the AMA specifically called out that this reporting requirement would fall heavily on POLs—physician practices that are already facing quality reporting, Meaningful Use requirements, and implementation of alternative delivery (and payment) models. A three-month data collection requirement would ensure that the Agency had an enhanced possibility of receiving current and accurate data.

The extreme difficulties experienced by even the largest reference laboratories (that were involved in crafting the PAMA legislation, knew the statutory requirements, contract with sophisticated clearinghouses for claims management, and followed the rulemaking process) underscores that retrospective data collection constituted an impossibility for many clinical laboratories, particularly the small, regional independent clinical laboratories and the physician office-based laboratories. The physician community was not engaged in the development of the legislation and most physician office-based laboratories have still not received effective outreach from the Agency on whether or not they are an applicable laboratory.

It is notable that the largest reference laboratories sought extensions for the data reporting because of the challenges associated with paper claims reporting, in particular. Many POLs and regional, rural, small independent clinical laboratories serving underserved areas are more likely to have a larger number of paper claims and less likely to have resources to hire additional staff and vendors to assist with the claims tracking and validation. This data collection and reporting obligation was designed for sole source clinical tests and the large reference clinical laboratories, but not even the large clinical laboratories could report on time and there remain many questions as to the methods used to collect data after the fact given the sheer volume and the complexity of the reporting requirement. We emphasize that the AMA is not asserting that applicable laboratories failed to utilize best efforts to submit accurate data. Instead, based on what we have learned it appears that for most, if not all, applicable laboratories the retrospective, six-month data collection requirement constituted an impossibility.

There are two additional examples that raise questions vis-à-vis whether accurate reporting was possible. First, the difficulties with accurate reporting have been exacerbated by the practice of Medicare contractors, in particular the molecular diagnostic program administered by Palmetto GBA requiring clinical laboratories to use codes other than the applicable CPT codes to report a clinical test in that jurisdiction. Because private payers require clinical laboratories to utilize the applicable CPT codes consistent with the mandate of the Health Insurance Portability and Accountability Act, there is a mismatch between the codes used to report the clinical test in the Medicare program and among private payers. This practice must be curtailed as it is in conflict with the clear requirements of PAMA. If Palmetto GBA requires differential identification, it must either direct clinical laboratories to assign a modifier to the applicable CPT code or direct clinical laboratories to obtain a proprietary CPT code (which were created to accommodate PAMA requirements).

Second, CMS noted earlier this summer that it had not received any data and/or insufficient data to calculate a weighted median private payer rate for 60 codes (clinical tests). As noted during the AMA's public comments as part of the Annual CLFS meeting, our concern with the lack of data accuracy have been reinforced by the late notice provided by CMS that no data was produced for 60 codes. CMS requested comments on whether 60 codes should be included on the CLFS. On the one hand the 60 codes may no longer be offered by applicable laboratories, on the other hand these tests may still be offered. We do not know.

We are extremely concerned that patient access will be harmed in early 2018 which would be challenging and difficult, but will undermine nascent and important efforts to implement payment and delivery reform under the Medicare Access and CHIP Reauthorization Act (MACRA). Reasonable and measured policy adjustments are needed so that the most frail and vulnerable are not required to shoulder the consequences of poor implementation. This will also ripple across the health care infrastructure and impose additional pressure that is not necessary because there are reasonable and sensible alternatives that will provide

CMS with essential facts to guide policy decision-making. Furthermore, we are very concerned that implementation of inaccurate and excessively low payment for clinical tests will lead to many POLs and small, independent clinical laboratories around the country to stop offering testing for patients for rapid, near patient testing for infectious disease. This will degrade the necessary clinical laboratory infrastructure that ensures accurate detection of infectious disease outbreaks. Many rural regions will be especially vulnerable where coverage from the large national reference clinical laboratories is more limited.

The AMA strongly urges CMS to conduct a market segment survey (to include consideration of the market for reference laboratories, physician office–based laboratories, independent laboratories, and hospital laboratories) in order to assess the accuracy of the data collected as part of the data collection exercise. The foregoing is needed in order to validate and adjust the final amount calculated based on the data collection to ensure it accurately reflects private payer payments—which CMS has the authority to do under a general grant of authority in the Social Security Act to administer the Medicare program and to ensure the integrity of the Medicare program.[12] At a time when relief from overly burdensome regulation has become a top priority of the current administration, we urge CMS to ensure that implementation of PAMA results in as little administrative burden and disruption as possible.

B. Payment for Biosimilar Biological Products under Section 1847A of the Act

CMS has requested comment and information on the current policy for payment of biosimilars under the Part B drug benefit. The current policy requires that all biosimilars related to a single reference product are assigned a shared HCPCS code. For Medicare Part B, reimbursement is then calculated based on the average sales price (ASP) of all of the biosimilars with that HCPCS code plus the prevailing percentage adjustment. CMS implemented the policy in the CY 2016 MPFS Final Rule. **The AMA urges CMS to revise this policy and instead of blending prices for multiple biosimilars into a single code with one payment rate, we urge instead that each biosimilar should be assigned a unique HCPCS code for billing and payment effective January 1, 2018, in order to ensure continuity of a patient's course of treatment (clinical benefit) and to lower overall costs to the Medicare program (fiscal benefit).**

As a threshold matter, the AMA has clear policy providing that unless a biosimilar has been deemed interchangeable with an innovator and with other biosimilar(s), it is not clinically appropriate to compel physicians and patients to treat the products as interchangeable. Thus, to the extent that the current policy provides for a blended rate for biosimilar products for which a determination of interchangeability has not been established, the AMA strongly opposes the use of a single code. This raises the same concerns as outlined below, but heightens concerns related to pharmacovigilance and creates inappropriate incentives to treat biosimilar products as interchangeable, when the accepted evidentiary basis has not been established by the applicable regulator: the U.S Food and Drug Administration (FDA).

In addition to the foregoing, and even where interchangeability has been established by the FDA, current CMS policy creates a strong clinical justification and financial incentives to utilize the biological

[12]We urge CMS to exclude from the interim final rule sole source clinical tests including those that could be considered advanced diagnostic laboratory tests (ADLTS) and other clinical tests with a limited number of laboratories that perform such clinical tests. Laboratories with such tests had little to no difficulty, reportedly, preparing to report accurate data given their small test menu and overall awareness of the PAMA provisions. Furthermore, if the final weighted median is inaccurate, it will be easier to assess by such clinical laboratories given the limited universe of data sources.

reference product over biosimilar alternatives, thereby undermining the cost savings associated with biosimilars. Why? In short, physicians and their patients seek treatment options that are predictable and reliably available and where switching between products is minimized in order to reduce the possibility of unanticipated adverse events including unexpected interactions with other treatment products (drugs and biologicals). In general, physicians and patients reasonably strive to maintain consistent treatment selection even when the treatment involves simple brand drugs and generics. Even inactive ingredients in simple drugs and generics may cause unexpected adverse events that negatively impact a patient's health outcomes. Biologicals and biosimilars are far more complex organisms and while greater outcomes data is needed to assess the prevalence and risk associated with switching between products and immunogenicity, until this data becomes available there is a valid clinical interest to ensure patients remain with a course of treatment that does not precipitate unexpected adverse events. This is particularly a concern where a patient may have a number of prescriptions and where drug-to-biological/biosimilar interactions are unpredictable. When the patient population is a particularly vulnerable one, such as oncology patients or those with rheumatoid arthritis or Crohn's disease, these clinical considerations and concerns become more pronounced. In addition, pharmacovigilance does become more complicated when product switching occurs. It adds another layer of complication when attempting to attribute causation to adverse outcomes when multiple products have been used.

If the overall goal is to minimize switching, why would the innovator biological represent a preferable alternative to the biosimilars? Simply stated, the innovator biological will have a relatively predictable ASP. The variability of the innovator ASP will be stable relative to a blended ASP of the biosimilars associated with the reference biological. The blended biosimilar rate will fluctuate and physicians must make a calculated risk that the biosimilar that they have selected for their patient's treatment is the one where the total cost will be covered under the blended ASP method. Thus, the blended approach introduces an element of financial risk that is not present for the reference biological ASP calculation. In addition, if the physician initially selects a more costly biosimilar, there will be a financial incentive to switch to a less costly biosimilar (though even that selection will involve risk as there could be, yet other, less costly biosimilars).

The introduction of new products (biosimilars) creates a strong element of competition to the innovator reference biological as well as other biosimilars. Allowing physicians and patients to make the best selection based on the relative cost and clinical benefit of one biosimilar relative to another while driving cost savings, predictability, and continuity of treatment is achievable by assigning unique HCPCS.

C. Appropriate Use Criteria

The AMA appreciates CMS' decision to delay implementation of the Appropriate Use Criteria (AUC) program mandated in the Protecting Access to Medicare Act of 2014 (PAMA). We strongly agree that delay is necessary to allow ordering providers to choose a clinical decision support system (CDSM) and maximize the opportunity for public and stakeholder input. However, we are concerned that given the scale and complexity of the PAMA mandate, CMS' proposed January 1, 2019 start date will not provide sufficient time for proper education and preparation. Both CMS and physician practices will have to work out significant technical and workflow challenges prior to full-scale implementation. Additional time would also allow CMS to determine whether incentives in the Quality Payment Program (QPP) offer a less burdensome means of achieving the AUC objectives. This means that further delay may be necessary. **Thus, at the least, AMA recommends that the proposed educational and operation testing period last an additional year.** Then, having gained additional information, CMS can evaluate

physicians' experience with the program and determine whether the AUC program is ready for full implementation.

Technical and Workflow Challenges

To implement the complex AUC system envisioned in PAMA, the proposed rule creates a plan that would track consultation and response any time a physician consulted AUC criteria. We have serious reservations about the feasibility of incorporating and transmitting data between the ordering and furnishing physicians.

Although the requirements for communications between the ordering and furnishing providers are not entirely clear, it appears that as currently proposed, both would need to record and the furnishing provider would be required to include on the claim:

- A G-code for the qualified CDSM that was consulted before ordering the imaging services (or a temporary generic G-code for CDSM that does not yet have its own specific G-code);
- A modifier on whether or not the ordering physician adheres to the AUC; and
- NPI of the ordering physician.

The new G-code and modifier represent new data on the claim. **Reporting this additional information on every imaging claim would be extremely burdensome to providers in multiple respects**.

First, requiring physicians to report a specific G-code for a specific CDSM for imaging services in all eight priority clinical areas is burdensome. We realize the law requires that each claim identify the specific G-code; however, given the burden, CMS may need to consider discussing potential legislative fixes with Congress or limiting the number of priority areas. We also have concerns regarding the burden of tracking when G-codes are available for newly approved CDSMs. CMS should tie the availability of newly-approved CDSMs to the time when a specific G-code becomes available or establish an annual date when the temporary G-code can no longer be used. Either of these approaches provides more certainty than when the specific G-code "becomes available."

Second, we have significant concerns about numerous workflow challenges and questions that will result from the AUC program requirements. Ordering physicians must be able to easily identify the diagnoses and specific advanced diagnostic imaging services to which the AUC requirements apply so they can consult the CDSM at the time of ordering. Information regarding the CDSM consultation will then somehow need to be communicated between ordering and furnishing providers, as the physician ordering the imaging service will often 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). There is currently no standard process, technological solution, or workflow for communication of this information between ordering and furnishing providers. 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?

Third, we are also concerned that inclusion of these additional data elements on the claim could lead to adjudication errors, disruption of claims processing and payment, and an increase in improper payments based on hyper technical requirements. Additionally, because the furnishing provider receives remittance

advice and payment, CMS needs to consider what happens if the claim is rejected for reasons related to the reported AUC information and who appeals the claim if it is rejected for AUC reasons.

Additional clarification and education is also needed on how exceptions should be reported on the claim. In emergency situations or in cases where the physician meets a hardship exemption, no CDSM query takes place, and there will be no G-code for a CDSM product reported on the claim. A modifier reflecting the emergency or hardship exception would presumably be reported with the procedure code for the imaging service, but CMS should clarify how these various scenarios must be coded to ensure acceptance into the adjudication system. **The numerous workflow challenges and technical issues underscore the need for an extensive preparation period before full implementation of the AUC program.**

Fourth, providing two free CDSMs to physicians is laudable. However, a standalone CDSM introduces additional issues. Without tight clinical workflow integration, many physicians and staff will need to remove themselves from patient care in order to transcribe information from the EHR into a separate third-party application or website. This will drastically increase the data entry burden—further increasing physician dissatisfaction with their IT tools, adding human error, or ultimately delaying patient care.

Fifth, the AMA also believes that for most specialists, requiring CDSM consultation for services outside their area of expertise will serve only to increase growing frustration with Medicare paperwork. **In our view, it likely would be more productive to give specialist physicians the option to purchase and consult specialty-specific CDSMs that could include several sets of criteria for services normally ordered or performed by that specialty.** The option might be less expensive than what CMS is proposing and could be especially useful on complex cases where consultation of multiple criteria might make the ordering physician aware of a wider array of alternatives and/or issues to be considered. If claims data showed that some physicians within the specialty were frequently ordering advanced imaging outside their specialty's normal services, additional steps could be taken, including requiring physicians with more than some specified number of such claims for services not normally provided by this specialty to consult a product that included all the priority areas.

Given the number of technical and workflow challenges identified above, the AMA urges CMS to add a second year to the educational and operational testing period.

Interaction with the Quality Payment Program

The AMA appreciates CMS' willingness to consider how the AUC program could serve to support a quality measure under the MIPS quality performance category and CMS' request for comment on the feasibility and value of pursuing the idea further. **We fully support providing MIPS credit to ordering professionals who consult AUC using a qualified CDSM as a high-weight improvement activity beginning in 2018.** We encourage CMS to make the activity and associated weight permanent.

In general, the AMA supports program alignment when feasible and so long as it does not lead to increased administrative burden. Based on our understanding of the AUC program and MIPS quality performance category, we offer the following ideas for CMS to consider to improve alignment between the AUC program and the MIPS quality performance category:

- Develop an optional quality measure or offer bonus points in MIPS if physicians provide feedback to the Physician Led Entities (PLEs) and CDSMs about why they decided to proceed with ordering a test even if it did not fit AUC. This will enable PLEs and CDSMs to learn from their users as experience is gained. It would also provide a less burdensome and more informative alternative to the current requirement that physicians consult on and CDSMs track consultation and ordering on all imaging services whether they are addressed in the CDSM or not.
- Provide credit for utilization of a Qualified Clinical Data Registry (QCDR) that is led by a relevant medical specialty and that incorporates CDSM and reports the information to CMS on the physician's behalf. We assume that physicians reporting through a QCDR would all be automatically reviewing the same criteria and could therefore be compared to others using the same QCDR. The more extreme and burdensome claims tracking requirements envisioned in the AUC mandate could be avoided as a result.
- Exempt a physician from AUC requirements when the physician is participating in an Alternative Payment Model (APM) or MIPS APM because that physician is already being held accountable for costs and outcomes and is assuming risk. It is in the practice's best interest to avoid inappropriate over- or under-utilization if they are participating in an APM. CMMI could utilize its waiver authority to create this exemption.
- Provide two points for reporting on appropriate use measures. This further incentivizes reporting on an appropriate use measure, which is considered a high priority measure under MIPS. We offer a similar recommendation in our 2018 QPP proposed rule comments.

In addition, we caution CMS that any potential quality measure developed around appropriate use criteria, would have to meet the standards set for other quality measures—reliability, validity, and testing. We also would discourage CMS from creating AUC quality measures based off of administrative claims. We refer CMS to our 2018 QPP comments on the AMA's recommendations on reliability, testing and administrative claims quality measures. Furthermore, any proposal(s) CMS considers in the future or develops through contracts must be developed in a transparent manner, include input from appropriate physician experts, and provide an opportunity for public comment.

Educational and Operational Testing Period

The AMA applauds the proposal of an educational and operations testing period to allow for active participation while avoiding claims denials and having no impact on reimbursement. As CMS has recognized, the AUC program is novel and complex for both CMS claims processers and for ordering and furnishing professionals. As described above, the AUC program is a new requirement with broad application and requires complex communication and transferring of information. **Thus, given this complexity and potential for errors, AMA believes the educational and operations testing period should be extended to two years**.

The two-year testing period could reflect the gradual implementation of the AUC requirements. The first year of the testing period could be a hold harmless year where ordering physicians would not have to provide the necessary data on the claims but would receive credit through the MIPS improvement activity category and/or quality categories if they did. The second year should require data on the claim—whether or not such information is correct. As with the first year, no claims would be denied and there would be no impact on payment. With two full years, CMS would have adequate data to demonstrate whether the appropriate use criteria should be fully implemented or require further delay. Alternatively,

CMS may want to consider focusing on certain priority areas for the first year of testing and expand to a full list in second year.

Regardless of the specific adjustments to the testing period, CMS should clarify the requirements for claim approval during the transition: will claims be approved even if none of the AUC data elements are included, or must the furnishing provider at least attempt to populate the claim with the three required data elements (even if this is done incorrectly) to receive payment?

Outliers and Prior Authorization

AMA has numerous concerns regarding outlier identification and prior authorization. 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 prior to implementing any type of outlier approach.

Outliers can occur for a variety of reasons. While some may represent an inappropriate test, outliers may also occur 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 take care not to apply the outlier label and penalties to physicians who are actually innovators 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 may also wish to consider creating optional modifiers to test during the educational and operational testing period for situations where the physician did not order the treatment recommended by a CDSM. These optional "no" modifiers would allow physicians to provide justification for why they did not follow the CDSM's recommendation. More detailed modifiers could include:

- No, patient-specific conditions required a different treatment;
- No, the CDSM recommended treatment is inconsistent with current clinical recommendations; and
- No, patient refused recommended treatment.

More specific modifiers such as those suggested above could provide CMS with sufficient details to differentiate between true outlier physicians and those who may have attempted to adhere to the CDSM's recommendations but were required to provide alternative treatment in particular instances.

CMS should focus its outlier identification on areas where there is an underutilization of services that are always appropriate and overutilization of services that are almost always never appropriate. 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. CMS may also want to consider whether to focus outlier identification on a few of the clinical priority areas and whether to stratify by specialty when comparing physicians to criteria in a particular CDSM.

With the CMS proposed delay of the AUC program until January 1, 2019, the AMA believes there should be at least a similar delay as to when prior authorization begins. For example, the statute has AUC program starting in 2017 with prior authorization starting in 2020. Thus, if AUC is fully operational in 2019, prior authorization should not start until at least 2022. Furthermore, any calculation in determining prior authorization 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.

Hardship Exceptions

Given the technical and workflow challenges, the AMA urges CMS to develop an automatic hardship exemption for any physician who does not have access to free integrated CDSMs because of the costs associated with integrating a CDSM into an EHR and ensuring interoperability between ordering and referring physicians. In addition, AMA opposes the proposed removal of the practicing-for-fewer-than-2-years hardship exception and the 12-month cap on hardship exemptions.

No Access to Low-Cost Integrated CDSMs

We expect that most physicians will request their CDSM to be integrated within their EHRs. This will require additional functionality from their EHR vendors and undoubtedly force physicians to pay their EHR vendors and CDSM vendor for a "custom" interface. We expect this to trigger a new wave of health information technology (IT) costs just as physicians are also facing significant costs related to the upcoming MACRA requirements.

CMS proposes a number of new items that must be included on the claim in order for the physician to be paid. In any case where consultation of the AUC is followed by an order, the furnishing professional must supply the ordering physician's AUC-use information to CMS. In many instances, the ordering physician and furnishing professional will not share the same office space, EHR, or technology platform. This will demand new or additional health IT interoperability between the ordering physician's EHR and the imaging center's systems.

Practicing-for-Fewer-Than-Two-Years Hardship Exception

In addition, the AMA opposes the proposed removal of the practicing-for-fewer-than-two-years hardship exception. Due to the hardship exceptions coming from the sunsetting Medicare EHR Incentive Program, CMS proposes to remove the two-year hardship exception from the AUC program because, under MIPS, eligible clinicians are exempted from participating in MIPS for one year. The AMA does not understand why CMS is proposing identical exemptions within two different programs. Although new physicians are exempted from participating in MIPS for one year, AUC is a separate program with highly complex and potentially expensive requirements that must be met by all ordering physicians with none of the MIPS exceptions or special rules for practices that are small or have a low volume of Medicare patients.

Therefore, AMA urges that CMS either maintain the two-year hardship exemption for the AUC program or adopt a low-volume threshold exemption for the AUC program based off of the MIPS exemption.

Twelve-Month Cap on Hardship Exceptions

AMA also opposes CMS' proposal to limit hardship exemptions to no longer than 12 months because certain hardships may justifiably last longer than 12 months and the circumstances may be out of the control of the physician. CMS should not punish physicians for circumstances outside of the physician's control. For example, under this proposal, if an ordering physician practices at multiple locations, does not control the availability of CEHRT at the practice locations, and the situation remains unchanged for over a year, then the furnishing physician will not be able to receive payment for the services rendered beyond the 12-month period. This approach is unfair, unjustified, and disproportionately affects rural providers. **Thus, the AMA opposes the proposal to cap hardship exemptions at 12 months.**

Unintended Consequences

Throughout the above comments, the AMA makes multiple suggestions to avoid unintended consequences. These suggestions include:

- Allowing a longer testing period to address the complexities of and gain familiarity with AUC;
- Reducing the burden of the AUC program to avoid unnecessary work that takes physicians away from providing care;
- Promoting specialty-specific CDSMs to avoid having physicians consulting criteria that does not apply to their practice;
- Reducing or phasing in the number of high priority clinical areas that all CDSMs must include and that all ordering physicians must consult in order to lower the burden that will be faced by primary care physicians;
- Focusing outlier identification on specific circumstances to avoid unnecessarily labeling physicians as outliers for providing innovative care; and
- Ensuring that the AUC program does not result in patient harms by reducing ordering of appropriate advanced diagnostic services.

CMS has already taken some steps to avoid unintended consequences. Specifically, CMS has been clear that the AUC program should have multiple CDSMs and not just one tool for everyone to use. Congress intended that the AUC program be competitive by avoiding the development or emergence of a monopoly. The AMA applauds the selection and designation of a wide range of developers of AUC.

We are concerned, however, that a number of the CDSMs (including one of the two free products) that CMS has approved appear to be little more than radiology benefit managers and commercial insurers whose preauthorization and utilization management programs are distrusted and reviled by many physicians. We are also concerned that without more information, physicians will have little way of knowing which, if any of the approved CDSMs will meet their needs. Currently, the only information CMS has on its website is a list of seven qualified and nine preliminarily qualified CDSMs. There is no additional information on the company behind these CDSMs, whose criteria the CDSM will include, which, if any, EHRs it potentially may be integrated into, what its cost will be and how to contact the company to obtain this information. **Consequently, the AMA strongly urges CMS to provide more specific information that will enable physicians to better evaluate the backgrounds, incentives, and capabilities of the products they are being required to incorporate into their practices.**

Overall, 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 approach, CMS needs to adequately address technical and workflow challenges with its implementation and any interaction between AUC and the QPP prior to fully implementing the AUC. Adding an additional year to the testing period may provide CMS adequate data to demonstrate whether the AUC program should be fully implemented or requires further delay.

D. 2016 Physician Quality Reporting System (PQRS) Reporting Requirement Changes and 2018 Value Modifier Penalty Reductions

The AMA supports CMS' proposals to align the 2016 PQRS reporting requirements with the MIPS quality reporting requirements and to reduce the penalties physicians will receive under the Value Modifier (VM) in 2018.

First, the AMA supports CMS' proposal to revise the reporting criteria for the CY 2016 PQRS reporting period to lower the requirement from nine measures across three domains with one cross-cutting measure, to six measures with no domain or cross-cutting measure requirements. The AMA agrees that these changes to the reporting criteria are simpler, more understandable, and more consistent with the MIPS quality reporting requirements.

In addition, the AMA strongly supports CMS' proposal to reduce the 2018 negative payment adjustments for physicians under the VM. Specifically, CMS proposes to reduce the penalties for physicians who do not meet the 2018 PQRS reporting criteria from negative four percent to negative two percent for groups with 10 or more eligible professionals, and from negative two percent to negative one percent for groups with fewer than 10 eligible professionals. In addition, CMS proposes to hold all physicians who meet the criteria to avoid the 2018 PQRS payment adjustment harmless from downward payment adjustments under quality tiering in 2018. The AMA previously joined a large group of state and specialty medical societies in a sign-on letter urging CMS to take steps to protect physicians from the high penalties under the 2018 VM, and we specifically asked CMS to exempt any physician who met the 2018 PQRS reporting requirements from mandatory quality tiering under the VM. **We appreciate CMS' attention to our letter, and strongly support the proposed changes to 2018 PQRS and VM requirements.**

Finally, the AMA is disappointed that CMS did not create an additional hardship exemption for the Meaningful Use (MU) 2016 performance year. CMS was directed by the 21st Century Cures Act to establish a strategy to relieve the electronic health record (EHR) documentation burden. The AMA and other stakeholders encouraged CMS to fulfill this directive by establishing a new "Administrative Burden" category of hardship exemption for the 2016 MU performance year. This additional hardship exemption would have ensured physicians were not penalized for focusing on providing quality patient care rather than the MU requirements that are not relevant for many specialties.

E. Medicare Shared Savings Program Accountable Care Organizations

The AMA supports CMS' proposals to decrease physicians' regulatory burden by reducing documentation submission requirements for MSSP ACOs. Reducing the administrative burden for physicians participating in ACOs will encourage more physicians to join APMs that aim to reduce spending without harming quality of care.

First, CMS proposes to improve the process used to validate ACO quality data reporting. CMS' Quality Measures Validation audit process selects a subset of web interface measures and a random sample of 30 confirmed beneficiaries for auditing purposes. The ACO is required to provide medical records to support the data reported in the web interface for those beneficiaries. If the audit match rate falls below 90 percent, CMS adjusts the overall quality score proportional to the ACO's audit performance. CMS has found, however, that many of the documentation errors were not indicative of poor quality of care, but were minor errors in process or understanding the measure specifications. Therefore, CMS proposes to lower the audit match rate threshold to 80 percent, and only adjust an ACO's overall score if their match rate falls below that level. **The AMA supports this change that will reduce the documentation burden for physicians participating in MSSP ACOs.**

In addition, the AMA supports CMS' proposal to reduce the burden on ACOs applying for Skilled Nursing Facility (SNF) three-day waivers. Specifically, CMS proposes to remove the requirement that ACOs include a narrative describing any financial relationships that exist between the ACO, SNF affiliates, and acute care hospitals on the SNF three-day waiver application. CMS also proposes to remove the requirement that an ACO must submit documentation demonstrating that each SNF on their list of SNF affiliates has an overall rating of three stars under the CMS Five-Star Quality Rating System. **The AMA supports the removal of this documentation requirement, however, we would also support removal of the full requirement that SNF affiliates must have and maintain an overall rating of at least three stars in the Quality Rating System in order to partner with ACOs for purposes of the SNF three-day waiver.** Specifically, we believe that the Medicare SNF five-star quality rating system is flawed and overly relies on self-reported data by nursing homes. In addition, APMs are payment models that reward physicians for delivering high-quality and low-cost care. Therefore, APMs are already self-regulated to provide high quality care to patients at low cost, and it is in their best interest to contract with high-quality SNFs. There are also times a patient may need to go to a nursing home and the highest rated one may not have available beds, or the patient may choose to go to a facility close to family and friends. **For these reasons, we urge CMS to remove the requirement that SNF affiliates must have and maintain an overall rating of at least three stars in the Quality Rating System in order to partner with ACOs for the purposes of the SNF three-day waiver.**

CMS also proposes to eliminate many of the requirements on the MSSP application form. Instead of requiring submission of certain materials, narratives, and supporting documentation, CMS instead proposes to require ACOs to certify that they meet the applicable eligibility and documentation requirements. **We agree that reducing these documentation requirements will reduce the application burden without affecting CMS' ability to determine whether an ACO meets the requirements for participating in the MSSP**.

Finally, CMS proposes to take a more flexible approach to the issue of Tax Identification Numbers (TINs) being exclusive to one ACO if their claims are used in the patient attribution process. **The AMA supports the proposed approach which would streamline the process for ensuring ACOs comply with the ACO exclusivity requirement. The AMA strongly supports these regulatory relief proposals which we believe will help reduce the burden for ACOs.**

F. Physician Compare

Physician Quality Reporting System

The AMA urges CMS not to move forward with finalized 2017 Physician Compare policies for public reporting of 2016 PQRS data. The AMA has previously expressed our concerns to CMS that they have not allowed for adequate time or provided sufficient detail when proposing changes to Physician Compare. The expansion of the Achievable Benchmark of Care (ABC) methodology (equal range and cluster methods) is complex and requires stakeholders to review and analyze how these two methods may affect how physicians' data is reflected on Physician Compare. Given that 2016 is the final year for PQRS data, we urge CMS not to move forward with new complex methodologies at this time. Instead, we believe that CMS and physicians' efforts would be better spent focusing on how to best present future MIPS data so it accurately reflects physicians' performance.

In addition, we urge CMS to consider how PQRS and MIPS policies will affect Physician Compare data. For example, under PQRS a physician may report measures through multiple submission mechanisms or report more than the required number of measures, but for purposes of avoiding a penalty CMS only considers the most successful method and measures. However, under Physician Compare, as long as a physician successfully satisfies PQRS reporting requirements, all data, regardless of whether the data was used to calculate the physician's score, is publicly posted and included in the downloadable database. **Physician Compare should align with PQRS calculations and only information that was utilized for the final PQRS determination (and in the future MIPS) should be publicly released and utilized for Star Ratings.**

The AMA is also aware of many instances where a physician may have changed reporting mechanisms mid-year for reasons such as lack of continued vendor support or endorsement. In these circumstances, the physician would not rely on the data from the discontinued vendor for his or her PQRS reporting calculations. Therefore, publicly releasing and rating all information on Physician Compare may send conflicting messages to patients and physicians, since the information posted might be lower than the data utilized for penalty avoidance. A physician may essentially be penalized for reporting extra data to ensure they avoid a PQRS penalty.

The inconsistency in policy between PQRS and Physician Compare will be further exacerbated under CMS' transition year policy for calculating 2016 PQRS data. Under the transition year policy, CMS is proposing to only calculate a physician's PQRS score on six measures, but many physicians may have reported on nine measures due to CMS proposing to change the requirements after the close of the 2016 reporting period, which we support. Therefore, Physician Compare will reflect data on quality measures that were not used to determine whether a physician successfully avoided a PQRS penalty. **Due to the recent change in 2016 PQRS requirements, inconsistencies between PQRS and Physician Compare policies, and the transition to MIPS in 2017, we urge CMS to refrain from publicly posting 2016 PQRS data on Physician Compare.** Our recommendation is similar to the policy CMS has proposed for deciding to not move forward with publicly releasing 2016 Value Modifier data. **Alternatively, if CMS feels it does not have the statutory authority to exclude 2016 PQRS data from Physician Compare, any information posted on Physician Compare or the downloadable database should only be based off of data CMS used to calculate a PQRS penalty—six measures through a single submission source.**

Once again, **we urge CMS to extend the Physician Compare preview period from 30-days to 90-days, in order for physicians to review and ensure the accuracy of their data.** This is particularly necessary if CMS decides to move forward with the finalized 2017 Physician Compare policies. Physicians and practices will need time to review and understand the additional information CMS posts outside of the information utilized to determine PQRS payment adjustments.

Value Modifier

The AMA supports CMS' decision to not move forward with releasing 2016 Value Modifier information through the Physician Compare downloadable database in late 2017. 2016 is the last year of the Value Modifier program and we do not see the value in publicly releasing and posting data related to only one year of a program. Also, as we have commented repeatedly, results under the Value Modifier are based on flawed data stemming from inappropriate measures and methodologies that lack reliability and have routinely disadvantaged physicians treating complex and disadvantaged patients. We would not support inclusion of Value Modifier results in Physician Compare even if the Value Modifier was not being discontinued. As CMS states, and as we echo earlier in our comments, physician time and efforts are better spent focusing on MIPS implementation and learning the complex methodologies related to MIPS calculations and public reporting methodologies.

Board Certification

The AMA is concerned with the lack of standards CMS has set for adding additional board certification organizations on Physician Compare for use on individual physician profile pages. If a specialty board is not certified by the American Board of Medical Specialties, American Osteopathic Association (AOA), or American Board of Optometry (ABO) CMS' policy is to allow any certification organization to bring their board to CMS on a case-by-case basis and request selection for additional board certification information on Physician Compare. In addition, CMS proposed in the 2018 Quality Payment Program proposed rule to base the determination on whether a board fills a gap in currently available board certification information listed on Physician Compare. **The AMA urges CMS to put criteria in place to evaluate appropriate board certification organizations. We recommend the following criteria: when the equivalency of board certification must be determined, accepted standards, such as those adopted by state medical boards or the Essentials for Approval of Examining Boards in Medical Specialties, should be utilized to make the determination. We also continue to support optional posting of board certification and oppose mandatory board certification and other policies that would discriminate against physicians that are not board certified.**

Data Release

In addition to the data being publicly reported on the Physician Compare website, the AMA remains concerned about CMS' Medicare Provider Utilization and Payment Data. The AMA has repeatedly highlighted that this data, without sufficient context, is likely to be misconstrued by the general public and could lead to false assumptions about individual physicians. In particular, individuals using this data are unlikely to realize that Medicare payments include practice and malpractice expenses and that these are not part of a physician's actual revenue. **To avoid this confusion, the AMA asks that CMS remove practice expense and malpractice expense from data reported to the public.** We believe this will improve the existing data while still allowing the information to be used for research and other activities that could improve patient care.

G. Patient Relationship Categories

As noted in the proposed rule, MACRA required CMS to develop several new tools intended to improve the measurement and comparison of physician resource use for the cost component of MIPS. One of these tools involved the development of a set of categories describing different types of relationships or roles that physicians have with their patients. The expectation is that these categories will facilitate more accurate attribution of costs among a patient's various physicians. The law directed that they be converted to codes that physicians would be required to include on claims for services provided as of January 1, 2018.

The AMA agrees that current cost measures are seriously flawed and that attribution methods tied to a physician's role in a patient's care could potentially lead to a more accurate distribution of costs among physicians. In an effort to help advance the development and testing of this concept, a subcommittee of CPT Editorial Panel and RUC members recommended five broad categories of patient relationship categories and we are pleased that this is the list that CMS is proposing to use. We also support CMS' decision to have physicians identify their roles using patient relationship modifiers rather than codes and to adopt official CPT modifiers once they are available.

Given the myriad of other changes CMS and physicians are coping with during the MACRA transition, it is entirely appropriate to make reporting of these modifiers voluntary in 2018. On the other hand, we are not as convinced as CMS that these categories are not necessary for any of its currently available or contemplated cost measures. Attribution for each of the two cost measures (total cost of care and Medicare spending per beneficiary) carried over from the value-based modifier has flaws that perhaps could be addressed with improvements in the way it assigns costs. It might also be that patient relationship codes could play some role in assigning costs for new cost episodes.

We therefore encourage CMS to consider our recently-submitted QPP proposal under which all physicians would receive a neutral/average score on the cost category but could voluntarily report patient relationship codes and/or participate in testing of new episode and revised VBM cost measures in order to accrue bonus points. Voluntarily-reported patient relationship categories might also be useful in implementing another AMA suggestion that CMS design a system where physicians would choose or CMS would assign default patient relationship categories that would apply for all claims except those where the physician had used a modifier indicating a different relationship.

H. Medicare Diabetes Prevention Program

The AMA wants to reiterate its support for the MDPP expanded model. Allowing Medicare patients to have coverage for this evidence-based intervention will benefit the health of the nation's seniors and the health of the nation. The AMA was one of several national organizations that partnered with the YMCA of the USA on the innovation award.

Eligibility Criteria

CMS should reconsider its decision not to cover the hemoglobin A1C test to identify Medicare patients eligible for the MDPP. While originally only indicated for the management and control of diabetes, this test is increasingly being used to diagnose prediabetes and diabetes, especially as costs have declined. Many physicians view it as more reliable than other diagnostic tests because it does not require patients to

fast beforehand. The AMA urges CMS to support accurate diagnosis and access to care by adding the Hemoglobin A1C test to the list of MDPP-covered diagnostic tests.

While CMS has stressed that its MDPP eligibility aligns with Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) standards, there is a discrepancy for fasting glucose results. The differences between the eligibility criteria to participate in a DPP using CDC recognition program guidelines compared to the proposed criteria for Medicare DPP eligibility may limit access. The MDPP proposed fasting plasma glucose testing threshold of 110-125 mg/dL is higher than the threshold of 100-125 mg/dL recommended by the US Preventive Services Task Force (USPSTF) screening guidelines and virtually all other clinical guidelines for managing prediabetes. This is inconsistent with accepted standards of care in the U.S. and is likely to cause confusion among physicians about when to diagnose a Medicare patient with prediabetes and when to refer them to the MDPP. The AMA urges CMS to support access to population-based health care by aligning the MDPP eligibility criteria with accepted standards of care and clinical practice guidelines.

The AMA supports CMS' proposal to permit patients who meet the proposed blood value criteria to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral. We ask for further clarification as to how the MDPP provider will obtain and document the required blood value in order to verify the participant meets MDPP eligibility for the benefit.

Medicare Diabetes Prevention Program Supplier Enrollment

In previous rulemaking, CMS stipulated that all coaches will be required to obtain a National Provider Identifier (NPI) number that would be used to track participant outcomes to the specific coach. If all coaches are required to have NPIs, then a new taxonomy for "lifestyle change coach" should be created. The AMA is concerned that, absent such a policy change, coaches will select a wide variety of taxonomies (like community health worker, health educator, etc.). Also, given that lay individuals may become lifestyle change coaches, none of the existing taxonomies may apply.

A single taxonomy with accompanying guidance to MDPP coaches would eliminate confusion in the NPI application process and facilitate tracking of coaches. The NPI application allows for a provider to indicate multiple taxonomy codes. Many DPP coaches may already have NPI numbers (for example, if they are a registered dietician who is also a DPP coach); we recommend that these individuals be advised to update their NPI with the additional taxonomy of "lifestyle change coach."

Payment Structure

The AMA greatly appreciates the modifications to the proposed payment model that were made by CMS in response to comments on its previous proposal, as well as the proposals regarding patient engagement. Nonetheless, the revised proposed payment model for the Medicare DPP continues to tie a large proportion of payments to "performance" of the MDPP supplier, which is linked to patient adherence in attending the sessions and health outcomes as measured by weight loss. The AMA urges CMS to give serious consideration to comments on this payment model that may be submitted by organizations with experience delivering the DPP to diverse patient populations. We remain concerned that adoption of a one-size-fits-all payment model with no risk stratification could potentially lead to DPP providers cherry-picking locations for service delivery based on the probability that the patient population will attend more sessions, be more adherent to the education and counseling they receive, and be more likely to lose

weight, while avoiding Medicare-Medicaid patients and others who might find DPP attendance and adherence more challenging.

Evidence shows that any weight loss is beneficial, so even patients who achieve less than five percent weight loss are still accruing savings to the Medicare program that will not be fully reflected in payments to the MDPP supplier. According to an analysis of CDC's own program outcomes data, only 35 percent achieved the minimum weight loss of 5 percent, while the average was 4 percent. The odds of meeting the weight loss goal of 5 percent was lower among African Americans and other race/ethnicity categories compared to white participants.[13] These individuals are at higher risk for the negative health outcomes associated with type 2 diabetes. We urge CMS to test mechanisms for making risk-adjusted payments. This will be especially important data for states as increasing numbers consider covering DPP in their Medicaid programs.

Virtual MDPP

The AMA strongly urges CMS to include online/virtual diabetes prevention programs in the expanded model. CMS and the CMS Actuary have the discretion to consider data either submitted or referenced in the comments to this rulemaking to make a final determination of improved patient health outcomes and/or cost neutrality or cost savings. The foregoing data exist to support expansion of the virtual programs in tandem with in-person programs. Furthermore, there is a tremendous population health need to expeditiously increase access to diabetes prevention programs and many individual Medicare beneficiaries will not be able to access the program without an online/virtual option because of a geographic mismatch between where many beneficiaries are located and the in-person programs. The AMA is concerned because the current access and availability of the in-person program is limited and non-existent in certain markets. The online/virtual option ensures that Medicare beneficiaries could take full advantage of the benefit.

The AMA notes that there are no extant statutory or regulatory prohibitions on CMS and the CMS Actuary considering data that is currently available that establishes improved patient health outcomes and cost savings associated with the online/virtual diabetes prevention program. While the online/virtual program was not part of the initial demonstration project, it is appropriate that CMS and the CMS Actuary consider data from the demonstration project as well as relevant data that establish the conditions under which there is a clinical benefit(s) to patient health outcomes as well as applicable cost neutrality or cost savings. Since the PFS for CY 2017 was released in July 2016, the CDC has gathered additional data from virtual providers who have pending status in the current DPRP. This data demonstrates similar efficacy to that of the in-person DPP providers on the CDC database. This is the same data source that CMS relied upon when making a determination that expansion of the in-person program is justified because of the improved patient health outcomes and overall efficacy. Second, the CMS Actuary is permitted to consider relevant cost and savings data and analysis when ascertaining whether the expanded scope and conditions of a program would result in cost savings or cost neutrality.

The AMA strongly urges the CMS Actuary to consider the following information that establishes cost savings or cost neutrality for virtual programs:

[13]Ely EK, Gruss SM, Luman ET, et al. A National Effort to Prevent Type 2 Diabetes: Participant-Level Evaluation of CDC's National Diabetes Prevention Program Diabetes Care. 2017;ePub ahead of print.

Source	Summary
Diabetes Prevention Programs: Effectiveness and Value Final Evidence Report and Meeting Summary July 25, 2016, Institute for Clinical and Economic Review	A Markov based model with a 10-year time horizon was used to compare Omada DPP participants with propensity score-matched community controls with prediabetes. The simulation found a breakeven point at three years, with a positive savings of $1,565 at five years. One limitation of this study is that it relied on 26 weeks of weight loss data from Omada participants, which required assumptions about longer-term weight loss. Smith *et al.* assessed the cost-effectiveness of the Canary Health Virtual Lifestyle Management (VLM) DPP using a Markov model with a 10-year time horizon. Costs and changes in weight came from a pre-post study of the VLM intervention, which estimated an incremental cost of $458 and incremental gain of approximately 0.06 quality average life year (QALYs) compared to usual care in a hypothetical cohort without diabetes. Estimated that the intervention would cost approximately $7,800 per QALY gained from a health system perspective. Using a $100,000 per QALY threshold, the intervention was found to be cost-effective in over 95% of model iterations in a probabilistic sensitivity analysis. However, it should be noted that these results are based on data from one study using a one-year before/after design in 50 patients, 14 of whom already had diabetes.
Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease. Chen F, Su W, Becker SH, Payne M, Castro Sweet CM, Peters AL, et al. (2016), *PLoS* ONE 11(10): e0163627.doi:10.1371/journal .pone.0163627	Participants in the digital IBC intervention, the Omada program, included 1,121 overweight or obese seniors with additional risk factors for diabetes or heart disease. Weight changes were objectively measured via participant use of a networked weight scale. Participants averaged 6.8% reduction in body weight within 26 weeks, and 89% of participants completed 9 or more of the 16 core phase lessons. We used a Markov-based microsimulation model to simulate the impact of weight loss on future health states and medical expenditures over 10 years. Cumulative per capita medical expenditure savings over 3, 5 and 10 years ranged from $1,720 to 1,770 (3 years), $3,840 to $4,240 (5 years) and $11,550 to $14,200 (10 years). The range reflects assumptions of weight re-gain similar to that seen in the DPP clinical trial (lower bound) or minimal weight re-gain aligned with age-adjusted national averages (upper bound). The estimated net economic benefit after IBC costs is $10,250 to $12,840 cumulative over 10 years. Simulation outcomes suggest reduced incidence of diabetes by 27±41% for participants with prediabetes, and stroke by approximately 15% over 5 years.

If CMS does not exercise its discretion to consider additional relevant data related to improved patient health outcomes and cost savings/cost neutrality, we support, in the alternative, CMS moving forward with a model demonstration to further confirm that virtual program participants reach the outcomes seen in the in-person model test. The AMA asks CMS to use the current available data when determining the model test duration as well as the enrollment targets. Any opportunity to expedite the model test would give patients access to this needed service as soon as possible. The AMA also strongly urges that CMS move quickly forward so that the demonstration will launch on the same date as the in-person program.

The AMA wants a shortened time frame for two reasons:

- A substantial body of evidence already supports that the virtual programs meet the outcomes required of in-person programs from the same data source (the CDC) that CMS relied upon when deciding an expansion of the in-person program.
- Participants have an option in markets with no DPP available.

The AMA is also concerned about MDPP providers who lose their vendor license (temporarily or permanently). The rule makes the assumption that there are multiple in-person programs available to beneficiaries. This assumption is not supported by the current list of programs. There are many areas of the country with only one in-person program in a wide geographic area. In the rule, if a participant's program loses their MDPP supplier status, the beneficiary can enroll in a different program. But in reality virtual could be the only other option. The AMA asks for clarification on what happens to a beneficiary if the program they are enrolled in loses recognition and the ability to bill Medicare for reimbursement.

One-Per-Lifetime Limitation

The AMA recommends that CMS add an exception to the one per lifetime provision for major life events such as the death of a spouse, surgery, or hospitalization. These are major life events that would disrupt participation according to the timeline required by the MDPP, but not prohibit someone from eventually completing or restarting the program. In other words, beneficiaries who are forced to drop out due to major life events could still be capable of successfully completing the program with the desired outcomes if allowed to re-enroll.

Participant Develops Diabetes

Patients with diabetes are not eligible to participate in the MDPP, however there have been instances in which some participants have progressed to type 2 diabetes during the program. CMS and CDC allow for these participants to remain in the program, but prohibit the MDPP from billing Medicare further. The AMA supports this provision, but if a MDPP supplier determines that a beneficiary has developed type 2 diabetes, the MDPP supplier should be required to document that they have instructed the beneficiary to consult a physician to confirm the diagnosis and to receive adequate and appropriate medical care.

I. Medicare Preventive Services

Diabetes Self-Management Training (DSMT)

The AMA shares CMS' concern that only about five percent of Medicare patients with newly diagnosed diabetes utilize DSMT services. DSMT services are an important educational resource for patients with diabetes who must manage this complicated disease. There are a number of barriers that impact the utilization of DSMT including confusion about how and when to make referrals, lack of access to and affordability of these services, including a lack of or poor reimbursement for DSMT. Potential solutions to overcome these barriers include:

- using hemoglobin A1c as an eligible criteria for diagnosing diabetes;
- allowing DSMT to be provided in additional clinical and non-clinical settings including the ability of hospital outpatient DSMT programs to be provided in local community settings;

- extending the availability of the initial 10 hours beyond the first year and covering additional hours of DSMT based on individual need
- eliminating the restrictions on who is eligible for individual DSMT; and
- expanding the list of providers eligible to refer for DSMT.

We strongly believe that clarifications and updates to the benefit are needed to help improve utilization rates. As CMS indicated in the 2017 final rule, we urge CMS to increase efforts to make the benefit more accessible to Medicare beneficiaries with diabetes and improve utilization of DSMT. The AMA looks forward to clarifications and would support further opportunities to provide feedback to CMS on this issue.

Colon Cancer Copayment

The AMA urges CMS to waive the coinsurance for colorectal screening tests, including therapeutic interventions required during the procedure. The AMA has continuously supported clinical preventive services and noted the benefits and cost-effectiveness of preventive procedures. We support health plan coverage for the full range of colorectal cancer screening tests, and believe waiving the coinsurance for patients is a cost-effective way to encourage patients to receive preventive screening tests.

Vaccines to Medicare Patients

The AMA urges CMS to cover tetanus and Tdap vaccines at both the Welcome to Medicare and Annual Wellness visits, as both vaccines are important to the Medicare population and recommended adult vaccines have been consistently underutilized by Medicare patients.[14] Typically, CMS only covers the tetanus vaccine when a patient experienced a cut or laceration. The AMA believes this would successfully expand access to the tetanus and Tdap vaccines within the context of current Medicare rules.

J. Emergency Medical Services

The AMA urges CMS to pay emergency medical service providers for the evaluation and transport of patients to the most appropriate site of care, rather than limit payment to the current CMS defined transport locations. The current list of limited transport locations may impede patient care. Instead, CMS expanded the list of eligible transport locations from the current three sites of care (nearest hospital, critical access hospital, or skilled-nursing facility) based on the onsite evaluation and transport of patients to the appropriate next site of care.

III. Request for Information on CMS Flexibilities and Efficiencies

The AMA applauds CMS' commitment to transforming the health care delivery system by focusing on patient-centered care and working with physicians to improve outcomes. The AMA believes that by reducing physicians' administrative burden, the health care delivery system will improve quality of care, decrease costs, and be more effective, simple and accessible.

[14] Tan, L. *Adult Vaccination: Now is the time to realize an unfulfilled potential.* Hum Vaccin Immunother. 2015 Sep; 11(9): 2158–2166. Published online 2015 Jun 19. Available at 10.4161/21645515.2014.982998.

The increasing amount of administrative responsibility forced upon physicians adds unnecessary costs not only to physicians and Medicare program but also to patients. 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**.[15] 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.

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.

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.

Prior Authorization and Utilization Management

According to a recent AMA survey of 1,000 practicing physicians, a medical practice completes an average of 37 prior authorization (PA) requirements weekly per physician, taking a physician and their staff an average of 16 hours, or the equivalent of two business days, to process. In response to this waste of resources and the resulting delays in care, the AMA and more than 100 other organizations representing physicians, hospitals, pharmacists, medical groups, and patients have endorsed 21 Prior Authorization and Utilization Management Reform Principles that are intended to serve as best practices and reasonable reforms for utilization management (UM) programs. The AMA urges all entities engaged in UM—including CMS—to follow these principles.

One critical area addressed in the principles is PA process automation to improve efficiency and reduce costs for providers and payers by requiring payers to adopt the HIPAA-mandated transaction for medical services PA (X12 278) and the National Council for Prescription Drug Programs' (NCPDP) standard electronic transactions for pharmacy PA. Beyond the need for automation, UM requirements are overused and bluntly applied to all physicians, regardless of adherence to evidence-based guidelines. PA requirements now cover a wide range of services, including imaging, psychiatric hospital admissions, inpatient versus outpatient status and various surgical conditions. Rules may vary depending on whether the service is being provided on an inpatient versus an outpatient basis. Increasingly, tools intended as flexible guidelines instead are used as arbitrary standards, leading to denials for appropriate use. The problems are particularly pervasive in prescription drug coverage where physicians may be forced to rewrite prescriptions just to achieve a small, temporary discount from a particular company or to take advantage of a short-term strength-related discount on the same drug the patient is already taking at a different strength. Patients' confusion over changes in their medications' appearance and directions can lead to significant and sometimes life-threatening clinical outcomes.

[15] 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.

Recommendations:

- CMS should require Part D plans to accept and respond to pharmacy PA and step therapy over-ride requests through the NCPDP electronic PA transactions;
- CMS should accelerate automation of medical services PA by (a) issuing a rule for an electronic clinical attachment standard and (b) enforcing health plan compliance with the X12 278;
- 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 Medicare Advantage (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 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;
- 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.

Certification and Documentation

Eliminating and streamlining reporting, monitoring, and documentation requirements will improve the healthcare 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.

Physicians are also expected to keep other providers honest by certifying and recertifying the need for virtually any other service the patient requires—from power wheel chairs, to repeat orders of glucose strips, colostomy bags for patients with chronic ongoing conditions, to physical therapy plans, to home health and hospice services. All durable medical equipment (DME) and home health orders must be signed by hand by the physician and no stamps are allowed. All DME prescriptions require an in-person visit within a prescribed period of time for certification (even if it is for replacement of stolen or broken equipment). The task is further complicated when, for example, every home health agency uses a different form to confirm the physician's involvement and new paperwork is required every time a patient switches to a new glucose monitoring system requiring different strips than the prior one.

Health care providers need a more targeted approach that focuses on providers and suppliers who are repeat offenders, who could be identified through Medicare claims analysis rather than imposing volumes of certificates signed by physicians. We need to standardize forms and eliminate the requirements for physicians to recertify patient conditions every year when it is a permanent chronic condition, non-acute. Authorization for supplies should be generic so that physicians are not required to fill out a new form every time a patient switches brands.

Recommendation:

- CMS should create a stakeholder workgroup to address CMS' program integrity needs while simplifying the bureaucratic requirements.

Appropriate Use Criteria (AUC)

As discussed previously, Protecting Access to Medicare Act (PAMA) enacted a new mandate which would require physicians ordering diagnostic imaging services to consult appropriateness use criteria in order for the physician who provides the imaging to be paid. Ordering physicians do not have to follow the criteria but after three years, so-called "outliers" who diverge from the criteria most often will be subject to preauthorization when ordering these services. This was supposed to begin in 2017 but due to complexity and necessity to build a complicated new infrastructure, CMS delayed the start date to January 1, 2018 and has now proposed a start date of January 1, 2019 with an educational and operations testing period. While AMA appreciates these efforts, we believe that neither CMS nor physicians have the bandwidth to implement both AUC and MACRA at the same time. For example, CMS identified eight clinical areas that would be used to identify outlier physicians and that must be included in all approved clinical decision support mechanisms. We think that this is too big a first-year burden—especially for primary care physicians and that it is unnecessary to require Clinical Decision Support Mechanisms (CDSMs) used by specialties to include criteria for services the specialty rarely or never orders. We also think that the requirements for what must be documented in the CDSM are extremely complex and will exacerbate the existing problems physicians are having with EHRs.

Recommendations:

- CMS should delay the start date at least until CMS can adequately address technical and workflow challenges with its implementation;
- CMS should add an additional year to the educational and operational testing period;
- CMS should reduce, simplify and phase-in requirements; and
- CMS should expand use of hardship exemptions as the AUC requirement is implemented.

Clarify Data Entry Requirements

Medicare rules allow physicians to delegate entering in certain data elements of a patient record to ancillary staff, which allows the physician to focus on providing patient care. The physician still signs off on the entire record to ensure its accuracy but is not burdened with keying in specific elements of the record. It is not clear if all the data entry can be delegated to ancillary staff. Specifically, Medicare rules do not explicitly indicate if physicians can delegate data entry for the History of Present Illness or Chief Complaint. Several Medicare Administrative Contractors currently interpret CMS regulations to prohibit the physician from delegating data entry for these elements.

Recommendation:

- CMS should clarify that such information may be recorded in the medical record by non-physician staff.

Increase Transparency Around Electronic Health Record (EHR) Costs

Physicians have already made significant investments in their EHRs, yet vendors often require additional, yearly fees to connect those EHRs to registries, information exchanges, and public health agencies. The Office of the National Coordinator for Health Information Technology (ONC) already requires vendors to state that extra charges may be required; however, the dollar figures are not made public. Most EHR vendors overly generalize costs and are not upfront with physicians when selling their products. This drastically affects small and solo physician offices. These fees are often both a surprise and overly excessive—acting as a roadblock to the exchange of vital patient data while limiting the interoperability between EHRs.

Recommendations:

- CMS should work with ONC to require vendors seeking certification to publicly provide detailed examples of fees (including dollar figures) typically charged to physicians to enable EHR features and functions required for physician participation in federal reporting programs, i.e. Meaningful Use (MU) and Advancing Care Information (ACI); and
- CMS must also consider the physician impact of these fees (e.g. small and rural practices) when developing future MU and ACI measures.

Prohibit Vendor Data Blocking

While CMS' implementation of MACRA requires physicians to attest to a multipart attestation on data blocking, vendors currently do not face any limits on data-blocking activities. In the vast majority of cases, the vendors implement cost, technical, or contractual limitations to block the flow of patient data.

Recommendation:

- CMS should work with ONC to implement a vendor data-blocking attestation requirement as part of all current and future health information technology certification editions.

Prioritize ONC's Efforts Around Interoperability Use Cases

Interoperability across EHRs, mobile devices, registries and patient-specific health IT products is a top priority for physicians. Current product development efforts, based on federal regulations, have resulted in health IT accommodating measurement and reporting, rather than enabling the free flow of data. Today, accessing and moving data comes at a major cost for physicians and disrupts patient care. We need a health IT environment that is focused on and responds to the needs of physicians, patients, and researchers. This will require the administration to convene clinical experts, technology vendors, standards developers, and other stakeholders to identify barriers and find solutions.

Recommendations:

- CMS should work with ONC to:
    - Leverage priority use cases outlined in the 21st Century Cures Act and convene stakeholders to assess the common needs of physicians, patients, and researchers;
    - Provide a detailed summary of findings to the Health Information Technology Advisory Committee as a starting point for use case prioritization;
    - Prioritize technical (syntax), semantic (machine usable), and process (human usable) interoperability;
    - Ensure interoperability solutions are scalable and can be replicated with minimal cost, time, and effort; and
    - Broaden future MU and ACI measures to support health outcomes and patient goals, rather than the current prescriptive measure approach.

Refocus ONC's Certification Program

Currently ONC certifies that EHRs are able to meet a low-bar of requirements directly attached to CMS' reporting program. In order to further the interoperability goals outlined above, ONC needs to improve its certification program.

Recommendations:

- CMS should work with ONC to refocus its certification program to test and validate an EHR's ability to conform to interoperable standards, features, functions, and capabilities that reflect the real-world needs of patient care; and
- CMS should refrain from any MU or ACI objectives that solely measure the process physicians take when using EHRs in patient care. CMS should coordinate with ONC on limiting "measure calculation" in the MU and ACI programs.

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 FDA have called for including part of the UDI in the next claims form template update—slated for 2021. However, new certification requirements that will allow EHRs to capture and transmit the full UDI will be implemented throughout 2018. 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 as a whole, 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 PI 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 device identifier 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 electronic health records could gather this UDI data from the EHRs in the aggregate to support comparative studies and post market surveillance.

Interpretation and Translation Services

Physicians are required to provide translators for Medicare and Medicaid patients with hearing impairments or limited English proficiency. These accommodations amount to an unfunded mandate that the AMA has long opposed as an unfair burden imposed upon physicians, especially those who are operating small businesses.

For example, qualified interpreters for those with hearing impairments can cost up to $150 per hour, with a one- or two-hour minimum, plus transportation costs. The practice may also incur a fee if the patient cancels without sufficient advance notice. We believe these costs should be taken into account as part of the cost of delivering care and should be fully reimbursed by the patient's health insurance plan.

Physicians report that individuals with limited English proficiency often bring trusted adults with them to an appointment to facilitate communication. However, the Office of Civil Rights states that a physician may rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication only if reliance on that adult for such assistance is "appropriate under the circumstances." This standard remains unclear to physicians, causing them to take on the additional burden and expense of interpreters out of an abundance of caution when it may not be always necessary to do so.

Recommendation:

- CMS should work with the Office of Civil Rights to clarify the circumstances under which an adult accompanying an individual with limited English proficiency may interpret or facilitate communication.

Clinical Testing Access and Pricing

As discussed in our comments on the 2018 fee schedule proposals, PAMA established a new method for calculating rates for clinical testing services paid on the Medicare CLFS. Congress provided that PAMA would establish rates based on private payer payments. Certain laboratories, including physician office-based labs, are required to report private payer payment data on tests performed for their patients so CMS is able to calculate rates. Data collected will be used by CMS to re-price tests on the CLFS, with new rates scheduled to take effect on January 1, 2018. Due to problematic implementation, including the decision by CMS to implement a retrospective data collection period, reporting accurate private payer payment data has proven to be exceptionally difficult and, in some cases, impossible. There is widespread concern that the data collected is incomplete and inaccurate despite the expenditure of substantial resources by many laboratories that were required to report. In addition, CMS has not identified for stakeholders how they can validate that the final calculation reflects the combined data without error.

Recommendations:

- CMS publish preliminary information concerning the number of clinical laboratories that have reported based on market segment and geographic locations;
- CMS publish proposed Medicare clinical laboratory fee schedule rates for CY 2018 in early September 2017 as the Agency indicated it would do in order to provide physicians and patients time to prepare for any potential disruptions to care delivery resulting from potential significant cuts; and
- CMS issue an interim final rule to modify existing regulation and:

    - provide that CMS will conduct market segment surveys (reference laboratories, physician office–based laboratories, independent laboratories, and hospital community laboratories) **to validate and adjust** the final amount calculated based on the data collection to ensure congressional intent achieved that payments reflect private market payments; and
    - allow pricing to proceed as planned on January 1, 2018, based on data collection and submission under existing rule for sole source clinical tests since the data submissions are reasonably expected to be accurate given the limited test menus, the final amount calculated easily validated by the sole source clinical laboratory.

Social Security Number Removal Initiative (SSNRI)

The Medicare Access and CHIP Reauthorization Act (MACRA) included a provision requiring CMS to remove the Social Security Number (SSN) from Medicare cards due to concerns of identity theft–the Social Security Number Removal Initiative (SSNRI). The new identification cards (ID) will be sent out in phases over a 12-month period beginning April 1, 2018. While we understand the importance of protecting Medicare beneficiaries from identity theft by replacing SSNs with new Medicare Beneficiary Identifier (MBI) on Medicare ID cards, we have had concerns about the size and characteristics of this vulnerable population and the need for CMS to handle this change efficiently and effectively. We appreciate CMS' recent decision to address our earlier concerns about insufficient outreach and the lack of a look-up database to make it possible for providers to find or confirm a beneficiary's MBI after the transition period ends.

The AMA is concerned, however, that health IT vendors are not focused on making the upgrades necessary to help practices prepare for this transition; rather, the end of the SSNRI transition period is viewed as the deadline for such upgrades to occur. We believe these upgrades must occur at the beginning of the transition period to enable physicians' systems to maintain both the MBI and health insurance claim number (HICN) for an indefinite amount of time (for example, if a physician practice is audited, it may need to be able to identify a patient based not only on MBI, but also the HICN). Failure for this capability to be in place at the start of the transition may require practices to maintain two separate beneficiary identification systems, creating a tremendous burden on the practice's human and financial resources.

Recommendations:

- CMS should work with the AMA and other stakeholders, including health information technology (IT) vendors to:

- Implement its newly-announced MBI look-up database;
- Consider whether health IT vendors will have upgrades available to their customers' systems at the start of the transition period;
- Evaluate the capacity of Medicare's systems to simultaneously accept both the HICN and MBI and ensure the appropriate workflow associated with each identifier; and
- Effectively message information about the SSNRI to beneficiaries and providers.

In-office Drug Compounding

In an attempt to crackdown on unsafe drug compounding practices, the FDA has proposed new standards for compounding facilities that may severely limit the ability of physician to prepare sterile drugs for administration to patients in office settings. In its draft guidance "Insanitary Conditions for Compounding Facilities," FDA has included physician offices that "compound" sterile drug products in the definition of a compounding facility. The guidance lays out a number of requirements that compounding facilities must meet in order to be considered "sanitary." Failure to meet these requirements could lead to FDA action for compounding in insanitary conditions. Those requirements include onerous equipment requirements, essentially requiring that all sterile preparations take place in an ISO Class 5 cleanroom. We have significant concerns about both the inclusion of physician offices in this guidance and the continued inclusion of in-office preparation of sterile drug products by a physician for administration to patients in the definition of compounding. We also have concerns about the impact on patients and their access to necessary drugs. These types of activities are considered the practice of medicine and are not pharmacy compounding activities under the purview of FDA.

Recommendation:

- CMS should work with the FDA to exempt physician preparation of sterile drug products for administration to patients in an office-setting from its definition of compounding so that this draft guidance is not applicable to those activities, and/or remove the reference to "physicians' offices" from its draft guidance "Insanitary Conditions for Compounding Facilities."

Medicare Advantage (MA) 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 and compliance. 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. 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; and
- Denominators of quality measures should be appropriately defined to ensure patients for whom the treatment may not be appropriate are excluded from measurement.

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 are 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 (i.e., 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

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 physicians. The Medicare Payment Advisory Commission voted unanimously on a draft 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 and instead rely on physicians' clinical judgment to determine a patient's inpatient/outpatient status.

Skilled-Nursing Facility Three Day Stay Requirement

Currently under Medicare, beneficiaries are eligible for Medicare covered skilled-nursing facility services when a beneficiary has an inpatient hospital stay of three consecutive days or more, starting with the day the hospital admits the beneficiary as an inpatient, but not including the day the beneficiary leaves the hospital. Patients who do not meet the three-day stay requirement, but need skilled-nursing facility care can face a coverage gap when they are most vulnerable.

Recommendation:

- CMS should count time spent in a hospital as an outpatient toward the three-day stay requirement for Medicare coverage of skilled-nursing facility services.

Lack of HIPAA Mandate for CPT Guidelines

The current lack of HIPAA mandate for the CPT Guidelines causes administrative burden because payers are able to issue their own instructions that may not conform to the CPT Guidelines. The CPT code set includes CPT Guidelines that are developed through the same rigorous, open process at the time the CPT codes are developed. The CPT code set was adopted under HIPAA as a standard in the 2000 Transactions and Code Sets Final Rule, but the CPT Guidelines were specifically left out, which impedes the standardization intended by the regulation.

Mandating the CPT Guidelines under HIPAA would bring efficiencies through less administrative errors and less time determining correct coding, which will lower costs. In 2010, the Colorado Clean Claims Task Force was started to standardize CPT claim edits across payers and address the broader burdens of claim edits, of which the use of standardized CPT Guidelines was a component. Colorado estimated at that time that standardizing the broader CPT claim edits could save the state over $80 million a year.[16]

Recommendation:

- The AMA strongly recommends that the CPT Guidelines be adopted under HIPAA with the CPT code set. The AMA would be happy to work with the Department to further explain the issues and assist in developing a strategy to adopt the CPT Guidelines under HIPAA and eliminate this costly burden on the industry.

Open Payments Reporting of Peer Reviewed Scientific Medical Information

The Sunshine Act was designed to promote transparency with regard to payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined twelve specific exclusions from the reporting requirement, including educational

[16] Colorado Medical Society, *Clean Claims Task Force* (May 1, 2014), http://www.cms.org/communications/clean-claims-task-force3.

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.

Recommendation:

- 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.

Program Integrity

CMS also requested information on reducing unnecessary burdens by improving program integrity. The AMA is firmly committed to eliminating fraud and abuse from health care. While Congress, federal agencies, and states have made unprecedented investments in improving program integrity, significant challenges remain. Efforts to fight health care fraud or to identify areas of waste or abuse have a tangible impact on physician practices. To comply with the federal program integrity requirements, physicians proactively conduct internal audits and adopt compliance programs at their own cost.

Broad brush requirements that impose burdens on physicians, rather than focusing on those providers who have demonstrated a propensity to commit fraud or abuse, inequitably affect physicians and providers who are good actors, and result in unnecessary costs to the health care system. This fact is especially true in pre- and post-payment review. The regulatory burden placed on physicians is a major component of physician burnout. Physicians can spend too much of their time on administrative tasks rather than providing care to patients. The evolving health care system needs easier enrollment, more rational program integrity rules and, overall, fewer reporting requirements.

AMA recommends that CMS work with both public and private stakeholders, including the AMA, to determine and discuss how to develop a framework that properly balances eliminating fraud and abuse while not negatively impacting honest providers with burdensome and unnecessary requirements.

Contractor Transparency and Oversight

CMS should demonstrate operational flexibility by eliminating or streamlining the audits and reviews by pre- and post-payment contractors. Physicians are facing an increasing amount of pre-payment and post-payment scrutiny from a variety of government entities and contractors including CMS, Medicare Administrative Contractors *(*MAC), Recovery Audit Contractors (RAC), Unified Program Integrity Contractors (UPIC) (combining program safeguard, zone program integrity, and Medicaid integrity contractors), Quality Improvement Organizations (QIO), Comprehensive Error Rate Testing (CERT), and Supplemental Medical Review Contractors (SMRC). 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. Furthermore, some contractors are auditing and attempting to recoup against services that Medicare does not require 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. The AMA recommends that CMS:

- 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;
- Work with U.S. Department of Health and Human Services (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;
- Contractors face a financial penalty when denials are overturned on appeal; and
- Replace financial penalties with corrective action plans.

While CMS needs to streamline the amount and type of all reviewers, focusing on 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 2015, **70 percent of Medicare RAC Part B determinations appealed were decided in the provider's favor**.[17] This is an unacceptable rate and cannot continue.

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;
- Require RACs to reimburse for medical records (hospitals are now partially reimbursed for medical records; physicians are not); and
- Ensure that RAC audits are reviewed by a practicing physician of the same specialty or subspecialty and in the same jurisdiction.

Data Analytics

The federal health care programs and law enforcement are moving to a fraud prevention model that utilizes data analytics to identify aberrant claims in real time, and cross references such claims with other data sets to recognize fraudulent or abusive activity. This focused, streamlined approach—if clinically-informed and carefully developed—has the potential to prevent funds from being fraudulently misappropriated from the health care system.

Importantly, data analytic systems also have the potential to decrease the administrative burden that has traditionally accompanied the "pay and chase" model. The concept involves identifying and preventing fraud and abuse on the front end, then post-payment activities, which have historically inequitably impacted many non-fraudulent physicians and other providers, may be minimized. For example, CMS recently announced that it plans to expand its Targeted Probe and Educate program to all MAC jurisdictions. The AMA believes this announcement is a step in the right direction. We look forward to working with CMS as it moves forward to implement this program to ensure that it is done in a thoughtful manner.

Implicit in the success of data analytics in fraud identification is the ongoing clinical input of physicians. Such expertise is required to enable data analytic systems to operate properly and reach a zero false positive rate. Medical claims data analysis requires complex clinical knowledge. Thus, the review and analysis of such claims necessitates the clinical lens of physician education and training.

[17] CMS, *Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2015*, p.18, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY2015-Medicare-FFS-RAC-Report-to-Congress.pdf.

By using data analytics, CMS can improve feedback to and training for providers, thereby improving the accuracy and validity of reporting. Furthermore, data analytics can accurately identify poor performers to target for outreach and assess future performance.

The AMA recommends that CMS:

- Formalize a process for ongoing, independent clinical review of its data analytics system;
- When conducting oversight activities, identify providers with questionable patterns of claims and prioritize providers that most warrant further review;
- Avoid using automatic threshold-based criteria in determining when and whom to review; and
- Use previous experiences with fraudulent providers to create and continuously improve models to prevent future misconduct.

Loosen Stark and Anti-kickback Restrictions

Physicians are barred from participating in innovative and cost-saving care models due to outdated regulations, including Anti-Kickback and complicated Stark prohibitions. These models may require the use of EHR software and technology in order to be viable and effective. While safe harbors exist in this area, they are temporary and limited in scope. In addition, physicians are inadvertently subjected to large fines or penalties for Stark technical violations (e.g., missing or out-of-date paperwork).

Recommendations:

- Create new exceptions or safe harbors for Stark and Anti-kickback to facilitate coordinated care and promote cost reductions including extending existing waivers from the Medicare Shared Savings Program's ACOs to other individuals and entities implementing alternative payment models outside this program;
- HHS should amend and revise the definition of "fair market value" to account for new payment models that are based on value and outcomes rather than productivity (e.g., allowing incentive payments for efficient and better care rather than on the number of hours or RVUs worked);
- Make permanent the existing safe harbors for EHR software and technologies and should broaden the definition of "electronic health record" beyond clinical diagnosis and treatment. The definition should include such things like information sharing and cybersecurity and allow for flexibility as technology evolves; and
- HHS should also focus more on educating physicians on technical violations (and work with the U.S. Department of Justice and the Office of Inspector General so that technical violations are not subject to any Stark penalty).

The AMA is committed to engaging with CMS and other stakeholders going forward to identify and inform focused and efficient program integrity measures. Clinically-developed data analytics systems, streamlined and integrated audits, increased contractor oversight, a greater emphasis on physician education, and additional recommendations discussed above can produce cost-efficient results that decrease physician burden, increase savings, and let physicians focus on providing patient-centered care.

IV. CONCLUSION

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.

ATTACHMENT B

Non-covered or Bundled Medicare Services Without Published Values in the CY 2018 MPRS Proposed Rule

CPT Code	Modi-fier	Description	RUC Meeting Date	RUC Recommended Work RVU	Medicare Status Code	Work RVU (CMS RVU File)
37216		Transcath stent cca w/o eps	Apr04	17.98	N	0.00
44705		Prepare fecal microbiota	Apr12	1.42	I	0.00
54440		Repair of penis	Nov93	11.84	C	0.00
62380		Ndsc dcmprn 1 ntrspc lumbar	Jan16	10.47	C	0.00
65757		Prep corneal endo allograft	Apr08	1.44	C	0.00
77061		Breast tomosynthesis uni	Apr14	0.70	I	0.00
77062		Breast tomosynthesis bi	Apr14	0.90	I	0.00
77387		Guidance for radiaj tx dlvr	Jan14	0.58	I	0.00
90863		Pharmacologic mgmt w/psytx	Apr13	0.48	I	0.00
90867		Tcranial magn stim tx plan	Feb11	3.52	C	0.00
90868		Tcranial magn stim tx deli	Feb11	0.48	C	0.00
90869		Tcran magn stim redetemine	Feb11	3.20	C	0.00
92558		Evoked auditory test qual	Apr11	0.17	X	0.00
92921		Prq cardiac angio addl art	Jan12	4.00	B	0.00
92925		Prq card angio/athrect addl	Jan12	5.00	B	0.00
92929		Prq card stent w/angio addl	Jan12	4.44	B	0.00
92934		Prq card stent/ath/angio	Jan12	5.50	B	0.00
92938		Prq revasc byp graft addl	Jan12	6.00	B	0.00
92944		Prq card revasc chronic addl	Jan12	6.00	B	0.00
95941		Ionm remote/>1 pt or per hr	Jan12	2.00	I	0.00
97602		Wound(s) care non-selective	Feb01	0.32	B	0.00
97607		Neg press wnd tx </=50 sq cm	Jan14	0.41	C	0.00
97608		Neg press wound tx >50 cm	Jan14	0.46	C	0.00
99446		Interprof phone/online 5-10	Oct12	0.35	B	0.00

99447		Interprof phone/online 11-20	Oct12	0.70	B	0.00
99448		Interprof phone/online 21-30	Oct12	1.05	B	0.00
99449		Interprof phone/online 31/>	Oct12	1.40	B	0.00