



September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: 2022 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule

Submitted via *Federal eRulemaking Portal* at www.regulations.gov

Dear Administrator Brooks-LaSure:

On behalf of the Texas Medical Association's (TMA's) more than 55,000 physician and medical student members, I write with comments on the 2022 Medicare Physician Fee Schedule and Quality Payment Program [proposed rule](#) as published by the Centers for Medicare & Medicaid Services (CMS) in the July 23, 2021, *Federal Register*.

TMA is the largest state medical society in the nation and is committed to improving the health of all Texans. TMA charters 110 county medical societies. It is the mission of TMA to stand up for Texas physicians by providing distinctive solutions to the challenges they encounter in the care of patients.

Of grave concern to Texas physicians is that the proposed rule estimates the 2022 conversion factor to be \$33.5848, a 3.75% decrease from the 2021 conversion factor. The reduced conversion factor is exacerbated by already low Medicare payment for physician services. Taken along with the imminent payment cuts from the Medicare sequester and the Statutory Pay-As-You-Go Act, this cut will be financially disastrous for physician practices. TMA will call on Congress to immediately address the forecasted cut before the end of the year. Otherwise, patients may experience a reduced ability to access care as physicians are unable to sustain their practices. **CMS should work with Congress to recognize the need for critical reforms to the Medicare Physician Fee Schedule system, including addressing the budget neutrality requirement, which can lead to arbitrary reductions in payment unrelated to the increasing cost of providing care.**

Specific to the Merit-Based Incentive Payment System (MIPS), we are also concerned with the proposed changes that will create additional complexity and confusion for physicians and patients. As discussed in our detailed comments, and especially in the context of the current and ongoing public health emergency (PHE), CMS must strive to maintain existing policies to the greatest extent possible. Annual proposed changes to MIPS contribute greatly to physician regulatory compliance challenges, leading to physician burnout. **TMA pleads with the agency to tweak MIPS requirements only as needed or when doing so significantly reduces burdens physicians bore navigating the MIPS program.**

Attached to this cover letter TMA offers our detailed comments, recommendations, and suggestions to improve the Medicare program. In summary, TMA:

- Fully supports Relative Value Scale Update Committee (RUC) recommendations to value and describe Current Procedure Terminology® (CPT®) codes and calls on CMS to fully adopt all RUC recommendations.
- Asks the agency to institute a four-year transition for new practice expense RVU wage data and to update the data more frequently to avoid disruptive impacts to the fee schedule.
- Fully agrees with CMS' proposal to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of 2023.
- Believes a physician-led and collaborative team-based approach is optimal for patient care delivery and overall health care outcomes, especially when using telehealth.
- Recommends that CMS and Congress consider paying physicians appropriately for time spent caring for patients regardless of delivery type.
- Calls on CMS to implement and pay for CPT code 99072 regarding PHE-related costs.
- Especially appreciates CMS leaving incident-to policies intact in the context of evaluation and management (E&M) split billing.
- Recommends that CMS apply the office visit E&M increases uniformly across all services and specialties and not hold specific specialties to a different standard from others.
- Urges the agency to acknowledge that scope of practice is defined by state law, not by CMS.
- Strongly supports the proposal to delay enforcement of the Appropriate Use Criteria program by at least one year until the latter of Jan. 1, 2023, or the Jan. 1 that follows the end of the public health emergency.
- Supports the proposal to freeze the quality performance standard at the 30th percentile of MIPS quality performance category scores for an additional year for the Medicare Shared Savings Program.
- Supports revisions to the vaccine exemption in the physician self-referral regulations but suggests the proposed changes to the indirect compensation arrangement definition be narrowed.
- Fully supports the proposal to postpone electronic prescribing of controlled substances compliance by another year to Jan. 1, 2023, and emphatically asks CMS not to impose penalties for noncompliance.

Regarding the proposed changes to the Quality Payment Program, in summary, TMA:

- Urges CMS to not add to the burden of MIPS requirements and pleads with the agency to tweak requirements only as needed.
- Calls on CMS to aggressively focus on the development of voluntary, physician-led alternative payment models instead of pursuing MIPS Value Pathways.
- Implores CMS to maintain the quality performance category weight at 40% of a MIPS score, especially in the context of a public health emergency.
- Opposes the cost category weight being increased to 30% and urges CMS to delay increases to it until the end of the PHE. Instead, CMS should maintain the quality performance category weight at 40% of a MIPS score.
- Cautions CMS that the cost category is administratively burdensome to many physicians, and building further complexities into this category exacerbates the burden.
- Urges CMS not to penalize physicians who report on a suspended improvement activity and asks CMS to modify and remove improvement activities only when absolutely necessary.
- Supports and appreciates CMS' proposal to maintain the Query of PDMP measure as optional and worth 10 bonus points in the MIPS promoting interoperability category.
- Strongly opposes CMS' proposal that physicians be required to make patient health information available indefinitely starting with encounters on or after Jan. 1, 2016, since the tools to do so are unavailable and the proposed requirement is absolutely premature. Instead, TMA strongly encourages CMS to fully align with 21st Century Cures Act date and data requirements.

- Recommends that CMS make the SAFER Guides attestation an optional bonus measure for conducting an annual self-assessment of the high-priority practices listed in Office of the National Coordinator for Health Information Technology's Safety Assurance Factors for EHR Resilience (SAFER) Guides.
- Fully supports and thanks CMS for the proposal not to require small practices to submit a hardship application for exemption from promoting interoperability.

Thank you for the opportunity to comment. TMA stands ready to provide you and others within the agency with our policy expertise and any additional assistance you may find useful. If you have any questions, please do not hesitate to contact Robert Bennett, TMA vice president of medical economics, at Robert.Bennett@texmed.org.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Linda Villarreal". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

E. Linda Villarreal, MD
President
Texas Medical Association

Attachment

COMMENTS OF THE TEXAS MEDICAL ASSOCIATION

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post Payment Medical Review Requirements.

Practice Expense Relative Value Units

Summary

The Centers for Medicare & Medicaid Services (CMS) proposes to implement 76% of the AMA/Specialty Society RVS Update Committee (RUC) recommendations related to the physician work of performing services articulated by new and revised Current Procedure Terminology® (CPT®) 2022 codes.

The agency discusses how, in 2022, CMS will implement new wage data from the U.S. Bureau of Labor Statistics to update clinical labor costs and requests feedback on whether to fully implement the proposal or institute a four-year transition.

TMA Response

TMA fully supports RUC recommendations to value and describe CPT codes. Thus we call on CMS to fully adopt all RUC recommendations. **Since the new wage data significantly impact the fee schedule, TMA asks the agency to institute a four-year transition for changes to be realized gradually.** We also call on CMS to update these data more frequently so as not to lead to such dramatic changes.

Telehealth and Other Services Involving Communications Technology

Summary of Retention of Category 3 Services Through the End of 2023

CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of 2023. This allows CMS more time to collect information regarding utilization of these services during the pandemic. It also provides stakeholders the opportunity to develop support for the permanent addition of appropriate services to the list of approved telehealth services.

TMA Response

Since the public health emergency (PHE), TMA has seen rapid adoption of telehealth, and patients continue to find value in the added service when the condition is appropriate for this delivery type. TMA appreciates that CMS continues to offer telehealth flexibilities, especially as the COVID-19 delta variant continues to put all patients at risk, even those vaccinated. **TMA fully agrees with CMS' proposal to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of 2023.**

TMA recommends that CMS follow the recommendations of the national physician specialty societies representing physicians in the various specialties reflected by those services listed in Table 11, "Services Added to the Medicare Telehealth Services List for the Duration of the PHE for COVID-19 but Were not Added to the Medicare Telehealth Services List on a Category 3 Basis."

Summary of Implementation of Provisions of the Consolidated Appropriations Act of 2021

CMS proposes to amend its regulation to define "interactive telecommunications system" to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health and substance-use disorders furnished to established patients when the originating site is the patient's home. CMS is further proposing to adopt a similar, ongoing requirement that an in-person item or service must be furnished within six months of such a mental health telehealth service.

TMA Response

TMA agrees with the requirement that an in-person visit must take place within six months prior to the first time an audio visit is furnished for substance-use disorder and mental health counseling. If the visits are for counseling only, the in-person requirement may not be needed, but if medications are prescribed, an in-person visit is appropriate.

TMA urges CMS to consider expansion of audio-only visits to patients without mental health and substance-use disorders. For audio-only visits, CMS should seek public input for new, permanent, separately payable services – beyond the existing and low-paying check-in services – that can be provided appropriately through that technology and in a manner consistent with other applicable state and federal law. These new services would significantly impact rural and underserved populations as well as complex and chronically ill patients who do not have access to two-way audio-visual technology.

Regarding whether the required in-person, nontelehealth visit could be furnished by another physician of the same specialty and within the same group as the physician who furnishes the telehealth service, TMA believes it is appropriate. Further, TMA concurs with CMS that the patient may virtually see other physicians in the group who are covering for each other or if the first physician is unavailable or has left the group.

Summary of Expiration of PHE Flexibilities for Direct Supervision Requirements

During the public health emergency, CMS allowed the requirement for direct supervision to be met for diagnostic tests, physicians' services, and some hospital outpatient services through the use of virtual presence using real-time audio-video technology, instead of requiring a physician's physical presence. CMS seeks comment on whether this policy should be extended beyond the PHE, and, if so, whether it should be extended for only a subset of services and whether these services should require a service level modifier.

TMA Response

TMA believes direct supervision should revert to the pre-PHE standards that require a supervising physician's physical presence. **TMA believes a physician-led and collaborative team-based approach is optimal for patient care delivery and overall health care outcomes, especially when using telehealth.**

Summary of Payment Parity

CMS did not propose payment parity for services provided via telehealth with services provided in person.

TMA Response

TMA believes CMS and Congress should consider paying physicians appropriately for time spent caring for patients regardless of delivery type. The public health emergency widely opened the doors to telehealth, and patients and physicians alike quickly adapted. Patients will now expect telemedicine visits when they're appropriate. In fact, telemedicine really is about convenience for the patient more so than the physician.

Physicians must have the flexibility to decide whether to see their patients via telehealth or in person without unnecessary and disconnected pricing incentives. Physician payment is determined using the [resource-based relative value scale](#), which aligns payments based on the cost and resources used to provide services using three factors: (1) physician work (54%), (2) practice expense (41%), and (3) medical liability (5%). A recent RAND [study](#) lists five practice expense categories for care delivery and some components within each one.

Staffing	Clinical services supplies and equipment	Office space	Office Supplies and services	Professional Services
<ul style="list-style-type: none"> • Nonphysician clinical staff • Nonclinical support staff • Other labor 	<ul style="list-style-type: none"> • Clinical and clinical support services • Disposable supplies and drugs • Acquisition, operating, and depreciation costs of equipment 	<ul style="list-style-type: none"> • Rent/lease • Building services and maintenance • Utilities • Repairs 	<ul style="list-style-type: none"> • IT-related supplies, equipment, and services • EHR costs • Appliances and furniture • Non-IT office supplies 	<ul style="list-style-type: none"> • Billing services from third party • Accounting, management, and consultant fees • Professional memberships • Certifications

For continuity of care and thus better health outcomes, patients should be encouraged to seek telemedicine visits from their own physician. Augmenting a physician's practice with telemedicine incurs additional expenses different from those of delivering only in-person care. Clinical staff in the physician's practice still have integral roles in telemedicine visits by gathering the history of present illness and other visit-related information. Plus, offering telemedicine adds these expenses to a brick-and-mortar practice:

- Telemedicine software and supporting equipment (monitors, cameras, digital exam tools);
- Staff and physician telemedicine training;
- Additional staff time assisting patients with technology challenges;
- Enhanced security;
- Remote patient monitoring tools;
- Telemedicine-specific policies and procedures;
- Supplemental telemedicine patient-education materials; and
- Expanded internet bandwidth.

When physicians use their existing practice to conduct a telemedicine visit for new and established patients, they should be paid at least the same rate as for an in-person visit. **TMA's recommendation is that CMS and Congress ensure that services provided to a Medicare patient are paid according to the physician fee schedule regardless of whether the care is delivered in person or via telemedicine.**

Valuation of Specific Codes

Summary

CMS proposes valuation of multiple codes that are new or revised for 2022. This includes proposals related to use recommendations by the Relative Value Scale Update Committee for chronic care management (CCM) and principal care management (PCM) services.

CMS also seeks comments on PHE-related costs, such as disease control measures, research-related activities and services, or PHE-related preventive or therapeutic counseling services.

The agency also seeks comments on coding and payment for chronic pain management.

TMA Response

TMA strongly supports CMS' proposal to follow the RUC recommendations for CCM and PCM services.

Regarding PHE-related costs, TMA calls on CMS to implement and pay for CPT code 99072

(Additional supplies, materials, and clinical staff time over and above those usually included in an office

visit or other non-facility service[s], when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease) to compensate physician practices for the additional supplies and new staff activities required to provide safe patient care during the COVID-19 PHE without patient cost-sharing.

Regarding chronic pain management, TMA appreciates the agency addressing and achieving safe and effective dose reduction of opioid medications when appropriate. TMA supports improved access to substance-use disorder treatment, especially through co-location of physical health, mental health, and substance-use services and through wider availability of evidence-based medication-assisted treatments.

Evaluation and Management Visits

Summary

In this proposed rule, the agency is reviewing other evaluation and management (E&M) visit code sets and proposes clarifications regarding split (or shared) visits, critical care services, and teaching physician visits. Specifically, CMS proposes to define a split (or shared) visit as an E&M visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner (NPP) who are in the same group.

The agency proposes to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain skilled nursing facility and nursing facility E&M visits.

Unfortunately, not included in the proposed regulation is a physician stakeholder recommendation calling on CMS to apply increased 2021 valuation of the office E&M visits to the visits incorporated in the surgical global packages. This request resulted from CMS implementing significant revisions to office and outpatient E&M codes in 2021, as recommended by TMA and others.

TMA Response

We are generally supportive of the proposal to define a split (or shared) visit as an E&M visit in the facility setting for which incident-to payment is not available and that is performed in part by both a physician and a nonphysician practitioner. However, we urge CMS not to require a modifier to be reported for split (or shared) visits since modifiers add a level of administrative burden that the new E&M coding structure and guidelines were designed to alleviate. We also support CMS allowing such visits for new and established patients. **We especially appreciate CMS leaving incident-to policies intact.**

TMA supports the proposal to adopt CPT guideline language for critical care services. However, we ask the agency to allow, when clinically appropriate, additional services to be furnished on the same calendar day that the critical care services are furnished.

We are concerned regarding the values of E&M office visits within global surgery codes. Medicare statute specifically prohibits CMS from paying physicians differently for the same work: “The Secretary may not vary the ... number of relative value units for a physicians’ service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.”¹ Thus TMA emphatically urges CMS to apply the increased 2021 valuation of the office E&M visits to the visits incorporated in the surgical global packages. CMS’ position implies that the physician work for office visits is not the same when performed in a surgical global period, which is an inaccurate assumption. **TMA recommends that CMS apply the office visit E&M increases uniformly across all services and specialties and not hold specific specialties to a different standard from others.**

¹ 42 U.S. Code §1395w-4(c)(6).

Finally, we support the proposal that counts only the time the teaching physician was present in determining the office or outpatient E&M visit level for teaching physician services.

Billing for Physician Assistant Services

Summary

Currently, Medicare pays the employer of a physician assistant (PA) and does not pay the PA directly. In this proposed rule, CMS implements a provision of the Consolidated Appropriations Act of 2021 that will allow PAs to bill Medicare for professional services provided under Medicare Part B beginning Jan. 1, 2022. As part of this, CMS notes that PAs may reassign their rights to payment for their services and may choose to incorporate as a group composed solely of practitioners in their specialty and bill the Medicare program, in the same way nurse practitioners and clinical nurse specialists may do.

TMA Response

While TMA recognizes the important role that PAs play in the health care system and we acknowledge the agency is required to implement the policy from the Consolidated Appropriations Act of 2021, TMA believes a physician-led and collaborative team-based approach is optimal for patient care delivery and overall health care outcomes. Furthermore, it remains TMA's [policy](#) that payment for services performed by a physician assistant should be made directly to the responsible physician. While greater use of nonphysician practitioners can improve the system, responsibility for care must be clearly defined if various personnel are to work together effectively to provide high-quality services for the patient. It is critical that CMS not expand scope of practice to an extent that surpasses the state licensure, education, and training of nonphysician practitioners. **As CMS contemplates ways to expand NPPs' scope of practice, it is critical for CMS to acknowledge that scope is defined by state law, not by CMS.** TMA calls on the agency to adopt policies that ensure Medicare beneficiaries continue to have access to physician services. We also call for policy that promotes patients' ability to know and understand who are providing care, what their licensure is, and what education and training they have.

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Summary

Colorectal cancer screening tests fall within the scope of Medicare Part B benefits and under the definition of "preventive services." The Affordable Care Act provides for payment for U.S. Preventive Services Task Force grade A or B preventive services at 100% of the lesser of the actual charge or the fee schedule amount; thus no beneficiary coinsurance is required. When a flexible sigmoidoscopy or colonoscopy is performed as a diagnostic test, the beneficiary is responsible for Part B coinsurance (normally 20%) associated with the service.

In this section, CMS is implementing a provision from the Consolidated Appropriations Act of 2021. This law establishes patient coinsurance rules for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. Effective Jan. 1, 2022, the rule expands the definition of the colorectal cancer screening test to include a "related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter." In addition, the proposed rule establishes a phased-in increase in the Medicare payment with a decrease in the patient's coinsurance. The new payment structure will be set at 80% Medicare payment with 20% patient coinsurance gradually shifting to 100% Medicare payment and no coinsurance by 2030.

TMA Response

TMA supports coverage for colorectal cancer screening in which patients and physicians should have the option to use a variety of tests, such as a fecal occult blood test, fecal immunochemical test, stool DNA

test, flexible sigmoidoscopy, colonoscopy, double-contrast barium enema, CT colonography (virtual colonoscopy), or other appropriate techniques, in accordance with the most recently established national guidelines in consultation with interested specialty societies and scientific organizations for the ages, family histories, and frequencies referenced in these guidelines.

TMA supports the agency's proposal to change CMS' current regulations to include "colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure" in the definition of colorectal screening services. The eventual elimination of coinsurance for this procedure is sound policy that will reduce the financial burden facing Medicare beneficiaries whose screenings result in a diagnostic procedure. In turn, this change will promote utilization of colorectal cancer screenings that save lives.

Vaccine Administration Services

Summary

In the proposed rule, CMS discusses that Medicare payment for vaccine administration services is increasingly insufficient. The agency seeks comments on the cost of vaccine supplies and administration and indicates it may use this information to create a new, more sustainable payment methodology for vaccine administration services under the Medicare Physician Fee Schedule.

CMS also seeks comments on whether monoclonal antibody products used to treat COVID-19 should be treated the same way as other physician-administered drugs and biologicals under Part B.

TMA Response

TMA appreciates CMS acknowledging and addressing insufficient payment for vaccine administration services, especially since our members have consistently expressed how inadequate vaccination administration payment is. Complicating the issue is the COVID-19 vaccine, given its onerous reporting, complicated storage, and specific handling requirements. Many Texas physician offices have hired new staff just to input vaccination data into ImmTrac2, the state's immunization registry, and purchased data loggers for their refrigerators/freezers to comply with the COVID-19 vaccine administrator requirements. We urge CMS to factor these expenses into new payment methodology for vaccine administration services.

TMA supports Medicare Part B coverage of monoclonal antibodies to treat the rapid rise of COVID-19 infections. Demand for monoclonal antibody therapy is increasing, and we urge CMS to pay physicians accordingly.

Appropriate Use Criteria for Advanced Diagnostic Imaging

Summary

The Appropriate Use Criteria (AUC) program requires ordering physicians to consult appropriate-use criteria using a clinical decision support mechanism prior to ordering advanced imaging services for Medicare beneficiaries, and furnishing physicians to report this information on the claim.

CMS now proposes to delay enforcement of the AUC program by at least one year until the latter of Jan. 1, 2023, or the Jan. 1 that follows the end of the public health emergency.

TMA Response

TMA strongly supports this proposal and applauds CMS for recognizing the significant challenges AUC creates, the disruptions caused by the COVID-19 pandemic, and the need for more time for an educational campaign and operations testing period.

While TMA acknowledges the importance of evidence-driven ordering, we maintain operational concerns with the AUC program that must be addressed before its enforcement. Further, the COVID-19 PHE greatly limits physician practices' ability to prepare or to participate in an educational campaign and operations testing period. Therefore, TMA strongly supports the CMS proposal to delay enforcement of the AUC program.

Medicare Shared Savings Program

Summary

Under the Medicare Shared Savings Program (MSSP), physicians and other practitioners may create accountable care organizations (ACOs), which are designed to hold participating physicians and practitioners accountable for the quality, cost, and experience of care for Medicare fee-for-service beneficiaries. MSSP has multiple tracks, including the Basic and Enhanced tracks.

In this regulation, CMS makes several proposals to the MSSP, including these proposals to:

- Freeze the quality performance standard at the 30th percentile of the Merit-Based Incentive Payment System (MIPS) quality performance category scores for an additional year;
- Add several codes to the list of primary care services, which CMS uses to attribute patients to the ACO;
- Extend the CMS Web Interface reporting option two more years;
- Ease burdens and costs of ACO repayment mechanisms by cutting in half the percentages used in the existing repayment mechanism amount calculations;
- Reduce MSSP application burden by lowering document submission requirements around prior participation and sample and executed ACO participant agreements; and
- Change beneficiary notification requirements for ACOs that select prospective assignment by only requiring notices to be sent to beneficiaries prospectively assigned to the ACO.

TMA Response

TMA fully supports the CMS proposal to freeze the quality performance standard at the 30th percentile of MIPS quality performance category scores for an additional year. During the COVID public health emergency, physicians have found it increasingly difficult to meet [HEDIS quality measures](#).

Regarding the proposal to add new codes to the list of primary care services, we understand the need for CMS to refine the attribution process, though we urge CMS to carefully monitor primary care services to ensure they are performed predominately by primary care physicians.

We support the proposal to extend the CMS Web Interface reporting option for an additional two years.

TMA supports CMS efforts to reduce administrative burdens by simplifying documentation requirements for MSSP application and beneficiary notification requirements under the prospective assignment option. These types of administrative reductions especially benefit small ACOs led and managed by small, independent physician groups.

Medicare Provider and Supplier Enrollment Changes

Summary

With the goal of strengthening program integrity, CMS proposes several revisions to the physician and provider enrollment process. These include:

- Expanding the agency's authority to deny or revoke a physician, provider, or supplier's enrollment based on Office of Inspector General (OIG) exclusion – specifically, CMS proposes to include

administrative and management services personnel, such as human resources specialists and accountants, within the purview of the denial or revocation;

- Expanding CMS authority to deny a physician’s enrollment if his or her Drug Enforcement Administration (DEA) certificate of registration to dispense a controlled substance is currently suspended or revoked by allowing denial in cases where the physician surrenders his or her DEA certificate in response to an order to show cause;
- Allowing physicians, providers, or suppliers to reverse a revocation against an individual such as an owner or managing employee due to adverse activity if they terminate their relationship with that individual within 30 days;
- Clarifying the deactivation rebuttal process; and
- Increasing flexibility for revocation of physicians, providers, and suppliers engaging in noncompliant billing.

TMA Response

TMA generally supports these efforts since they improve the ability of the agency to identify and remove individuals acting improperly. We have some concerns with physicians being removed from the program due to actions by relatively low-level employees but understand that the agency and OIG will closely examine these individual situations.

We support the proposal to reverse physicians’ revocation when they terminate the employee within 30 days but ask the agency to expound on how this impacts a physician’s claims during that time frame.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Summary

When or if two-way video is not available to a Medicare beneficiary, CMS proposes to permanently allow physicians to provide OUD therapy and counseling services using audio-only technology. CMS also proposes that, during and after the public health emergency, OTPs will be required to indicate in a patient’s medical record when and why a visit for substance-use counseling or therapy was audio-only.

TMA Response

TMA supports multidimensional strategies to optimize the treatment of pain and works to educate Texas physicians about the latest evidence-based literature on responsible opioid analgesia management with the goal of reducing the risk to patients and enhancing public safety regarding opioid use, misuse, abuse, diversion, and nontherapeutic prescribing. TMA therefore supports the agency’s proposal to allow continued use of audio-only technology after the pandemic ends. As proposed, the rule limits use of audio-only to Medicare beneficiaries for whom two-way video is not available. However, even when two-way video is available, some patients may prefer audio-only services for a variety of reasons – convenience, unstable internet connections, and so forth. Audio-only services also may, in fact, increase compliance for people undergoing OUD treatment. Thus, we recommend that the agency allow continued payment for audio-only OUD treatment services regardless of availability of two-way video. As relates to mental health and substance-use disorders, a growing body of [literature](#), including [research](#) conducted by the Substance Abuse and Mental Health Services Administration, indicates that virtual care – two-way video and audio-only – has outcomes comparable to in-person care. Thus we believe OTPs should have the discretion to continue using the technology if it is the patient’s preference.

However, to ensure equitable use of the modality, we also strongly support continued oversight and research to ensure all Medicare patients, regardless of socioeconomic and geographic background, have access to the technology. TMA also recommends that as the OTPs evolve, services should be paid at parity regardless of service modality, whether in person, audio-visual, or audio only.

Updates to the Physician Self-Referral Regulations

Summary

In the proposed rule, CMS would broaden the definition of indirect compensation arrangements subject to the physician self-referral regulations, or self-referral law, and would also consider changes to the vaccine exemption.

TMA Response

For the proposed rule on indirect compensation arrangements (ICA), TMA recommends that CMS narrow the proposed language that would add a fourth way the individual unit of compensation would qualify the arrangement as an ICA. For the proposed rule on the law's vaccine exemptions, TMA supports allowing the exception to apply to COVID-19 vaccines even if they are not subject to CMS-mandated frequency limits. TMA also supports CMS' alternative proposal to remove the frequency-limits requirement for all vaccines.

Indirect Compensation Arrangements

Generally, self-referral law prohibits a physician from referring certain designated health services to an entity with which the physician has a financial relationship. The prohibited relationships include an ICA.

Under the self-referral law, an ICA exists if three prongs are met. The second prong addresses the aggregate and per-unit compensation necessary for there to be an ICA. For the per-unit compensation, the current rules contain three qualifying types. The proposed rule would add a fourth:

[P]ayment for anything other than services personally performed by the physician (or immediate family member).

The stated purpose of this addition is to address prior rulemaking's inadvertent exclusion of "arrangements involving unit of service-based payment for the rental of office space or equipment."

However, this broad proposed language would likely encompass arrangements beyond those involving unit-of-service-based payments. If the latter arrangements pose a risk of program abuse, then the ICA definition could be narrowly amended to include those specific arrangements – cf. §411.357(p) – instead of sweeping in all services not personally performed by the physician. This would also be consistent with CMS's previous efforts to simplify the ICA analysis and accordingly reduce unnecessary compliance burdens on physicians.²

Vaccine Exceptions

TMA supports efforts to remove barriers to vaccine delivery and supports CMS' proposals to remove regulatory requirements that could limit future distribution of the COVID-19 vaccines and other vaccines.

The physician self-referral law's prohibition on referrals contains an exception for vaccinations in §411.355(h). However, to qualify for the exception, the vaccine must be subject to CMS-mandated frequency limits.

As explained in CMS's proposed rules, COVID-19 vaccines are currently not subject to the physician self-referral law. This is because the vaccines are not a designated health service, due to Medicare not making payment for the vaccines. CMS has also not imposed a mandated frequency limit for the COVID-19 vaccines. However, should COVID-19 vaccines become payable by Medicare in the future – and thus

² See 85 Fed.Reg. 77545-46 (Dec. 2, 2020) ("We are finalizing revisions to the regulations at §411.354(c)(2) that we believe achieve the same result as the Phase I regulatory construct in protecting against program or patient abuse but reduce unnecessary burden on the regulated industry.").

a designated health service – but not be subject to frequency limits, then the vaccines would not meet the current requirements to qualify for the vaccine exception.

To address the concern that this could impede availability of the vaccine, CMS proposes to amend the vaccine exemption to exclude COVID-19 vaccines from the frequency-limits requirement. Alternatively, CMS proposes to remove the CMS-mandated frequency limit requirement for all vaccines.

TMA supports the proposed removals of required frequency limits for COVID-19 vaccines and for all vaccines. Both proposals would reduce barriers to vaccine delivery.

In the proposed rules, CMS asks whether the removing the requirement for all vaccines would necessitate alternative program integrity requirements. TMA does not believe additional requirements would be needed. Generally, vaccines are administered at discrete intervals, based on age or medical indications.³ As such, vaccines do not present the same program integrity concerns as other outpatient drugs and can even reduce health care costs by preventing more serious diseases.⁴

Requirement for Electronic Prescribing for Controlled Substances

Summary

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment Act of 2018 requires that Medicare Part D prescriptions for Schedule II, III, IV, and V controlled substances be prescribed electronically starting on Jan. 1, 2021. In 2021, CMS finalized a policy stating the agency would not take compliance actions before Jan. 1, 2022.

In this proposed rule, CMS continues to encourage electronic prescribing of controlled substances (EPCS) adoption and notes that EPCS increased from 38% of prescriptions in 2019 to 70% in 2021. However, CMS proposes to delay compliance actions until Jan. 1, 2023, due to the COVID-19 public health emergency. For patients in long-term care facilities, the EPCS compliance deadline would be 2025. CMS also proposes EPCS exceptions based on prescribing volume, location, disaster declarations, and infeasibility. In addition, CMS proposes that the threshold prescribers would need to meet for compliance is 70% of their controlled substances being sent electronically.

TMA Response

TMA fully supports the proposal to postpone the EPCS compliance by another year to Jan. 1, 2023. Even though Texas began requiring EPCS on Jan. 1, 2021, the state has issued waivers for physicians citing technical or financial hardships. Physicians continue to be overwhelmed and impacted by the COVID-19 PHE, and the delays and waivers are sincerely appreciated. TMA encourages CMS to continue to monitor the viability of practices due to the financial devastation from COVID-19, particularly small and rural primary care practices that regularly operate on thin profit margins.

TMA believes the 70% compliance threshold is reasonable but encourages CMS to phase in the threshold beginning with 50% in year one of compliance, 60% in year two, and 70% in year three. This allows physicians time to adjust, set patient expectations, and ensure industry preparedness.

³ See CENTERS FOR DISEASE CONTROL AND PREVENTION. [Immunization Schedules](#) (Feb. 11, 2021).

⁴ See DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL. *OIG Advisory Opinion No. 16-09* (Sept. 23, 2016) (“[T]he Proposed Arrangement focuses on adult vaccines, which are administered in a limited manner. Unlike drugs that are necessary to treat illness and ongoing, chronic conditions, vaccines protect against preventable diseases that could lead to additional and more costly services.”); see also DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL. *OIG Advisory Opinion No. 11-07* (Jun. 8, 2011) (“[T]he Arrangement is unlikely to result in overutilization. The Requestor certified that administration of the Expanded Vaccine is the standard of care and is universally recommended except where contra-indicated. Thus, the Arrangement is unlikely to induce a health care practitioner to prescribe and administer a vaccine that the practitioner would not otherwise have furnished in the absence of the inducement.”).

TMA agrees with the proposed exceptions and urges CMS to finalize exceptions for physicians who prescribe 100 or fewer Part D controlled substance prescriptions per year. This allows physicians who rarely prescribe controlled substances to still have the ability to care for their patients during those rare circumstances without causing undue financial hardship.

TMA agrees that in cases of emergency or declared disaster, an exemption should be available for prescribers in affected ZIP codes and urges CMS to finalize this proposal.

TMA agrees that CMS should grant waivers to prescribers facing extraordinary circumstances such as working in a services area that lacks broadband access. TMA strongly recommends that CMS allow waivers to be renewed annually. A physician who is unable to e-prescribe controlled substances due to economic hardship or technical limitations may not have relief from those barriers after one year.

TMA urges CMS to consider an additional waiver for physicians who prescribe compounded medications that qualify as controlled substances but cannot electronically prescribe the compounded medication because it is not listed on the prescribing software's medication list.

As mentioned, Texas began requiring EPCS effective Jan. 1, 2021. There continues to be confusion among pharmacists who deny paper prescriptions for controlled substances because they incorrectly think all controlled substances have to be sent to the pharmacy electronically. This causes delays in patients receiving their needed medications to get timely relief and healing. TMA suggests that when CMS requires compliance, there should be an accompanying campaign or messaging to pharmacists educating them about the exceptions and waivers, thus allowing pharmacists to fill controlled substances prescriptions when the order is delivered to the pharmacy via paper.

CMS solicited comments on whether penalties or other compliance action should be imposed for not electronically prescribing controlled substances. **While TMA recognizes the value of EPCS, TMA emphatically asks CMS not to impose penalties for noncompliance.** Financial penalties have additional and unintended consequences such as limiting access to care or physicians not prescribing needed medications to patients. CMS should first seek to understand why a minority of controlled-substance prescribers do not use EPCS and help those prescribers move to compliance in a nonpunitive fashion.

Updates to the Quality Payment Program (QPP)

Summary

To adjust for eventual statutory requirements, CMS proposes the following Merit-Based Incentive Payment System performance category weights to be applied to the final score methodology for the 2022 performance year (2024 payment year):

- Quality: 30% (is currently 40% for 2021 performance year);
- Cost: 30% (is currently 20%);
- Improvement activities: 15% (is currently 15%); and
- Promoting interoperability: 25% (is currently 25%).

TMA Response

Physician burnout is a serious consequence for physicians who also operate a small business and must comply with myriad regulations. Physicians' primary mission is to help, treat, and heal their patients who are sick and suffering. Medicare only offers an incentive payment if physicians jump through several hoops to meet ever-changing and numerous requirements for the MIPS program. The proposed changes to the MIPS program are increasingly burdensome and clinically irrelevant. Moreover, it is overwhelming

for physicians to keep track of the constant changes. **TMA urges CMS to not add to the burden and pleads with the agency to tweak MIPS requirements only as needed.** Further, TMA urges CMS to not increase the MIPS performance threshold and instead maintain it at 50 points, especially as physician practices continue to be in the midst of the ongoing COVID-19 pandemic.

MIPS Value Pathways (MVPs) and Subgroups

Summary

CMS proposes seven MVP subgroups set to begin in early 2023: rheumatology, stroke care and prevention, heart disease, chronic disease management, emergency medicine, lower extremity joint repair, and anesthesia. MVP participants will select four, instead of six, quality measures and two medium-weighted or one high-weighted improvement activity. They will be scored only on the cost measures included in the MVP. Starting in 2025, multispecialty groups interested in MVP participation will aim at phasing out MIPS after the 2027 performance year.

TMA Response

Though TMA and CMS are both focused on moving physicians to risk-based systems in voluntary, physician-led advanced alternative payment models (APMs), CMS nevertheless continues to develop MVPs, which Congress did not establish in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The agency professes laudable goals regarding reducing physician burden, yet TMA and other physician stakeholders continue to express concern over the MVP framework and how such reporting tracks may increase physician burden and require unrealistic infrastructural investment. As TMA first commented in a 2019 [letter](#), the MVP Pathways further burden physicians to learn about a new program with different data requirements. Then, in a 2020 [letter](#) TMA sent the agency, we argued adding MVPs to a system whose overall foundation is defective only serves to create an increasingly unstable system. Physicians are struggling to keep practices viable during the pandemic; incessant modifications to MVPs and the MIPS program in general only increase these burdens and are untenable.

Given the complexities with MIPS, TMA generally supports CMS' proposal to phase out MIPS after 2027. **Instead of pursuing MVPs, CMS should aggressively focus on the development of voluntary, physician-led alternative payment models. TMA is concerned with recommendations to restrict the number and type of APMs.**

Quality Performance Category

Summary

Starting in 2022, CMS intends to reduce the weight of the quality performance category from 40% to 30% of the final MIPS score. In addition, the CMS Web Interface will be extended as a quality reporting option for registered groups, virtual groups, or other APM entities. Beginning 2023, the data completeness will be increased to 80%.

CMS also proposes changes to the MIPS quality category measure set, addition of new quality measures, updates to specialty sets, removal of existing quality measures, and substantive changes to existing measures.

TMA Response

Especially in the context of a public health emergency, TMA implores CMS to maintain the quality performance category weight at 40% of a MIPS score. TMA supports CMS' proposal to maintain the data completeness criteria threshold at 70% for the 2021 and 2022 MIPS performance periods. TMA urges CMS to consider a cap of 70% on the data completeness criteria until the year after the PHE ends before increasing the threshold. TMA further suggests that CMS continue to monitor data completeness statistics and appropriately adjust the threshold, ensuring physicians in all practice settings can continue to participate equitably. Additionally, increasing the data completeness threshold would result in

increased administrative and cost burdens for physician practices, which is contrary to CMS' Patients Over Paperwork Initiative.

Regarding changes to quality measures, TMA suggests that CMS adhere to the recommendations of the Core Quality Measures Collaborative (CQMC), in which TMA participates. CQMC is a broad-based coalition working to facilitate cross-payer measure alignment through the development of core sets of measures to assess the quality of health care in the U.S.

TMA supports efforts to improve meaningful measurement but opposes the continuous and evolving changes to the measures list in general. Quality performance requires a full calendar year of data, and continuous changes to quality measures often require immediate changes to workflow and data collection operations that are administratively burdensome. TMA also suggests that as substantive changes are made to quality measures, physicians be given a two-year grace period to adjust their processes for measure compliance. Therefore, physicians should be given credit for either the current or future quality measure data collection requirements.

Additionally, TMA urges CMS to maintain a sufficient number of quality measures for physicians who choose to report via claims submission. It is costly and time-consuming for physicians to pay registry and electronic health record (EHR) vendors for quality data submission. Though claims-based reporting has challenges, many physician practices have learned how to report effectively through this method. Vendor submission unnecessarily adds to physician financial and administrative burden associated with the quality category.

Cost Performance Category

Summary

CMS proposes to increase the cost performance category weight to be 30% for the 2022 performance year (2024 payment year).

Further, CMS plans to establish five new episode-based cost measures:

- Two procedural measures: melanoma resection, colon and rectal resection;
- One acute inpatient measure: sepsis; and
- Two chronic condition measures: diabetes, asthma/chronic obstructive pulmonary disease.

These five measures are in addition to the existing two global or population-based measures and the 18 episode-based measures. If a MIPS-eligible clinician meets eligibility for facility-based measurement but participates in MIPS as an individual or group, the higher final score between the facility-based scoring and MIPS submission-based scoring will be used.

TMA Response

TMA appreciates CMS' awareness of challenges stakeholders may encounter and ways to ensure that stakeholder-developed cost measures meet certain standards and are consistent with the goals of MIPS and MVPs. **We oppose the cost weight being increased to 30% and urge CMS to delay increases to it until the end of the public health emergency. Instead, CMS should maintain the quality performance category weight at 40% of a MIPS score.** Further, TMA cautions CMS that the cost category is administratively burdensome to many physicians, and building further complexities into this category exacerbates the burden. It is important for physicians in all practice settings to be able to access the data used to score the cost category. This requires having the ability to access and import into the EHR real-time information from labs, pharmacies/pharmacy benefit managers, hospitals, and/or rehabilitation services. CMS should ensure that small practices are not disadvantaged by the cost category.

Improvement Activities Category

Summary

CMS proposes to maintain the improvement activities performance category weight at 15% for the 2022 performance year (2024 payment year). Beginning with the 2022 performance period CMS proposes to:

- Revise group reporting requirements;
- Revise the time frame for improvement activities nominated during the public health emergency;
- Revise required criteria for improvement activity nominations;
- Suspend all activities that raise possible safety concerns or become obsolete from the program when this occurrence happens outside of rulemaking;
- Add seven new improvement activities, modify 15 existing improvement activities, and removed six previously adopted improvement activities;
- Revise the “Drug Cost Transparency to Include Requirements for Use of Real-Time Benefit Tools” improvement activity; and
- Add the COVID-19 “Clinical Data Reporting With or Without Clinical Trail” improvement activity.

TMA Response

TMA agrees with CMS’ approach to revising group reporting requirements so that multispecialty groups can report in subgroups while meeting the 50% threshold and still choose measures that are meaningful and applicable to the specialists within that group. TMA appreciates that CMS reviews the types of inquiries received through the Quality Payment Program help desk and reacts to the needs of physicians and other participants seeking to comply with the complex details of the program.

Because TMA does not historically nominate improvement activities for inclusion, we encourage CMS to heed the suggestions of those organizations that submit nominations so that interested stakeholders have a fair voice in the process.

Due to a circumstance where an improvement activity had expired and had to be removed during the calendar year, CMS proposes to promptly remove improvement activities outside of the rulemaking process. TMA agrees there should be a mechanism for promptly suspending an improvement activity, especially if there is potential for patient harm. TMA further agrees that CMS should use all communication channels to alert QPP participants that the activity is suspended. However, CMS should not penalize physicians who report on a suspended activity. CMS should allow any suspended activities to still count when the suspension happens outside of rulemaking.

CMS is adding seven new improvement activities, three of which are related to promoting health equity and better identify social determinants of health. TMA appreciates CMS’ commitment to achieving equity in health care outcomes for patients by supporting physicians in quality improvement activities to reduce health inequities and enabling them to make more informed decisions. CMS is also modifying 15 current improvement activities and removing six previously adopted improvement activities. **TMA remains concerned that physicians are continuously challenged with compliance in an ever-changing and increasingly complex program.** TMA urges CMS to only modify and remove activities when absolutely necessary.

Promoting Interoperability Performance Category Performance Period

Summary

CMS proposes to maintain the promoting interoperability performance category at 25% for the 2022 performance year (2024 payment year). CMS does not propose any changes to the promoting interoperability performance period of 90 days as established by the agency in previous rulemaking.

TMA Response

TMA appreciates the continuation of the 90-day performance period for the promoting interoperability category. As stated in the proposal, it is an appropriate performance period and offers consistency and stability to this category.

Proposed Changes to the “Query of Prescription Drug Monitoring Program (PDMP)” Measure Under the Electronic Prescribing Objective

Summary

CMS proposes to maintain the electronic prescribing objective measure, “Query of Prescription Drug Monitoring Program (PDMP),” as optional and worth 10 bonus points for 2022.

TMA Response

TMA supports and appreciates CMS’ proposal to maintain the query of PDMP measure as optional and worth 10 bonus points in the MIPS promoting interoperability category.

While TMA agrees that checking the PDMP provides clinical value at the point of care, the ability to track this measure can become burdensome to physicians. Texas generally requires that physicians check the state prescription monitoring program (PMP) prior to prescribing opioids, benzodiazepines, carisoprodol, or barbiturates. For two years, Texas funded the integration of Appriss’ PMP check via the EHR. This gave physicians access to the patient’s medication history for the previously mentioned drug classes at the point of care and within the physician’s workflow. The Texas funding for this integrated EHR access expired Sept. 1, 2021. Now physicians must bear that extra cost for integrated access or spend extra time by leaving their EHR and logging into PMP Aware to check their patient’s prescribing history. Some EHRs automatically denote that the PMP was checked while others require manual documentation. If a physician does not document the PMP check, an audit could be performed indicating the PMP was checked. For these reasons, TMA appreciates that CMS is reducing physicians’ burden by keeping Query of PDMP an optional and bonus measure.

CMS sought comment on the future of the Query of PDMP measure. While TMA believes most physicians are able to respond to this measure with a yes-or-no attestation, it is important that CMS maintain an exclusion for physicians who do not prescribe controlled substances of the aforementioned four drug classes.

Proposed Changes to the “Provide Patients Electronic Access to Their Health Information Measure” Under the Provider-to-Patient Exchange Objective

Summary

CMS proposes that, beginning in 2022, clinicians are required to make patient health information (PHI) available indefinitely starting with encounters on or after Jan. 1, 2016.

TMA Response

TMA strongly opposes CMS’ proposal that physicians be required to make patient health information available indefinitely starting with encounters on or after Jan. 1, 2016.

Expecting physicians to indefinitely maintain patient health information adds a financial and workforce burden that is not feasible. This proposed requirement is a far reach beyond what Congress intended when MACRA was designed. This kind of government overreach will frustrate physicians and patients, and cause further physician burnout and other unintended consequences. TMA does not believe it was the intention of Congress or is within the authority of CMS to supersede all state medical record retention laws in the U.S. In addition to cost concerns and physician burden, there are privacy concerns associated maintaining the troves of data called for by this requirement.

CMS should cite peer-reviewed scholarly studies supporting the concept that all patient data should be retained retroactively and indefinitely. For example, a hospital stay may produce hundreds of data points, some of which may be valuable while many may not be. Physicians need access to clinically useful information and should not have to navigate through countless pages of dated PHI. CMS should support industry efforts identifying what data should be retained, archived, or discarded.

As part of the information-blocking regulations under the 21st Century Cures Act, the U.S. Department of Health and Human Services (HHS) established April 5, 2021, as the date that physicians were required to make U.S. Core Data for Interoperability (USCDI) data available to patients. TMA encourages CMS to maintain this HHS start date and limit the PHI availability requirements to USCDI data. In October 2022, physicians are required to make all data available to patients. **TMA strongly encourages CMS to fully align with 21st Century Cures Act date and data requirements.**

Additionally, the proposed indefinite and retroactive (to Jan. 1, 2016) date is infeasible and ill-advised:

- Physicians may have switched EHRs, no longer have the patient data available on the active portal, and have no way to convert the data into the needed format due to the proprietary nature of EHRs.
- State medical boards set time limits for which physicians must retain medical records. In most cases in Texas, it is seven years from the date of last treatment for adult medical records and seven years from date of last treatment or until the patient reaches 21, whichever is later, for pediatric medical records.
- Electronically maintaining patient records indefinitely is simply not feasible as this requires additional data storage that can impact an EHR's performance and increases data storage costs.

Instead, TMA encourages CMS to support the development of a universal patient portal through which patients can easily send and access their data regardless of which EHR their physician(s) and other providers use. This would allow patients desiring to maintain a lifelong, longitudinal medical record a way to store and access their records. Physicians should **not** be unduly burdened with maintaining electronic records indefinitely.

Modifications to the Public Health and Clinical Data Exchange Objective

Summary

CMS proposes to require the immunization registry and electronic case reporting measures under the public health and clinical data exchange objective. CMS indicates there are gaps in exchanging data with public health agencies and that a more assertive approach is needed.

TMA Response

TMA suggests that a better approach is for CMS to retain the five public and clinical health registries as currently scored due to the challenges outlined below.

If CMS finalizes the proposal to convert the immunization registry reporting to a required measure, the requirement should apply **only** to the ability to send data to the state's immunization information system. In Texas, additional immunization registry consent requirements make it challenging for EHR vendors to support the bidirectional exchange of data between immunization information systems and physician practices. TMA has advocated heavily for Texas to change its consent requirements to a simple yes/no and will continue to do so. Until EHR vendors can support bidirectional exchange in all jurisdictions, CMS should not require it.

TMA encourages CMS to conduct an environmental scan of public health case reporting readiness and the ability of physician practices to efficiently connect to these registries. CMS should ensure industry

readiness prior to requiring the reporting of electronic case measures. TMA appreciates the continuance of the exclusion but still recommends keeping this measure as optional.

Safety Assurance Factors for EHR Resilience (SAFER) Guides

Summary

CMS proposes to require that physicians attest “yes” to having conducted an annual self-assessment of the high-priority practices listed in the Office of the National Coordinator for Health Information Technology’s (ONC’s) SAFER Guides.

TMA Response

TMA recommends that CMS make the SAFER Guides attestation an optional bonus measure for conducting an annual self-assessment of the high-priority practices listed in ONC’s SAFER Guides. Additionally, TMA recommends that CMS add the annual SAFER Guides self-assessment as an activity in the improvement activities category of MIPS.

TMA believes the SAFER Guides are a useful tool in physician practices. In fact, TMA has encouraged the use of the SAFER Guides since their development in 2016. With COVID-19 once again surging, this is not the time for CMS to add new required measures. At the very least, new measures should be optional with bonus points for the first two years while the industry acclimates to the new measures.

Proposed Changes to the Attestation Statements

Summary

In 2017, CMS finalized three attestation statements for MIPS eligible clinicians. These are:

- *Statement A:* Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.
- *Statement B:* Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers, including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
- *Statement C:* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers, and other persons, regardless of the requestor’s affiliation or technology vendor.

CMS proposes to reduce the required attestation statements physicians must make to only statement A.

TMA Response

TMA agrees with CMS that attestations statements B and C are no longer necessary since physicians are now required to comply with the 21st Century Cures Acts information-blocking regulations and both statements. TMA thus supports the removal of attestation statements B and C.

Reweighting the Promoting Interoperability Performance Category for MIPS-Eligible Clinicians in Small Practices

Summary

Citing the desire to support small practices and help them successfully participate in MIPS, CMS proposes to temporarily not require an application from physicians and small practices seeking to qualify for the small practice hardship exception and reweighting.

CMS seeks comments to understand why physicians in small practices are not submitting a hardship application and not attesting to promoting interoperability.

TMA Response

TMA fully supports and thanks CMS for the proposal to not require small practices to submit a hardship application for exemption from promoting interoperability. Thus physicians who do not submit data or attest to promoting interoperability would automatically have their MIPS promoting interoperability category set to zero and reweighted to another MIPS category. If a physician in a small practice chooses to submit data, then the physician would be scored appropriately based on data and attestations submitted.

As to why small practices are not submitting hardship applications or attesting to promoting interoperability, TMA frequently hears from physicians and practices who are overwhelmed and confused by the ever-changing details of the MIPS program. This is further exacerbated as many face significant financial and physical hardships during the public health emergency.

Other MIPS Policies

Summary

The final scores for all MIPS-eligible clinicians for a prior period must be either the mean or median of the final scores. This will begin in year six of MIPS (2024 MIPS payment year). CMS proposes to establish the performance threshold at 75 points and increase the additional performance threshold from 85 to 89 points.

Recognizing the effects of the COVID-19 PHE, CMS proposes to continue doubling the complex patient bonus for the 2021 MIPS performance year/2023 MIPS payment year.

TMA Response

Physicians will continue to struggle complying with the MIPS requirements as the performance threshold continues to increase. And in many cases, the quality performance category could be lower than the performance threshold for a group. TMA appreciates CMS' attempt to make the intention known to report to MIPS as a group before potential eligibility is expanded to other members of the group.

TMA appreciates CMS recognizing the impact of the public health emergency. We support proposals to continue to double the complex patient bonus score MIPS participants can receive during the 2021 performance period.

Projected 2022 MIPS Participation and 2024 Payment Adjustments

Summary

CMS states that 809,625 clinicians will be MIPS-eligible in 2022. The payment adjustments stemming from the 2022 performance period will be applied to the 2024 Medicare payments. The maximum positive payment adjustment, including the exceptional bonus, is estimated to be 14%, while the maximum penalty is 9%.

TMA Response

TMA supports CMS' recognition of the 75-point performance threshold as an attainable goal and that more clinicians will receive a positive adjustment than a negative adjustment.

Alternative Payment Models

Summary

CMS proposes changes to the Quality Payment Program to promote the adoption of alternative payment models. CMS proposes changes in how to increase the likelihood of making incentive payments in a timely manner by changing how it accesses the taxpayer identification number information for qualifying APM participants. A team-based approach to care is increasing in APMs, allowing physicians and NPPs in the same group to provide better continuity of care. This instills close collaboration and an element of coordination in providing care to the beneficiary.

TMA Response

TMA and CMS are both focused on moving physicians to risk-based systems in voluntary, physician-led advanced alternative payment models. To be blunt, TMA considers the frequent, never-ending, and complicated changes the agency annually proposes for the MIPS and MVP pathways to dramatically increase the attractiveness of participating in the QPP via APMs. **Therefore CMS should aggressively focus on the development of voluntary, physician-led alternative payment models.** TMA is concerned with recommendations by the Medicare Payment Advisory Committee to restrict the number and types of APMs. This recommendation does not align with and would therefore delay Congress' intent to create physician payment models that add incentive payments to provide high-quality and cost-efficient care to a specific clinical condition, a care episode, or a population.